

GEORGIA BOARD OF PHARMACY
2 MLK Jr. Drive, SE, 11th Floor, East Tower
Atlanta, GA 30334
September 13, 2023
9:00 a.m.

The following Board members were present:

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

Staff present:

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

Visitors:

Sandra J. Nielsen, Trulieve
Jonathan G. Marquess, GPhA
Jordan Khail, UGA
Melissa Reybold, GPhA
Dawn Lieber Sasine
Merrilee Gober, MAG
Brandon Brooks, Publix
Perry Walden, GMCC
Travis J. Clark
Vrinda Naik
Beth Jarrett, Walmart
Mary Kate Snead, Guardian Pharmacy
Jennifer Duckett, Walgreens
Becca Hallum, GHA
Stephanie Kirkland, Eldercare
Emily Yona, Cardinal Health
Helen Sloat, Kaiser/Scion Health/HOG
Rahul Bali, WABE News
Diane Sanders, Kaiser Permanente
Lauren Pollow, McKesson
Brian Dalton, Botanical Sciences
Reid Stone, Botanical Sciences
Sean O' Donnell, Botanical Sciences
Gary Long, Botanical Sciences
Michelle Blalock, Cardinal Health

Open Session

President Azzolin established that a quorum was present and called the meeting to order at 9:07 a.m.

Appearance

Trulieve: Ms. Sandra Nielsen, Trulieve, provided a presentation to the Board. She provided an overview of the company and discussed the products that are available and approved by the Georgia Access to Medical Cannabis Commission (“Commission”).

Demos of the products were passed around for the Board to review what the packaging would look like.

Ms. Nielsen explained that the products can only be found in dispensaries or approved pharmacies. She discussed the process of physician registering a patient for the Low THC Oil Registry. She stated that once a patient is issued a Low THC Oil Registry Card they are allowed to shop at a dispensary licensed by the Commission or independent pharmacy. Ms. Nielsen discussed the cannabis plant and the patient being allowed to purchase one, two or three bottles at a time. She stated that treatment is patient driven as the patient will understand how much product to take because it works differently for everyone. She further stated that the patient can purchase multiple bottles of the capsules.

Vice-President Page inquired as to the process of a patient coming back and saying a particular product is not working. Ms. Nielsen gave an example of a patient that purchased multiple bottles of a tincture and did not like it. She stated that the patient can return the products to a bin that the independent pharmacist will have in the pharmacy. She explained that the pharmacy can credit the patient with the money they purchased the product with. She continued by stating that hopefully the registry will allow for a section that states “x” number of bottles returned. Ms. Nielsen stated that it is not like prescription medication where if you take it and it does not work, you cannot return it. She further stated that at Trulieve, they want the patient to find what works best for them.

Vice-President Page inquired as to what happens with the returned products. Ms. Nielsen responded by stating that once the dispensing pharmacy has a certain amount of product that needs to be returned, Trulieve will come and pick it up. She explained that they will document in a manifest how much is picked up (i.e., type of product, the batch number, etc). She stated that the pharmacist will sign the manifest and Trulieve will take the product back. She added that it is part of the seed to sale tracking system required by the Commission.

Mr. Stone inquired if that is something that is done now in the dispensaries. Ms. Nielsen answered affirmatively. Ms. Nielsen stated that it is something that is allowed by the company. Mr. Stone stated that is not something pharmacists are used to. Director Troughton clarified that it is allowed by the company and their dispensaries, but there is no requirement to bring those products back to purchase something else or any time limit of any sort tied to it. Mr. Stone stated that he thinks the pharmacist should be involved in the whole process, even with the dispensaries. He further stated that the pharmacist helps keep the patient safe and helps with the dosing.

President Azzolin inquired if the pharmacist has the right to refuse to dispense the product. He stated that the pharmacist should be able to refuse to dispense the product if he/she feels it is unsafe. Mr. Stone responded by stating that it is in the pharmacy rules.

Director Troughton commented by stating that these are not prescriptions. Mr. Changus stated that there is not a requirement stating that everyone must participate in this. He explained that it is at the discretion of the pharmacist.

Director Troughton stated that this is a new industry. He further stated that there will be a lot of unanswered questions until GDNA goes into the pharmacy to see how this goes on. He added that the rules may need to be altered over the first year. Mr. Stone agreed and stated that the Board would need to move on rules quickly as it sees things that need adjustment.

