

GEORGIA BOARD OF PHARMACY
South University School of Pharmacy
709 Mall Blvd
Savannah, GA 31406
March 6, 2024
9:00 a.m.

The following Board members were present:

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

Staff present:

Eric Lacefield, Executive Director
Alec Mathis, Special Agent, GDNA
Max Changus, Senior Assistant Attorney General
Clint Joiner, Attorney
Brandi Howell, Business Support Analyst I
Sandra Mason, Licensing Analyst

Visitors:

Christina Green, Academy of Pharmacy Techs
Jonathan Marquess, GPhA/AIP
Jeenu Philip, Walgreens
Heather Hughes, Publix
Becca Hallum, GHA
Cameron Boyd, Walmart
Jennifer Duckett, Walgreens
Rondell Jagers, Grady Health System
Raven Oyagha, South University Student
Sara Little, UGA College of Pharmacy Student

Open Session

President Page established that a quorum was present and called the meeting to order at 9:00 a.m.

Approval of Minutes

Mr. Brinson made a motion to approve the Public and Executive Session minutes from the February 14, 2024, meeting. 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.

Correspondences

Correspondence from Jeenu Philip, Walgreens Co: The Board considered this request for approval of Walgreens ASHP/ACPE Pharmacy Technician Training Program as state certification for pharmacy technicians in Georgia. Discussion was held concerning what would happen if the technician obtained the certification and left Walgreens to go somewhere else. Mr. Azzolin stated the Board previously discussed a similar request that was specific to a specialty pharmacy whereas Mr. Philip's request was more general in nature and seems it would apply across all practice types. President Page commented that it would be up to the PIC to make sure the technician was certified wherever he/she may go.

Mr. Philip was present and spoke to the Board regarding the request. He stated the ASHP program offers the individual a certificate at the end of the program indicating they completed the Walgreens ASHP Training Program. He further stated that it is a nationally accredited program. Mr. Philip explained that Florida maintains a list of pre-approved ASHP accredited training programs. He continued by stating that if an individual comes from another state and has gone through any program as long as it was accredited, it would be considered an approved training program in Florida. Mr. Philip stated that the Board could decide that any ASHP accredited training program is considered a board-approved training program and would not have to go through any additional steps to determine whether that technician was certified or not. He noted that ASHP goes through a rigorous process in order to accredit training programs.

Mr. Stone inquired about renewal. He stated that PTCB (Pharmacy Technician Certification Board) has a renewal process. He inquired if the training program was a one-time process or did the individual have to renew the certification. Mr. Philip responded by stating that it was a one-time process. Mr. Stone commented that his only concern was having ongoing professional advancement. He noted that he did not have any issue with the training program.

Vice-President Cordle commented that he felt the Board was considering approving the program. He added that the Board was creating another pathway for any technician, whether they were with Walgreens or not, to use this training program as opposed to others. He stated that if a Walgreens employee were to leave and they were accredited, that accreditation would follow them.

After further discussion, Mr. Stone made a motion to approve the program. Mr. Azzolin seconded, and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Mr. Alec Mathis

Special Agent Mathis reported that GDNA conducted 2142 inspections and received 382 complaints for FY2024.

Attorney General’s Report – Mr. Max Changus

Mr. Changus announced that the March meeting would be his last meeting as he was leaving the Attorney General’s office to take a position elsewhere. He stated that he appreciated all of the learning and training by representing the Board over the years, not only with the members of the Board, but also with staff and GDNA. President Page thanked Mr. Changus for his hard work and service. He added that Mr. Changus had been invaluable to the Board. Mr. Changus stated that Mr. Justin Cotton would be working with the Board starting in April.

Executive Director’s Report – Mr. Eric Lacefield

Continuing Education Report: Mr. Lacefield reported that the course titled, “Medical Marijuana” from The Medical Center Navicent Health was denied in December by President Page, who was the Cognizant at the time. Mr. Lacefield explained that the course was being brought before the Board to either confirm the denial or have discussion regarding the course.

