

GEORGIA BOARD OF PHARMACY
University of Georgia School of Pharmacy
250 W. Green St. Room 230, Athens, GA 30334
July 17, 2024
9:00 a.m.

Board Members present:

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

Board Staff present:

James Joiner, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Russ Moore, Special Agent, GDNA
Justin Cotton, Assistant Attorney General
Itovia Evans, Deputy Director of Licensing

Visitors:

Johnathan Marquess, GPhA Academy of
Independent Pharmacies
Darrin Evans, Phoebe Putney

Dawn Randolph, CEO of GPhA

*In total, the number of members of the public present is
estimated to be approximately 15 persons. No sign-in
sheet was circulated at this meeting.*

Open Session

President Page welcomed the members of the public in attendance. President Page recognized Johnathan Marquess from GPhA. Mr. Marquess introduced GPhA's new CEO Dawn Randolph.

President Page established that a quorum was present and called the meeting to order at 9:03 a.m.

Approval of Minutes

Mr. Stone made a motion to approve the Public and Executive Session minutes from the June 5, 2024, meeting. Mr. Brinson 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

Medicine Center of Atlanta and Tracy's Medicine: These petitions were considered by the Board together. Each requests a waiver of Rule 480-10-.06, to change ownership and retain the same license number. President Page reminded the board that the rule has recently been changed and has been signed off on by Governor Kemp and is the hands of the Secretary of State. The rule change has not been posted yet. As the rule has been approved the Board is allowed approve the waiver requests. Mr. Brinson added that he has always been in favor of this rule change. Mr. Stone made a motion to approve both requests for waivers. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Optim Medical Center:

This facility is requested a waiver of Rule 480-13-.05(2)(b)1; 480-13-.06(2)(a); and 480-11-.04(3)(b)1, requesting to use an immediate use product model for compounding.

There being no further discussion, Mr. Stone made a motion to approve the waiver request. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Monticello Drugs: The Board considered this petition requesting waiver of Rule 480-50-.01(2) which refers to use of “Authorized Employees” in administration of long-term care facilities in accepting expired or unused medication for destruction. The Petitioner alleged that having to hire a secondary pharmacist for the sole purpose of complying with that rule is a hardship. They are requesting that a certified technician be allowed to process that roll and procedure.

Mr. Stone inquired as to whether anyone from Monticello Drugs was present. It was established that a representative was not present. Mr. Stone reminded the Board that the rule states that a pharmacist must be in charge of taking back those drugs for destruction.

Mr. Stone wanted to know what kind of system the facility was going to implement and stated that there was not enough information in the petition. Mr. Stone advised that with the limited information given he would suggest denying the waiver. President Page agreed that there is not enough information in the provided materials to approve the request. President Page advised that the question he has is whether it is necessary to hire a second full-time pharmacist. Mr. Brinson advised that he would not be opposed to the waiver request so long as the technician was taking the medicine from the facility to a pharmacist and as long as that pharmacist signs off. Mr. Brinson agreed that additional information on the facilities procedure will be needed before he is willing to approve the waiver. Mr. Stone also questioned if it was really a hardship to employ a second pharmacist. Mr. Farmer stated that the facility must show a true hardship and impact in order for waiver to be justified. Mr. Farmer remarked that many businesses today have financial hardships. He mentioned that he would like to see the facility provide details of their operation, verify the security of the product, and willingness to follow the rules correctly.

Mr. Joiner advised that a waiver requires not just showing of a hardship but a hardship unique to the individual petitioner.

Mr. Farmer made a motion to deny the petition. Mr. Brinson seconded, and the Board voted unanimously denying the waiver request. The Board is requesting additional information if the facility wishes to resubmit the waiver along with an invitation to appear before the Board to explain further and/or respond to the Board’s specific questions regarding the proposed system.

Correspondences

Correspondence from GlobalMed Logistix, LLC (GMLx): The Board discussed this correspondence seeking guidance on behalf of GlobalMed, Logistix, LLC. They stated that GMLx had recently expanded its business operation to include an adjacent building, is requesting to operate from the new building under their existing license. The correspondence request guidance regarding whether the adjacent building can be treated as a part of the existing license or whether a separation application for license needs to be submitted.