Mr. Brinson inquired if GDNA needed to ask permission to inspect one of the dispensaries licensed by the Commission. Director Troughton responded by stating that GDNA can inspect dispensaries at least once a year.

Discussion was held regarding the type of training a new employee of Trulieve goes through once hired.

Director Troughton inquired if the records and the software system utilized by Trulieve ended at the pharmacy door when the product is delivered, and records beyond that point are internal pharmacy records. In other words, the pharmacies will not utilize Trulieve's software other than having records that show they received "x" amount of product on a specific date. Ms. Nielsen responded affirmatively. She stated that the one thing that is shared between the pharmacies and dispensaries is the DPH public registry, which will verify the patient is active and can purchase the product.

Director Troughton inquired if a pharmacy could see what another Trulieve customer pharmacy has sold to a specific patient. He asked if that information is shared through any sort of system. Ms. Nielsen responded by stating that if a patient goes to a dispensary in Macon and then to another dispensary in Marietta, in Trulieve's point of sale system, they can see where the patient has purchased the product. She continued by stating that once the DPH registry is finalized or information is added, any Trulieve employee at a retail pharmacy can see where that product was purchased by the patient. She explained that eventually the DPH system will show the name of the patient and where the patient purchased the product. Director Troughton commented that the DPH system does not exist right now. He stated that when GDNA goes into a pharmacy, the only thing the agent can see is what the pharmacist did in that pharmacy. He added that GDNA cannot see anything based on Trulieve's software system. Director Troughton stated that he can only see what happens at that pharmacy on that particular day for a specific patient. He added that he wants the Board to be aware of what exactly GDNA is enforcing.

Vice-President Page inquired if there was a limit to what the patient is purchasing. Ms. Nielsen responded by stating that there is not a limit and stated that each patient will require something different. She added that the cannabis industry is run by patients because the patient knows which route works best for his/her body. She stated the patient will have this discussion with his/her doctor, but it is the patient that knows what works best for them.

Ms. Melissa Reybold, GPhA, stated that she was under the impression there was a limit to what the patient could have in his/her possession, otherwise they would be breaking the law if caught with more than what is allowed. Ms. Nielsen responded by stating it is 20 fluid ounces and in order to break that law the patient would need to buy 56 bottles. President Azzolin inquired if the patient wanted to purchase that amount would Trulieve allow them to do so. Ms. Nielsen responded affirmatively.

Discussion was held regarding the Low THC Oil identification card and the registry.

The Board thanked Ms. Nielsen for her time and presentation.

Approval of Minutes

Mr. Brinson made a motion to approve the Public and Executive Session Pharmacy Board minutes from the August 16, 2023, meeting as amended. Mr. Stone 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. Brinson seconded, and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

Rule Variance Petition from Medical Center Pharmacy, PHRE010800: The Board considered this petition for a variance of Rule 480-6-.01(3). Mr. Stone made a motion to grant the petition based on the petitioner demonstrating a substantial hardship in that patient care issues, such as delay of care, would occur as well as there being financial issues associated with a change of ownership. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Battelle Memorial Institute: The Board considered this petition for a waiver of Rule 480-7-.04(7)(b)(1). Mr. Changus noted that the rule states that the Board may choose to grant an exception to this rule upon receipt of a written request from such applicant stating the reason for such an exemption. Mr. Stone made a motion to grant the request. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Rehabilitation Hospital of Columbus, LLC: The Board considered this petition for a waiver of Rule 480-13-.05(2)(b). Mr. Stone made a motion to deny the request and directed staff to respond to the petitioner by stating that if the Board granted the petition in its current wording, the Board would be approving the facility to compound in violation of USP. Also, a closed system transfer device cannot be used in lieu of a laminar flow hood. If they are only requesting a waiver of the requirement for a laminar flow hood, the Board suggests they resubmit the petition with the correct rule number, Rule 480-13-.05(2)(b)(1), and terminology. Additionally, if the facility wishes to compound small volume parenterals using a closed system transfer device in lieu of a laminar flow hood, they will need to include the following rule numbers in their petition: Rule 480-13-.06(2)(a) and Rule 480-11-.04(3)(b)(1). Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from The Center of Renewed Promises, PHOP000052: The Board considered this petition for a waiver of Rule 480-18-.05(2)(d)(1). Director Troughton commented that GDNA inspected this facility and they have a sink located next door in the administration room and it has been functioning since 2009. Mr. Stone made a motion to grant the petition. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Appearance

Botanical Sciences: Mr. Gary Long, CEO of Botanical Sciences, provided a presentation to the Board. Also present from Botanical Sciences were Dr. Robin Fowler, who is the founder of the company, and Brian Dalton, Reid Stone, and Sean O'Donnell.