President Page stated that the course itself was fine. He explained that it was the timing of the request that was an issue. He stated that the DEA’s letter had been issued in November and he felt that it was not the right time to consider the course. He added that he was good if the Board wanted to have a discussion or move forward.

The Board discussed its concerns regarding a slide that stated there will be no prosecution by Georgia or Federal law enforcement for registering patients. The slide referenced O.C.G.A. § 16-12-231. Vice-President Cordle commented that O.C.G.A. § 16-12-231 reads, “The following persons and entities, when acting in accordance with the provisions of this article, shall not be subject to arrest, prosecution, or any

civil or administrative penalty, including a civil penalty or disciplinary action by a professional licensing board, or be denied any right or privilege, for the medical use, prescription, administration, manufacture, distribution, or transport of low THC oil or products:”. He continued by stating that section (3) of O.C.G.A. § 16-12-231 states, “A pharmacist or pharmacy that dispenses or provides low THC oil or products to a registered patient;” Vice-President Cordle stated the issue was that there was conflict between Georgia law and federal law.

Mr. Azzolin commented that there should be a disclaimer in the course information stating that O.C.G.A. § 16-12-231 is Georgia law only.

Mr. Farmer stated that the content of the course was great and would be a great tool to learn about the pharmacology of medical marijuana; however, he felt there should be a disclaimer noting to be conscious of federal guidelines.

Mr. Azzolin commented that the slide reads as follows:

Will I be Prosecuted by Georgia or Federal Law Enforcement for Registering Patients?

- *No!!!*

Georgia Code 16-12-231 provides:

- *Protection from arrest*
- *Prosecution*
- *Disciplinary action*

Mr. Azzolin stated if the person took continuing education course and read Georgia law, there is an implication that the federal government would not prosecute them, which may not be true. He added that the entire slide needs to be addressed. Mr. Azzolin stated that if the entity that submitted the course for review goes back and reads the minutes, they will know why the Board had issues with the course presented. Mr. Lacefield inquired if a letter should be sent noting the reason why the course was being denied, along with the slide number. Mr. Farmer agreed and stated the Board should give them the specifics of the issue and have them resubmit the course. Mr. Azzolin stated the letter should also reference the minutes.

There being no further discussion, Mr. Stone made a motion to deny the course. Mr. Azzolin seconded, and the Board voted unanimously in favor of the motion.

Low THC Renewals: Mr. Lacefield reported that there are currently thirty-two (32) active permits. He added that the permits expire annually and June 30th would be the first renewal. He requested the Board waive the renewal fee for this renewal cycle and allow staff to administratively renew the licenses with an expiration date of June 30, 2025, since it is the first renewal period and the permits were not being used at this point. Mr. Stone made a motion to grant the request. Mr. Farmer seconded, and the Board voted unanimously in favor of the motion.

Mr. Lacefield thanked the Board for all the kind words regarding his departure. President Page thanked Mr. Lacefield for all of his hard work. He added that the support and guidance given by Mr. Lacefield was invaluable.

Legal Services – Mr. Clint Joiner

No report.

Miscellaneous

Policy Manual Update: President Page stated that the Board was not at a point to vote on the updated policies. He further stated that he wanted to gather each member's feedback and look at the old policy and new information together.

Vice-President Cordle stated that he did not understand the history of some of the policies and inquired as to why they were in place because they seemed misleading. President Page responded by stating that some of the policies were questionable and it had been twenty (20) years since the last update. He stated that some policies needed to be either deleted or changed.

Mr. Changus commented that promulgating rules is an arduous process that involves not only the drafting of the rule, but the additional steps that have to take place such as posting the rule, holding a public hearing, and sending to the Governor's office for review. He continued by stating that policies vary among boards. He explained that the idea behind many of the policies was to circumvent some of the rules. Specifically, Policy 3B, for example. Mr. Changus stated that there is an administrative aspect to it that may not be there in a lot of rules. He further stated that a number of boards over the years have looked to use policies. He continued by stating that as statutes have changed, the General Assembly thinks if it is a policy that affects substantive rights, then it is really a rule. If it is a rule, then it needs to go through the formal rules process. He added that as the Board looks to delete some of the policies, the idea that the Board replaces them and thinks it will escape the entire regulatory process is something the Board should be careful about. Mr. Changus stated that O.C.G.A. § 43-1C discusses the Governor's review process and anything that effects rights should go through the Governor's review process.

