GEORGIA BOARD OF PHARMACY
2 MLK Jr. Drive, SE, 11th Floor, East Tower
Atlanta, GA 30334
April 10, 2024
9:00 a.m.

The following Board members were present:
Chuck Page, President
Cecil Cordle, Vice-President
Michael Azzolin
Michael Brinson
Young Chang
Michael Farmer
Dean Stone

Staff present:
James Joiner, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Nick Aderibigbe, Special Agent, GDNA
Alec Mathis, Special Agent, GDNA
Justin Cotton, Assistant Attorney General
Itovia Evans, Business Operations Manager
Brandi Howell, Business Support Analyst I

Visitors:
Dawn Sasine
Melissa Reybold, GPhA
Olivia Buckner, Nelson Mullins
Jonathan Marquess, GPhA/AIP
D. Scott Bass, GPhA
Jeenu Philip, Walgreens
Lokendra Upadhyoy
Stephanie Kirkland, Eldercare
Lauren Paul, CVS
Heather Hughes, Publix
Brandon Brooks, Publix
Susan DelMonico, Genoa
Jennifer Duckett, Walgreens
Kasey Knight, Senius Life Rx
Emily Doppel, BrightSpring
Becca Hallum, GHA
Diane Sanders, Kaiser Permanente
Helen Sloat, Nelson Mullins
Jason Strow, Encompass Health
Beth Jarrett, Walmart

Public Hearing

President Page called the public hearing to order at 9:03 a.m.

Rule 480-10A-.05 Transmission and Labeling

President Page stated the rule amendments were relative to adding language allowing electronic notation regarding the use of central filling on a prescription.

Written responses were received from Lauren Paul, CVS Health, and Jeenu Philip, Walgreens.

Ms. Heather Hughes, Publix, spoke to the Board. She thanked the Board for granting Publix a waiver regarding this matter last year. She stated that it worked well for their team and they were thankful for the burden that was alleviated. Additionally, Ms. Hughes thanked the Board for considering the amendment.

No further comments were received.

Mr. Stone made a motion to adopt Rule 480-10A-.05 Transmission and Labeling. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule 480-22-.06 Partial Filling of a Schedule II (C-II) Controlled Substance Prescription Order
No public comments or written responses were received.

Mr. Brinson made a motion to adopt Rule 480-22-.06 Partial Filling of a Schedule II (C-II) Controlled Substance Prescription Order. Mr. Farmer seconded, and the Board voted unanimously in favor of the motion.

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
Written responses were received from Melissa Reybold, GPhA.

Discussion was held by President Page. He stated there were questions regarding the law requiring the supervising physician's information being on the hard copy whereas electronic prescriptions do not require this information. President Page stated that O.C.G.A. § 43-34-103(e.1)(3) does reference the need for the hard copy prescription to have the supervising physician's information on the prescription. He further stated that O.C.G.A. § 26-4-80 does not have the same requirements for electronic prescriptions.

Mr. Azzolin inquired as to where the code section was relating to electronic prescriptions. President Page responded by stating that the information was in O.C.G.A. § 26-4-80. Mr. Azzolin stated that since O.C.G.A. § 43-34-103(e.1)(3) references prescription drugs and what the requirements for a prescription drug order are, he inquired if that code section umbrellas by default everything including electronic prescriptions even though O.C.G.A. § 26-4-80 does not apply that. Mr. Cotton responded by stating that later in that same section it breaks out electronic prescription orders specifically and points to O.C.G.A. § 26-4-80. He stated that for that reason it seems the first part of that section is for the hard copy. Mr. Azzolin commented that he was good with that if the Board was.

President Page stated that the rule as presented today does not break that out and a revised rule has been posted on Sharepoint for the members to review. He further stated the rule has been revised to include language stating that a hard copy must include the supervising physician's information. He added that the requirement for such on the electronic copy remained stricken from the proposed rule. President Page asked if the Board was satisfied with the revised amendment or if there were any comments or concerns. Director Troughton commented that GDNA receives questions regarding this matter all the time. He stated that he just saw the last minute changes and had not had a chance to review it closely. He stated that if the Board votes to post the revised rule and it is later adopted, he wanted to be sure that everyone was clear on the requirements. He continued by stating that from what he understood the only time the prescribing physician or delegating physician's name has to be on any of the scripts is if it is a paper script handed to the pharmacist and that on every other electronic prescription there is no need for that information. Mr. Azzolin commented that it also implies faxed prescriptions as well. He stated that if a written prescription was received, you could just fax it to yourself and be in compliance. He added that he wanted to point out the obvious of how ridiculous that was. He continued by stating that the problem will be for a pharmacist saying it is an e-prescription and they do not need to know the physician's information, or the pharmacist saying this is a hard copy prescription and the physician's information is needed. Mr. Azzolin stated that