Mr. Long provided the Board with background information regarding Botanical Sciences. He stated the company was founded in 2020 in advance of the state going through the formal request for proposal. The company was subsequently awarded the highest scoring company in the state's process and was then provided the Class I license to manufacture and distribute medicinal cannabis. Botanical Sciences was authorized by the Commission in September 2022. Mr. Long stated that Botanical Sciences recently opened its first two (2) dispensaries in Pooler and Marietta. He added that the company will be opening additional locations Atlanta and Augusta.

Mr. Long discussed Botanical Sciences' manufacturing facility in Glenville. He stated their license gives them complete seed to sale capability. He explained they do everything from cultivating the product, processing it, distributing it, and dispensing it.

Mr. Long stated that Botanical Sciences is following the highest levels of security and compliance. He added that they work closely with the Commission. He explained there are a list of things they do on a day to day basis to ensure they are in compliance. He stated that everything they do is secure, videotaped, and

archived. Mr. Long further stated that Botanical Sciences uses a state of the art seed to sale tracking system called Flourish.

Mr. Long explained that everything they do is tracked, including the waste of the product, in Flourish. He stated that the system shows everything that happens through the manufacturing process through patient consumption, but also shows a history of how the patient consumes the product.

Mr. Long stated that the company is in a position to work with statewide independent and compounding pharmacies across the state to provide equitable access to medical cannabis for patients in need through a trusted network. He added that the pharmacist holds a special place in the care/delivery process. He stated that pharmacists provide an incredible amount of patient education and consultation. He added that in a new industry, there is a lot of bad information out there and pharmacists are a valuable resource to patients of the state.

Mr. Long provided an overview of the product portfolio and provided samples for the members to review.

Vice-President Page inquired as to what the shelf life is for the product. Mr. Long responded by stating two (2) years. He continued by stating that the product only has to be retested to make sure the structure has not changed, and as long as it meets the purity standards, it can be put back on the shelf. He added that the product contains a date and lot number.

Director Troughton asked if a product was going out of date, would the pharmacy send it back to Botanical Sciences to retest. Mr. Long responded by stating that Botanical Sciences would be actively helping managing the inventory. He stated that Botanical Sciences will tell the pharmacy in advance what is on the shelf and where the product is at in the cycle.

Director Troughton stated if GDNA inspected a dispensary and found an expired product would Botanical Sciences recommend sending it back. Mr. Long responded affirmatively. Director Troughton asked if the product would be retested and then a new label would be applied. Mr. Long responded by stating that would be the process. Mr. Long stated that the seed to sale system gives them the ability to proactively look at the inventory that is on the shelves at any facility at any point in time.

A representative from Botanical Sciences stated they have been working with pharmacy systems for a while. He discussed Botanical Sciences opening a research and development lab in Roswell and another one in Glenville. He stated they hold two (2) pharmacy licenses, have had multiple inspections, and with all of that have encompassed their design on reverse distributorship. He added that the DEA has required Botanical Sciences to have formalized contracts for the schedule I portion, but will also at that same capacity for its pharmacists and dispensaries. The representative explained that it is a very formal process. He added that they would act as a reverse distributor and take it away from the pharmacy. He stated that there is an actual paper trail that follows the logistics that meet its standards with its schedule I numbers. Director Troughton responded by stating that the new rules pertaining to low THC address it, but the law did not specifically address it.

Discussion was held regarding Botanical Sciences holding researcher permits, but would be acting as a reverse distributor from these pharmacies. President Azzolin stated that the Board holds pharmacies accountable for allowing drugs to be reverse distributed to unlicensed reverse distributors. He inquired if Botanical Sciences needed a reverse distributor or wholesaler license. Director Troughton responded by stating that if Botanical Sciences is sending the product back to be tested and resent with a new label that is one thing; however, if a company sends it back, they will need to use a licensed reverse distributor. President Azzolin stated that if they take something back and will dispose of it, at that point it has been

reverse distributed from a retail pharmacy. He further stated that if he is a retail pharmacist, he will ask for the company to show a valid reverse distributor permit before the product is sent back.