Mr. Bracewell stated that there was much value in having policies. He further stated that they bring consistency, such as policies on misfills. He added that he thought it was worthy of looking over them and the Board should do so on a regular basis.

Mr. Brinson inquired if everything listed in the policy manual was also in the rules. Mr. Azzolin responded by stating that there is a policy on PBM's and PBM's are no longer reflected in a rule anymore. He stated that the policy does need to be addressed. Mr. Brinson stated that he was specifically talking about the policies regarding reinstatement. Mr. Lacefield responded by stating that the policies concerning reinstatement were not spelled out in the rules. He further stated that the policies for reinstatement are the administrative procedures for handling reinstatements.

After further discussion, the Board agreed to continue to work on the policy manual and discuss further at a later time.

USP 800: President Page discussed USP <800>. He stated that a discussion needed to be had regarding the guidelines and what they mean for the Board. He inquired if there was any room for interpretation on the guidelines.

Mr. Stone stated that O.C.G.A. § 26-4-86(a) states, "The board shall establish rules and regulations governing the compounding and distribution of drug products by pharmacists, practitioners, and pharmacies licensed or registered by this state. Such rules and regulations shall include provisions ensuring compliance with USP-NF standards." He stated that he has received many questions from pharmacists regarding how the Board will handle it. He expressed his concerns over what the Board is to enforce.

Mr. Azzolin inquired if the Board was required to enforce all of the USP standards because the law says the Board must ensure compliance with USB standards. He stated that two (2) years ago USP <800> did not exist, but now that it is there, does that imply the Board has to enforce everything that is added, or can the Board pick and choose the standards?

Mr. Farmer commented that when the Board previously discussed USP <800>, there was documentation provided from Mr. Stone showing what different states were doing. He stated there is a question of enforcement with non-compounding in the retail sector of the store and those products. He continued by stating that the interpretation of USP in a non-compounding retail sector is a whole other matter. He added that the Board should really discuss it further at its April meeting. President Page commented that the Board needed guidance.

Mr. Changus stated that O.C.G.A. § 26-4-86(a) states in part, "...Such rules and regulations shall include provisions ensuring compliance with USP-NF standards." He further stated that there seems to be additional hurdles in USP <800> versus what was in <795> and <797>, which makes it more difficult to comply. He continued by stating that the General Assembly recognized this was likely to change over time so they made it general and the evolution of these requirements have become more onerous than when the law was originally adopted. Mr. Changus stated that in terms of picking and choosing what the Board will ensure compliance with and what it will not, as a practical matter makes sense, but as a legal matter is tougher to articulate and likely not a good way to go. He inquired as to what makes USP <800> burdensome. Mr. Farmer responded by stating that in general, there is air handling with powder containment hoods that have to be in place. He also mentioned surfaces have to be impervious. He added that it is also cost prohibitive. Additional examples were provided by the members.

Mr. Azzolin stated that by making compounding stricter, they have made it more dangerous because it is causing pharmacies to do away with safeguards that allow them to safely dispense medication, such as doing away with IV administration hoods altogether and instead mixing immediate use products on nursing floors of hospitals. He further stated that he felt the Board could do a better job if it did not impart all of the strict nature of USP on all of the pharmacies in Georgia and come back to a more reasonable rule. President Page inquired if the Board was allowed to do that. Mr. Azzolin inquired if that required a change in the law.