President Page stated that he did not believe another application would be required but would like Director Troughton’s perspective on the issue.

Director Troughton expressed that there is precedent already involving manufacturers and wholesalers who operate under the same license with multiple buildings in an area that are contiguous. The Board has previously allowed the use of the same license to a multi-building facility as the buildings are doing the same business, under the same books and record keeping. From the stance of enforcement Director Troughton sees no reason to require a separate license for this request and further stated that another license might confuse things. President Page agreed with Director Troughton and asked the Board if they had any commits.

There being no further discussion, Board approved GMLx's request to operate under a single licensure.

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

Director Troughton introduced Special Agent Russ Moore to the Board. Director Troughton stated that Special Agent Moore currently covers eighteen (18) counties including Athens-Clark County. Director Troughton stated that Special Agent Moore stays "quite busy" here in middle East Georgia. Mr. Brinson expressed the Agent Moore was the "most awesome" special agent beside former Special Agent Kell.

Director Troughton reported that GDNA conducted 3,409 inspections and were involved in 536 investigations for FY2024 which is a 9% increase in investigations and 14% increase in inspections over FY2023.

GDNA expected that the numbers would increase due to the addition of one (1) special agent added in 2023 along with an additional two (2) more agent hired for 2024.

Director Troughton believes that GDNA is at full complement with twelve (12) fulltime agents. He further stated that he will not requesting funding at this time as GDNA is in a "good place" budget wise. Director Troughton believes that the new system will in place in about four (4) months. The new system will be combining licensing and will "touch" all aspects needed for the agency to run more efficiently without having to seek three (3) separate parts of the business.

Attorney General's Report – Mr. Justin Cotton

No report.

Executive Director's Report – Mr. James Joiner

No report.

Legal Services – Mr. James Joiner

No report.

Miscellaneous:

- a. **DEA Rescheduling Timeline:** The Board discussed DEA rescheduling THC to Schedule III. Mr. Stone reiterated that since the legislature passed law on low TCH that he believes that pharmacists need to be involved and get out in front of it. Mr. Stone believes that a conversation needs to get started on how create the rules on how to implement the law. Mr. Stone would also like to know the Attorney General's office's opinion on this matter and requests their help when the status changes.

Mr. Cotton stated that given the information received from the DEA and the Board's discussion that the AG's office has already begun the conversation regarding the changes and will be closely monitoring the issue and will be able to provide an opinion on the matter when it has been finalized.

President Page mentioned that he wants to make sure that the Board moves quickly to adjust as needed to move forward without any delays.

Director Troughton noted that he gets questioned frequently wanting to know what the Board is going to do and what GDNA is going to do. Director Troughton stated that GDNA does not have an opinion on the matter or the direction that DEA is going. They have no opinion on the use of low TCH oil and that GDNA is not in the opinion business.

Director Troughton believes that GDNA's roll is to wait for the direction of the federal government and the Attorney General's office that show GDNA the "guard rails" to fit those guidelines with the parameters. Director Troughton stated that this is a complex issue and that it would be best for GDNA to take those parameters as they come out, we will fit the enforcement based on rules, laws and opinions of the Board and Attorney General's Office.

Mr. Chang questioned Mr. Joiner as to whether any applications have been received. Mr. Joiner advised that he had not seen any come in. President Page mentioned that Mr. Chang's question reminded him that he wants to clarify that facilities can still apply for applications and that nothing has changed on that end.

Discussion was had regarding the expiration date of the applications. Mr. Joiner stated that ordinarily applications would expire after one year, but applications made this year were extended by the Board and the licenses were automatically reissued. The licenses will start expiring next year.

b. Hospital Pharmacy Lockboxes

Mr. Brinson briefly discussed the importance of having conversations about the use of smart lockers being the future. Mr. Brinson introduced Mr. Darrin Evans, Vice President of Pharmacy Services for Phoebe Putney Health System (Phoebe Putney).