Mr. Stone commented that they may need a wholesaler license. Director Troughton responded back by stating that the company has been issued a license by the Commission, and they have a pharmacy license in their dispensaries. He stated that this is an issue the Board and GDNA would need to work out.

President Azzolin stated that he was trying to preemptively address the issues as they arise. Mr. Brinson stated that the Commission has already licensed them and inquired as to why the Board should also license them. A representative with Botanical Sciences commented by stating that when these questions come up, they have a process in place that has gone through the DEA credentialing and they are prepared to go down those avenues of accepting that product back so they will not be recreating the wheel. He added that Botanical Sciences does not carry a reverse distributor license. He stated that they are a wholesaler and have a formal process that they can follow so it remains creditable with the Commission as well as the Board. Director Troughton commented by stating that if they will be the one destroying it, the Board may decide it would be required for Botanical Sciences to also have a reverse distributor license.

Discussion was held concerning record keeping. Director Troughton stated that these products are not prescriptions. He continued by stating that it sounds as if Botanical Sciences' system is set up to where it will appear like a pharmacy profile. He inquired if the system would encapture if a patient had been to a dispensary and a pharmacy. Mr. Long answered affirmatively. Mr. O'Donnell stated that everything does go through their point of sale, and with that, they have the ability to lock the inventory which is unique. He explained if the dispenser rings up the product, then they are not able to process the point of sale. He continued by stating that they have global visibility of the products and the quantities across all sites in real time. Director Troughton inquired if GDNA were to conduct an inspection, would reports be immediately available. Mr. Long answered affirmatively.

Mr. Chang inquired if there were labels with barcodes on every product and could the product be traced back to who it was dispensed to. Mr. Long answered affirmatively. Mr. O'Donnell stated that it is a parent/package relationship where it all ties back to the parent and all the way through the transaction.

Mr. Brinson inquired as to what form of payment is accepted at the dispensaries. Mr. Long responded by stating that all forms of payment are accepted. Mr. Brinson inquired as to how a pharmacy would order the product. Mr. O'Donnell responded by stating that they have a baseline inventory package. He explained that they have full visibility and administrative functions to review inventories, plan fulfillment, and schedule direct shipping. He added that the shipping manifest is very important. He stated that it is a very intentional step to ship it.

After the presentation from Botanical Sciences, Mr. Andrew Turnage, Executive Director, Georgia Access to Medical Cannabis Commission, spoke to the Board. He thanked the Board for what it is doing and stated that it has been a long journey to get to this day. He stated that not every patient can fit into the traditional pharmaceutical model. He explained that with the product the Commission regulates, the Commission is the sister state agency along with the Board of Pharmacy and GDNA. Mr. Turnage stated that both licensees are required to comply with the HOPE Act and the Commission's rules. In regards to the structure at the Commission, Mr. Turnage stated it is a license and a contract for these licensees. He further stated that he appreciated both Trulieve and Botanical Sciences for being present at the meeting. He explained that both were issued licenses almost one (1) year ago as Class I Production licensees.

Mr. Turnage stated that the Commission has not had a lot of opportunity to speak to the Board publicly because the law prohibits the Commission from talking about items that are confidential by law; however, the licensees can talk about their business processes. He thanked the Board for giving them the opportunity

to discuss their product and process with the Board. He also thanked the Board for taking a chance on Georgia's patients and giving them the opportunity to improve their health in non-traditional ways. Mr. Turnage stated that there have been many voices who have spoken in opposition or criticism in the way the law was written. He further stated that it is the Commission and the Board's job to apply the law. He continued by stating that the Commission has worked closely with these licensees to comply with the law.

Mr. Turnage discussed the Board's rules being approved by Governor Kemp. He stated that once the Board's rules become effective, the Commission will need to begin the rules promulgation process to update its rules. He added that the Commission's rules that are in place can be found in Chapter 351. He explained that one of the updates the Commission has to make to the rules is to afford its licensees a clear pathway that is governed by Commission rules on how they transport.

Mr. Turnage continued by stating that the Commission will also need to update its testing requirements. He stated that there is currently one (1) lab registered that is located in Macon. He further stated that when the Commission promulgated its rules it did not have a lab registrant and did not have anything more than a baseline. He continued by stating that now they have a year's worth of data and feedback from the licensee, along with feedback from the patients, and the Commission needs to update its rules to align with the market it now has in Georgia.