Mr. Changus inquired if there was pushback from NABP or other organizations when these changes were being discussed. Mr. Farmer responded by stating that there was a lengthy open comment period of time before they were adopted. Mr. Azzolin stated that prior to USP <797> existing, USP's recommendations were great from a pharmacist's perspective. He further stated that as <797> evolved and when <800> came out, it has gotten to the point where patients do not even have access because pharmacists will not do it. He noted the number of rule waiver requests for exemptions of hoods that are considered each month from pharmacies so they can mix on the counter.

Mr. Brinson asked Mr. Rondell Jagers if he would like to provide comments. Mr. Jagers stated that he appreciated the conversation regarding the complexities of USP <800>. He stated that he was the former Vice-President of Pharmacy Services at Grady Health System in Atlanta. He further stated that they have made every effort to be in compliance and have been inspected. He discussed there being an offsite infusion center that is low volume and there being some complexities with cleaning and other things. Mr. Jagers stated that he is also licensed in Kentucky. He explained that Kentucky regulations allow for a 2-3 year implementation period to come into compliance with USP <800> whereas Georgia regulations state that whatever the current USP standards are, Georgia shall ensure compliance.

Mr. Changus commented that the Board relies on Director Troughton's input with regards to enforcement. He stated that he would have a conversation with Director Troughton and Mr. Cotton to see what thoughts can be provided on how to negotiate that to the extent it is possible. He continued by stating that in terms of the implementation period, that is an ongoing thing in the statute. Mr. Changus stated that once a standard is adopted, the Board is obligated to identify rules that are in concert with that.

Mr. Stone made a motion and Mr. Cordle seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h), § 43-1-2(h), and § 50-14-3(b)(2) 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, Cecil Cordle, Michael Farmer, Chuck Page, and Dean Stone.

Executive Session

Georgia Drugs and Narcotics Agency – Mr. Alec Mathis

No report.

Cognizant's Report – Mr. Cecil Cordle

- GDNA Case # B35180
- GDNA Case # T35191
- GDNA Case # T35112
- GDNA Case # B35166
- GDNA Case # B35085
- GDNA Case # B35038
- GDNA Case # B35027
- GDNA Case # A35188
- GDNA Case # A35142
- GDNA Case # B35046
- GDNA Case # B35075
- GDNA Case # B35120
- GDNA Case # B35121
- GDNA Case # B35082
- GDNA Case # B35138
- GDNA Case # B34977
- GDNA Case # B35164
- GDNA Case # B35083
- GDNA Case # B35060

Cognizant's Report – Mr. Chuck Page

- GDNA Case # A34860
- GDNA Case # A35108

Attorney General's Report – Mr. Max Changus

Mr. Changus presented the following consent orders for acceptance:

- B.S.S.P.
- P.S.
- C.T.M.
- J.J.S.
- C.P.
- C.P.
- C.M.Q.P.
- C.P.
- R.H.C.P.
- S.N.

Mr. Changus discussed the following:

- P.N.B.
- M.K.
- E.F.P.
- M.P.

The Board received legal advice regarding Rule 480-22-.06. Partial Filling of a Schedule II (C-II) Controlled Substance Prescription Drug Order; and Rule 480-22-.12 Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA), or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia.

Executive Director's Report – Mr. Eric Lacefield

No report.

Legal Services – Mr. Clint Joiner

No report.

Applications

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

Correspondences/Requests

- A.I.
- C.P.
- S.P.
- T.S.P.
- C.P.
- M.K.A.
- J.J.R.
- T.O.B.
- F.B.P.D.

Miscellaneous

The Board discussed staffing matters.

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

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

Georgia Drugs and Narcotics Agency – Mr. Alec Mathis

No report.