GDNA will have to enforce the law and it puts the agents in a tough position. Director Troughton responded by stating that the Board needs to make it clear that is the way it wants GDNA to enforce it regardless of his opinion about the rule change and whether he agrees with it or not.

Mr. Stone commented that he agreed with the change. He stated that the pharmacy would be receiving fewer hard copies. President Page stated that it would be the Board's job to communicate that. Mr. Stone agreed, but stated that it was the pharmacist's responsibility to review the law and rules. He stated to Director Troughton that the hard copy would need the physician's information and the electronic copy would not. Director Troughton stated that would be turning onto a different road than they had been on before. He further stated that if that is how the Board wanted to enforce it, the agents would not waste time on looking for electronic prescriptions. He continued by stating that it does not make much sense from an enforcement standpoint to look for the paper prescriptions that do not have that information, but they will because that is the law.

Mr. Stone stated that he has received prescriptions from Nurse Practitioners and Physician's Assistants that were working in different clinics. He further stated that with the hard copies he is having to track and it delays patients receiving their medications. Mr. Joiner commented that the only legal route to make it more uniform would be to require it on everything. Mr. Azzolin stated that he would rather get what we can get under the confines of the rules and encourage the law to be changed. Mr. Stone agreed.

President Page stated to Director Troughton that section (1)(d) of Rule 480-22-.12 was amended to read: "(d) ~~The~~ A prescription drug order presented in a hard-copy format must include the following:"

Director Troughton responded by stating that it was a simple change for GDNA. He stated that it just prevents the agents from looking through more electronic prescriptions to see if they see something is off. He further stated that the whole purpose of including this information in the rule when it was written was to track it back to the person who wrote the script if there was a problem. He continued by stating that the purpose of the rule is to provide a paper trail back to who prescribed it and did they have authority to prescribe. Director Troughton stated that it would not be an issue for GDNA to enforce it.

Mr. Stone commented that it was his understanding that Nurse Practitioners and Physician's Assistants have to have the protocol filed with the Georgia Composite Medical Board. He stated that in order for them to be licensed they have to have the protocol filed and if they are licensed then that is a verification on their side and the pharmacist should not have to verify who the supervising physician is.

Mr. Cotton noted that O.C.G.A. § 26-4-80 does require of the electronic order that the signature of the prescribing practitioner is there, so there is still somewhat of a paper trail, but in a different form. He added that he was not sure if the signature versus the name just being there was a material difference to the Board or not. Director Troughton responded by stating that it does not mean the signature of the delegating physician, but rather it means the signature of the Physician's Assistant or Nurse Practitioner that wrote the prescription, which is separate.

No further comments were received.

Mr. Azzolin made a motion to not proceed with the current version of 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 posted for the public hearing. Vice-President Cordle seconded, and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion to post 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 as amended. Vice-President Cordle seconded, and the Board voted unanimously in favor of the motion.