Mr. Turnage stated that there will be some product specific guidelines coming out into the Commission's testing requirements and there will also be testing requirements for heavy metals and pesticides that have not been there previously. He continued by stating that even though the opportunity exist for independent pharmacies, the Commission will continue to issue dispensing licenses at the Commission as well; however, that is very restrictive and is governed by the HOPE Act, which dictates the specific number of licenses the Commission can issue. In closing, he stated that he appreciated all the hard work the Board has done.

President Azzolin stated that he is aware that this topic has been controversial over time. He explained that, as pharmacists, they need to be open minded as to how the product is used and be there to inform the patient about the risks involved.

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

Director Troughton introduced Special Agent Kimberly Kaptain to the Board. He stated that Special Agent Kaptain has been with GDNA for ten (10) years and does a terrific job.

Director Troughton reported that GDNA conducted 615 inspections and received 109 complaints for FY2024.

Director Troughton reported that GDNA's newest agent will graduate from the police academy on the 22nd of this month. He added that there is still an open position in Southwest Georgia.

Attorney General's Report – Mr. Max Changus

No report.

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.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
10/04/2023	.5	The Medical Center – Navicent Health	Vancomycin: First Order Kinetics vs AUC Dosing	2023-0010

Low THC Rules: Mr. Lacefield reported that the board office has received the certificate of authority for the rules. He added that they have been sent to the Secretary of State's office. He stated that he will inform the Board as to when the rules become effective.

Legal Services – Mr. Clint Joiner

Correspondence from Vrinda Naik, Vital Care Infusion Services: Ms. Naik was present and spoke to the Board regarding her correspondence. Ms. Naik stated that she is a small business owner and also a pharmacist. She explained that the pharmacy operates as a closed-door, home infusion pharmacy. She stated that she applied for a retail pharmacy license as the pharmacy did not fall under any other umbrella. She continued by stating that the rule requires a pharmacist to be onsite during hours of operation Monday through Friday. Ms. Naik requested approval for only having a pharmacist onsite during dispensing days which are Mondays and Tuesdays. She added that she would like to allow a work from home situation Wednesday-Friday. She stated that the pharmacy is still considered open, but it does not have a pharmacist on site Wednesday-Friday because there is no need for such since this is a new, small business.

Mr. Chang inquired if the pharmacist or technicians would work remotely. She responded by stating the pharmacist would.

Discussion was held regarding no personnel being in the office onsite Wednesday-Friday, but the phone lines would still be open. Mr. Stone commented that the Board's rule did not allow such. Ms. Naik stated that Monday and Tuesday would be the dispensing day and on those days she would have a pharmacist onsite. She explained that she does not have enough volume to have a pharmacist onsite Monday-Friday.

President Azzolin stated that in Ms. Naik's letter, she requested a variance of Rules 480-10-.02, 480-36-.06, and 480-36-.07. He further stated that Rules 480-36-.06 and 480-36-.07 are relatively condensed and just pertain to the requirement of the primary pharmacist to counsel and there to be a notification to patients. He continued by stating that Rule 480-10-.02 is very broad. Ms. Naik responded by stating that she was unsure as to how to properly request it.

President Azzolin inquired as to what section of Rule 480-10-.02 was Ms. Naik seeking a variance of. Ms. Naik responded by stating the portion concerning having a pharmacist onsite and the operating hours of the pharmacy.

President Azzolin read the following from Rule 480-10-.02:

- (4) Except for retail pharmacies located in the same space as hospital pharmacies, a Licensed Pharmacist shall be present and on duty in a licensed retail pharmacy as follows:
 - (a) Entire business establishments which are licensed under O.C.G.A. § 26-4-110 as a pharmacy shall have a pharmacist on duty at all times the pharmacy is open for business as follows:
 1. Such times when the pharmacist is absent from the pharmacy cannot exceed three (3) hours daily, or more than one and one half (1 1/2) hours at any one time. If a pharmacist is absent less than five minutes from the prescription department, this absence is not considered an "absence" within the meaning of this rule and will not require a posted notice, provided that the prescription department's security is not compromised.

President Azzolin inquired if Ms. Naik needed to submit her request in the form of a rule petition. He added that Ms. Naik would need to specify the actual rule and section for which she is seeking a variance of. He stated that he did not know if it would be appropriate for the Board to waive the entire section of Rule 480-10-.02.