Cognizant’s Report – Mr. Cecil Cordle

- GDNA Case # B35180 Accept Signed Voluntary Surrender
- GDNA Case # T35191 Accept Signed Voluntary Surrender
- GDNA Case # T35112 Revoke Technician Registration
- GDNA Case # B35166 Misfill Guidance #1A
- GDNA Case # B35085 Close with Letter of Concern
- GDNA Case # B35038 Misfill Guidance #/1A
- GDNA Case # B35027 Misfill Guidance #2A
- GDNA Case # A35188 Refer to the Department of Law
- GDNA Case # A35142 Refer to the Department of Law
- GDNA Case # B35046 Close with Letter of Concern
- GDNA Case # B35075 Misfill Guidance #1A
- GDNA Case # B35120 Close with Letter of Concern
- GDNA Case # B35121 Close with Letter of Concern
- GDNA Case # B35082 Close with Letter of Concern
- GDNA Case # B35138 Close with no action
- GDNA Case # B34977 Close with no action
- GDNA Case # B35164 Close with no action
- GDNA Case # B35083 Close with no action
- GDNA Case # B35060 Close with no action

Cognizant’s Report – Mr. Chuck Page

- GDNA Case # A34860 Close with Letter of Concern
- GDNA Case # A35108 Accept Signed Voluntary Surrender

Attorney General’s Report – Mr. Max Changus

Mr. Changus presented the following consent orders for acceptance:

- B.S.S.P. Private Consent Order accepted
- P.S. Private Consent Order accepted
- C.T.M. Public Consent Order accepted
- J.J.S. Public Consent Order accepted
- C.P. Public Consent Order accepted
- C.P. Public Consent Order accepted
- C.M.Q.P. Public Consent Order accepted
- C.P. Public Consent Order accepted
- R.H.C.P. Public Consent Order accepted
- S.N. Private Consent Order accepted

Mr. Changus discussed the following:

- P.N.B. Accept counterproposal
- M.K. Update provided
- E.F.P. Table pending receipt of additional information
- M.P. Accept counterproposal

The Board received legal advice regarding Rule 480-22-.06. Partial Filling of a Schedule II (C-II) Controlled Substance Prescription Drug Order; and Rule 480-22-.12 Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA), or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia.

Executive Director's Report – Mr. Eric Lacefield

No report.

Legal Services – Mr. Clint Joiner

No report.

Applications

- | | | |
|----------|---------------------------------|--|
| • R.C.B. | Pharmacy Technician | Approved for registration |
| • R.A.P. | Pharmacy Technician | Approved pending receipt of additional information |
| • D.J.L. | Pharmacy Technician | Approved for registration |
| • B.L.S. | Pharmacy Technician | Approved for registration |
| • A.L.B. | Pharmacy Technician | Denied application |
| • C.A.W. | Pharmacy Technician | Approved for registration |
| • M.K.D. | Pharmacist Reinstatement | Denied application |
| • M.U.M. | Nuclear Pharmacist | Approved application |
| • S.T.B. | Nuclear Pharmacist | Approved application |
| • A.E.L. | Pharmacist Certification of DTM | Approved application |
| • G.R.M. | Pharmacist Certification of DTM | Approved application |
| • K.O.A. | Pharmacist Certification of DTM | Approved application |
| • K.L. | Pharmacist Certification of DTM | Approved application |
| • M.J.P. | Pharmacist Certification of DTM | Approved application |

Correspondences/Requests

- | | | |
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| • A.I. | Notice of Discipline | No action |
| • C.P. | Notice of Discipline | No action |
| • S.P. | Notice of Discipline | No action |
| • T.S.P. | Notice of Discipline | No action |
| • C.P. | Notice of Discipline | No action |
| • M.K.A. | Request to Lift Suspension | Approved request |
| • J.J.R. | Request for 4 th attempt to retake MPJE | Approved request |
| • T.O.B. | Request for 5 th attempt to retake NAPLEX | Approved request |
| • F.B.P.D. | Request for waiver of reinstatement and late renewal fees | Approved request |

Miscellaneous

The Board discussed staffing matters. The Board appointed Mr. Clint Joiner as Executive Director of the Georgia Board of Pharmacy.

Mr. Brinson seconded, and the Board voted in favor of the motion, with the exception of Vice-President Cordle who recused himself from the vote regarding GDNA Case # A35108.

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

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, April 10, 2024, 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