Mr. Evans spoke about a need for evening and overnight employees to be able to access medicine after normal pharmacy business hours. The company has noticed the employees are having difficulty accessing their filled prescriptions. Phoebe Putney currently has two separate retail pharmacies and is working towards combining the two pharmacies. The newly combined pharmacy will be easier for patients to access but there is still a need for a way for the employees to be able to access their prescriptions. Phoebe Putney is requesting the ability to install smart lockers for their employees to be able to access their filled prescriptions. The smart lockers would only be accessible to the employees. The employees would need to have their badges to access the room where the lockers will be installed. The lockers would not be visible to the public. The employees will be provided a code to access their prescriptions in the locker. The lockers work similar to the way that the Amazon lockers work.

Phoebe Putney asserted that 70% of the prescriptions being returned to stock were from employees not being able to access the pharmacy. The employee's biggest complaint is that they cannot access the pharmacy due to the hours of the pharmacy versus their work hours. Also, Albany does not have a 24-hour pharmacy within appropriately 70 miles which also makes it harder for the employees to have access to pharmacies. The use of the lockers would allow flexibility to the employees.

Mr. Stone asked how the prescription would be added to the lockers. Mr. Evans advised that the pharmacy would fill the prescription and place them in the locker from the pharmacy side. The room where the lockers would be stored is in an employee accessible area of the facility. Mr. Evans provided illustrations for the placement of the lockers.

Mr. Brinson mentioned that he believes that these lockers would be beneficial for hospital employees. Mr. Brinson advised that he is against the public using these lockers as the patient will not always be the person picking up the prescriptions. Mr. Brinson stated that he believes these lockers a wave of the future. He noted that other states and chains are already using these lockers.

Mr. Stone brought up that there have been a couple of presentations from other facilities about the use of smart lockers in the past. Mr. Stone believed that some the problems the Board has had in the past is that about the card access because it was open to the public and how the pharmacy was

placing the filled prescriptions in these lockers. He also stressed that the Board was concerned with how the pharmacist would be able to provide counsel to the patients that use the smart lockers. Mr. Stone stated that he is not against the smart lockers, and he placed emphasis that the Board does need to explore new technology. Mr. Stone is concerned with protecting the patients and citizens. Mr. Stone stated that he understands the diversion risk, but that the Board tends to be behind the technology and need to look at how they can move forward. President Page stated that one of the aspects the Board needs to consider is how this method of dispensing differs from delivery in the way that the pharmacist is not there for immediate counseling.

President Page inquired as to whether there was any additional input from GDNA, and Director Troughton stated that whatever the Board's decision as to the permissibility of the practice was, that GDNA would enforce accordingly. President Page further inquired as to what Director Troughton saw as the downsides from his perspective. He responded that there are concerns about when the drugs are being dispensed and about pharmacist counseling where the Board has been very specific in its requirements for pharmacist counseling in the past. He concluded, stating that he does not believe this issue is as simple as saying yes or no, without delving further into the particulars of fact and legal authority.

Mr. Chang asked the representatives from Phoebe Putney if this system would be used only for refills. Mr. Evans confirmed that it would be just for refills.

Vice President Cordle stated that there was still an issue of employees being unable to access prescriptions during restricted hours. He asked if the Phoebe Putney employees had the option to go to other pharmacies with different hours. Mr. Evans responded that they do, and that Phoebe Putney has contracts with outside pharmacies that are open on weekends.

Vice President Cordle further commented, that he agrees with the sentiment expressed by the Board that there is a need to look at this issue again, as it was a few years ago when the Board last considered it. He continued, stating that the challenge he sees with this issue is that in this instance, the hospital staff are the entire population with access to this process. He stated that in a retail environment, there are no such guardrails and diversion becomes a much greater risk and he believes that there will need to be additional security measures in place to track it in a retail setting.

Mr. Brinson added that he thinks that Phoebe Putney has made big improvements over what has been presented in the past, in the way that employees have to scan in to access the lockboxes.

Vice President Cordle responded that this was his point, in its present form it works for the hospital setting but that retail would require additional security.