Mr. Stone stated that he understood what Ms. Naik was wanting to do, but was unsure if the Board could grant the request since it is a retail pharmacy. Vice-President Page agreed and stated that he did not believe the Board would be comfortable with granting it or if the rule allows for it. Ms. Naik responded by stating that she does not have to have staff there. President Azzolin inquired as to what staff would be there. Ms. Naik responded by stating that support staff would be there. President Azzolin asked if there was a prescription department. Ms. Naik stated that she really does not have a prescription department.

Director Troughton stated that there is nothing that says they cannot be open on Monday and Tuesday. He stated that would be a business decision she is making. He explained that she cannot have anyone in that pharmacy whether there are drugs or not because once she obtained a retail license there could be drugs in the pharmacy. Director Troughton stated that if Ms. Naik's business model changes the day after a variance is granted, nothing would prevent stocking with drugs. He further stated that there is nothing in the rules stating what days or hours the pharmacy can be open, but when it is open, that is when the limitations begin. He added that nobody can be inside the pharmacy without a pharmacist present. Director Troughton stated that the Board would have to decide about conducting business and matters concerning record keeping from home. He stated that this is a unique situation and a lot that the Board needs to consider.

President Azzolin stated that if they say they will only be open Monday and Tuesday that is acceptable as long as a licensed pharmacist is onsite. Discussion was held regarding there not being an actual pharmacy space. President Azzolin inquired if the space had been inspected by GDNA. Director Troughton responded by stating that if the pharmacy holds a license, it has been inspected. President Azzolin stated they would need to have a designated area that is considered to be their prescription department and that area would have to be secure and not accessible when the pharmacist is not there.

Discussion was held regarding patient counseling. Ms. Naik explained her process. She stated that once the prior authorization is approved, they make the call to the patient. She stated that she likes to have a pharmacist make the call prior to dispensing and then the patient has to decide if they want that drug. President Azzolin commented by stating that what she described is not considered patient counseling. He stated that the counseling is upon dispensing of the drug. Director Troughton stated that if she was doing everything prior to the patient getting the drug, there is the potential for a complaint to come to the Board. He explained that counseling is tied to the dispensing of the prescription.

President Azzolin stated that the reason he is asking is if the Board does not allow the waiver for counseling, then upon handing over the drug the pharmacist will be responsible for going over it and it is in their discretion how much they go over it. Director Troughton stated that the law requires counseling. President Azzolin stated that a waiver would not be needed because the practice of pharmacy includes providing clinical information. He added that a pharmacist can talk to a patient prior to the patient ever receiving the drug. Director Troughton stated that the Board allows counseling by paper and phone call now. He stated if it is delivered to the patient, it sounds like they are meeting the requirements of the rule. President Azzolin stated that, based on this conversation, it appears they would not need a waiver for 480-10-.02 or for the counseling piece because the pharmacist can still call and talk to the patient.

Director Troughton stated that when GDNA inspects a pharmacy, and all of these things Ms. Naik has described, GDNA has to inspect it just like it inspects other pharmacies regardless of all of these business hurdles. He explained that if the Board determines a waiver is not needed and GDNA comes in for an inspection, GDNA has to enforce the regulations no matter what. He stated that if she has the required space for the pharmacy and everything is protected and secured, she can do it.

Discussion was held concerning the pharmacy only being open on Monday and Tuesday, but an agent for GDNA showed up on one of the days the pharmacy was closed. Director Troughton stated that if GDNA attempted to do an inspection and the pharmacy was closed, GDNA would contact the pharmacist and make

arrangements for the inspection. President Azzolin stated that since he has been on the Board, he has never seen the Board consider a case for the purpose of punishment because the pharmacist was not available or the pharmacy was closed when GDNA showed up for an inspection. Ms. Naik responded by stating that she wanted to make sure she was in compliance. President Azzolin responded by stating that it was acceptable for her to continue doing what she has been doing.

Mr. Stone made a motion and Vice-President Page 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, Chuck Page, and Dean Stone.

Executive Session

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

- U.I.

Cognizant's Report – Mr. Chuck Page

- GDNA Case # T34908
- GDNA Case # B34877
- GDNA Case # B34893
- GDNA Case # B34878

Appearance

- N.D.S.

Cognizant's Report – Mr. Chuck Page

- GDNA Case # B34891
- GDNA Case # B34829
- GDNA Case # B34861
- GDNA Case # B34890
- GDNA Case # B34879
- GDNA Case # B34864
- GDNA Case # B34837
- GDNA Case # B34876
- GDNA Case # B34797
- GDNA Case # B34786
- GDNA Case # B34723

Attorney General's Report – Mr. Max Changus

Mr. Changus presented the following consent order for acceptance:

- T.M.S.

The Board received legal advice regarding Board Rules 480-1-.01 Organization of the Board, 480-6-.01 Pharmacy Licenses, 480-6-.02 Nonresident Pharmacy Permit, 480-7A-.06 Records and Recordkeeping; Reporting Requirements, 480-19-.04 Recordkeeping for OTC Sales of Exempt Schedule V Products, 480-38-.04 Communications, 480-40-.04 Witness Lists and Respondent Statements, 480-3-.03 Continuing Pharmacy Education, 480-5-.04 Impaired Pharmacists, Interns and Externs, 480-7-.05 Reverse Distributors, 480-7A-.03 Restriction on the Distribution of Listed Chemicals, 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes, 480-33-.01 Definitions,

Mr. Changus discussed the following:

- Pending litigation

Executive Director's Report – Mr. Eric Lacefield

No report.

Legal Services – Mr. Clint Joiner

No report.

Applications

- A.E.W.
- T.V.T.
- C.J.S.
- N.P.
- C.R.R.
- J.A.W.
- E.L.C.
- S.M.M.
- J.M.T.
- J.H.W.
- B.L.R.
- O.P.R.
- J.N.H.
- N.M.C.
- A.A.B.
- D.R.H.
- A.S.
- A.C.C.
- A.R.C.
- A.Y.
- A.H.O.
- J.T.M.
- M.I.
- M.I.
- S.P.
- S.P.
- A.R.I.

Correspondences/Requests

- F.B.I.
- F.B.I.
- F.B.I.
- I.H.S.P.
- I.H.S.P.
- R.E.P.
- P.C.C.

- A.A.
- E.P.
- E.P.
- E.P.
- L.P.
- M.V.S.
- M.V.S.
- M.V.S.
- M.V.S.
- C.C.P.
- L.C.C.
- A.A.L.
- Y.Y.
- A.E.A.
- O.S.A.
- N.T.
- S.S.
- Z.A.
- E.A.O.
- J.C.E.
- J.B.J.
- K.D.P.
- K.A.W.
- A.H.N.B.
- R.H.C.

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:

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

- U.I. Wholesaler Pharmacy Approved application

Cognizant’s Report – Mr. Chuck Page

- GDNA Case # T34908 Accept Voluntary Surrender
- GDNA Case # B34877 Close with Letter of Concern
- GDNA Case # B34893 Misfill Guidance #1A
- GDNA Case # B34878 Refer to the Department of Law

Appearance

- N.D.S. Denied request for 6th attempt to retake NAPLEX Overturned denial and approved request

Cognizant’s Report – Mr. Chuck Page

- GDNA Case # B34891 Close with Letter of Concern
- GDNA Case # B34829 Refer to the Department of Law
- GDNA Case # B34861 Close with Letter of Concern

- GDNA Case # B34890 Close with no action
- GDNA Case # B34879 Close with no action
- GDNA Case # B34864 Close with no action
- GDNA Case # B34837 Close with no action
- GDNA Case # B34876 Close with no action
- GDNA Case # B34797 Close with no action
- GDNA Case # B34786 Close with no action
- GDNA Case # B34723 Refer to the Department of Law

Attorney General’s Report – Mr. Max Changus

Mr. Changus presented the following consent order for acceptance:

- T.M.S. Private Consent Order accepted

The Board received legal advice regarding Board Rules 480-1-.01 Organization of the Board, 480-6-.01 Pharmacy Licenses, 480-6-.02 Nonresident Pharmacy Permit, 480-7A-.06 Records and Recordkeeping; Reporting Requirements, 480-19-.04 Recordkeeping for OTC Sales of Exempt Schedule V Products, 480-38-.04 Communications, 480-40-.04 Witness Lists and Respondent Statements, 480-3-.03 Continuing Pharmacy Education, 480-5-.04 Impaired Pharmacists, Interns and Externs, 480-7-.05 Reverse Distributors, 480-7A-.03 Restriction on the Distribution of Listed Chemicals, 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes, 480-33-.01 Definitions, 480-15-.02 Registration of Pharmacy Technicians and Continuing Education Requirements, and 480-34-.16 Naloxone Hydrochloride Nasal Spray.