President Page asked the representatives from Phoebe Putney what their timeline for opening the pharmacy was. They responded that they are looking to open the pharmacy in October. President Page continued, stating that he asked that question because he agreed with the sentiments stated by the Board, that there is more to look at and to delve into from factual and legal standpoints. President Page stated that it was his inclination to take this matter under advisement for the moment, research the issue further and bring it back to a future board meeting.

Mr Stone added that this type of dispensing may require new Board rules. Vice President Cordle responded that while he believes the rules should be researched again, he did not recall anything in the rules which was prohibitive of the practice when it was discussed previously.

President Page inquired whether a formal rule waiver request would have to be submitted if waiver

of a rule was necessary in this matter. Mr. Joiner responded in order to waive a rule, the Board must receive a waiver request and it must be posted at least 15 days prior to the meeting.

Discussing the waiver, the Board determined that it was not yet clear whether any rule would need to be waived.

Mr. Cotton added that part of the analysis of this decision is a legal analysis as to whether this practice transgresses a rule, which will drive the determination of whether a rule waiver is necessary. Mr. Cotton stated that he understood the position of the Board and GDNA was that they needed to be certain on this point.

Director Troughton added that he believes part of the analysis should be looking at prior decisions of the Board, which have always been to disallow the practice, and examine the rationale behind those prior decisions.

The Board decided to table this discussion, and to refer the matter to the Attorney General's office and to Georgia Drugs and Narcotics for research.

Mr. Brinson asked for a moment to make a few comments. He thanked GPhA for putting on a great convention and for inviting him to speak, he stated the convention was well attended and he had a great time. He also thanked Director Troughton and GDNA Special Agent Tommy Rowe for going with him to speak to the Georgia Society of Hospital Pharmacists, which he said it was a thoughtful discussion and well attended.

A member of the public asked a question about HB 557 with regard to physician's assistant and nurse practitioner prescribing authority, and whether the Board was considering a rule change. President Page responded that it was in the works and was coming up for consideration at the Board's next meeting.

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: Jim Bracewell, Mike Brinson, Young Chang, Cecil Cordle, Chuck Page, and Dean Stone.

Executive Session

Appearances

- J.M.
- E.O.
- A.S.

Georgia Drugs and Narcotics Agency

No report.

Cognizant's Report – Mr. Cecil Cordle

- GDNA Case #A35319
- GDNA Case #A35328
- GDNA Case #B35310
- GDNA Case #T35351
- GDNA Case #T35264

- GDNA Case #A35359
- GDNA Case #A35358
- GDNA Case #A35338
- GNDNA Case #A35278
- GDNA Case #A35305
- GDNA Case #A35323
- GDNA Case #B35293
- GDNA Case #B35321
- GDNA Case #A35279
- GDNA Case #B35285
- GDNA Case #B35287
- GDNA Case #A35334
- GDNA Case #A35329
- GDNA Case #B35241
- GDNA Case #B35296
- GDNA Case #B35332
- GDNA Case #B35320
- GDNA Case #B35311

Attorney General's Report – Mr. Justin Cotton

- Status Report:
 - M.C.
 - L.M.
 - M.P.S.
 - E.T.
 - R.P.P.
 - S.P.I.
 - W
 - C.
 - E.T.
 - M.S.M.I.
 - W.P.C.G.

Mr. Cotton presented the following counter proposals:

- P.A.J.
- A.H.
- E.F.P.

Executive Director's Report – Mr. James Joiner

- No report.

Legal Services – Mr. James Joiner

- M.E.I
- J.W.
- M.P

Applications

- J.B.

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

Correspondences/Requests

- A.G.
- A.P.L.
- A.P.
- B.T.P
- B.T.P.
- D.E.I.
- K.S.P.
- M.V.S.
- J.J.
- O.C.I.
- E.R.P.
- G.U.S.L.
- S.H.I

Correspondences/Requests

- A.C.
- A.M.
- J.E.
- J.R.
- J.R.
- J.M.C.
- K.H.
- O.A

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

Open Session

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 2:21 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, August 21, 2024, at 9:00 a.m. at 625 Old Peachtree Rd, NW Suwanee, GA 30024

Minutes recorded by Angela Johnson, Board Administrative Secretary

Minutes edited by J. Clinton Joiner, II, Executive Director