Mr. Changus discussed the following:

- Pending litigation Update provided

Executive Director’s Report – Mr. Eric Lacefield

No report.

Legal Services – Mr. Clint Joiner

No report.

Applications

- | | | |
|----------|---------------------|---|
| • A.E.W. | Pharmacy Technician | Approved for registration |
| • T.V.T. | Pharmacy Technician | Approved for registration |
| • C.J.S. | Pharmacy Technician | Table pending receipt of additional information |
| • N.P. | Pharmacy Technician | Approved for registration |
| • C.R.R. | Pharmacy Technician | Approved for registration |
| • J.A.W. | Pharmacy Technician | Approved for registration |
| • E.L.C. | Pharmacy Technician | Approved for registration |
| • S.M.M. | Pharmacy Technician | Approved for registration |
| • J.M.T. | Pharmacy Technician | Approved for registration |
| • J.H.W. | Pharmacy Technician | Approved for registration |
| • B.L.R. | Pharmacy Technician | Approved for registration |
| • O.P.R. | Pharmacy Technician | Approved for renewal |
| • J.N.H. | Pharmacy Technician | Approved for renewal |
| • N.M.C. | Pharmacy Technician | Approved for renewal |
| • A.A.B. | Pharmacy Technician | Approved for renewal |

- D.R.H. Pharmacist Intern Approved application
- A.S. Pharmacist Reciprocity Approved application
- A.C.C. Pharmacist Certification of DTM Approved application
- A.R.C. Pharmacist Certification of DTM Approved application
- A.Y. Pharmacist Certification of DTM Table pending receipt of additional information
- A.H.O. Pharmacist Certification of DTM Approved application
- J.T.M. Pharmacist Certification of DTM Approved application
- M.I. Wholesaler Pharmacy Approved for renewal
- M.I. Wholesaler Pharmacy Approved for renewal
- S.P. Wholesaler Pharmacy Approved application
- S.P. Wholesaler Pharmacy Approved for renewal
- A.R.I. Non-Resident Pharmacy Approved for renewal

Correspondences/Requests

- F.B.I. Notice of Discipline No action
- F.B.I. Notice of Discipline No action
- F.B.I. Notice of Discipline No action
- I.H.S.P. Notice of Discipline No action
- I.H.S.P. Notice of Discipline No action
- R.E.P. Notice of Discipline No action
- P.C.C. Notice of Discipline No action
- A.A. Notice of Discipline No action
- E.P. Notice of Discipline No action
- E.P. Notice of Discipline No action
- E.P. Notice of Discipline No action
- L.P. Notice of Discipline No action
- M.V.S. Notice of Discipline No action
- M.V.S. Notice of Discipline No action
- M.V.S. Notice of Discipline No action
- M.V.S. Notice of Discipline No action
- C.C.P. Notice of Discipline No action
- L.C.C. Correspondence Table pending receipt of additional information
- A.A.L. Request to terminate probation Approved request effective 10/18/2023
- Y.Y. Request regarding reactivating pharmacist license Accept hours and complete Policy 3B
- A.E.A. Request for extension of intern license Approved request through 07/31/2026
- O.S.A. Request for extension of intern license Approved request through 12/31/2023
- N.T. Request for extension of intern license Approved request through 07/31/2024
- S.S. Request for extension of intern license Approved request through 01/31/2024
- Z.A. Request for extension of application date Approved request through 10/31/2024
- E.A.O. Request for 4th attempt to retake NAPLEX Approved request

- J.C.E. Request for 4th attempt to retake NAPLEX Approved request
- J.B.J. Request for 4th attempt to retake NAPLEX Approved request
- K.D.P. Request for 4th attempt to retake MPJE Approved request
- K.A.W. Request for 4th attempt to retake MPJE Approved request
- A.H.N.B. Remote order entry Approved request
- R.H.C. Remote order entry Approved request

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

There being no further business to discuss, the meeting was adjourned at 2:30 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, October 18, 2023, at 9:00 a.m. at 2 MLK Jr., Drive, SE, 11th Floor, East Tower, Atlanta, GA 30334.

Minutes recorded by Brandi Howell, Business Support Analyst I

Minutes edited by Eric Lacefield, Executive Director