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

(1) Under O.C.G.A. § 43-34-103(e.1), a physician assistant (PA) licensed by the Georgia Composite Medical Board is permitted to issue a prescription drug order or orders for any dangerous drugs, as defined in O.C.G.A. § 16-13-71, or for any Schedule III, IV, or V controlled substance without the co-signature of a supervising physician under the following conditions:
   (a) The supervising physician has delegated the authority to prescribe dangerous drugs and/or controlled substances in the PA's job description on file with the Georgia Composite Medical Board.
   (b) If the prescription is for controlled substances, the PA has a DEA number.
   (c) If the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.
   (d) ~~The~~ A prescription drug order presented in a hard-copy format must include the following:
      1. ~~(i)~~ The name, address, and telephone number of the supervising physician and the PA;
      2. ~~(ii)~~ The patient's name and address;
      3. ~~(iii)~~ The drug name, strength and quantity prescribed;
      4. ~~(iv)~~ The directions to the patient with regard to taking the drug;
      5. ~~(v)~~ The number of authorized refills, if any; and
      6. ~~(vi)~~ If applicable, the DEA permit number of the PA.
   (e) If the prescription is transmitted by facsimile or computer, the prescription shall include:
      1. ~~(i)~~ The complete name and address of the ~~supervising physician and the~~ PA;
      2. ~~(ii)~~ In the case of a prescription drug order for a controlled substance, the DEA registration number of the PA;
      3. ~~(iii)~~ The telephone number of the PA for verbal confirmation;
      4. ~~(iv)~~ The name and address of the patient;
      5. ~~(v)~~ The time and date of the transmission;
      6. ~~(vi)~~ The full name of the person transmitting the order;
      7. ~~(vii)~~ The drug name, strength and quantity prescribed;
      8. ~~(viii)~~ The directions to the patient with regard to taking the drug;
      9. ~~(ix)~~ The number of authorized refills, if any; and
      10. ~~(x)~~ The signature of the PA as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.
   (f) No prescription drug order issued by a PA can be used to authorize refills more than twelve (12) months past the date of the original drug order.

(2) Under O.C.G.A. § 43-34-25, an advanced practice registered nurse (APRN) who is recognized by the Georgia Board of Nursing as having met the requirements to engage in advanced nursing practice, and whose registered nurse license and advanced practice registered nurse license are in good standing with the Georgia Board of Nursing, is permitted to issue a prescription drug order or orders for any dangerous drugs, O.C.G.A. § 16-13-71 except for drugs intended to cause an abortion to occur pharmacologically, or for any Schedule III, IV, or V controlled substance without the co-signature of a delegating physician under the following conditions:
   (a) The APRN has been delegated the authority to issue prescription for the dangerous drugs and controlled substances by a physician licensed by the Georgia Composite Medical Board in a nurse protocol agreement and that agreement has been filed with the Georgia Composite Medical Board.
   (b) If the prescription is for controlled substances, the APRN has a DEA number.

(c) If the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.

(d) ~~The~~ A prescription drug order presented in a hard-copy format must include the following:

1. ~~(i)~~ The name, address, and telephone number of the delegating physician and the APRN;
2. ~~(ii)~~ The patient's name and address;
3. ~~(iii)~~ The drug name, strength and quantity prescribed;
4. ~~(iv)~~ The directions to the patient with regard to taking the drug;
5. ~~(v)~~ The number of authorized refills, if any; and
6. ~~(vi)~~ If applicable, the DEA permit number of the APRN.

(e) If the prescription is transmitted by facsimile or computer, the prescription shall include:

1. ~~(i)~~ The complete name and address of the ~~delegating physician and the~~ APRN;
2. ~~(ii)~~ In the case of a prescription drug order for a controlled substance, the DEA registration number of the APRN;
3. ~~(iii)~~ The telephone number of the APRN for verbal confirmation;
4. ~~(iv)~~ The name and address of the patient;
5. ~~(v)~~ The time and date of the transmission;
6. ~~(vi)~~ The full name of the person transmitting the order;
7. ~~(vii)~~ The drug name, strength and quantity prescribed;
8. ~~(viii)~~ The directions to the patient with regard to taking the drug;
9. ~~(ix)~~ The number of authorized refills, if any; and
10. ~~(x)~~ The signature of the APRN as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.

(f) No prescription drug order issued by an APRN can be used to authorize refills more than twelve (12) months past the date of the original drug order unless the prescription drug order is for oral contraceptives, hormone replacement, or prenatal vitamins. Oral contraceptives, hormone replacement and prenatal vitamins may be refilled up to twenty-four (24) months from the date of the original drug order.

(3) Nothing in this Rule, Title 16, Chapter 13 or Title 43, Chapter 34, shall be construed to create a presumption of liability, either civil or criminal, on the part of a pharmacist who in good faith fills a prescription drug order presented by a patient that had been issued by a PA or an APRN consistent with this Rule.

(a) A pharmacist shall presume that a prescription drug order issued by a PA or APRN was issued by a PA or APRN duly licensed and qualified under Title 43, Chapter 34 to prescribe pharmaceutical agents.

(b) A pharmacist shall presume that the drug prescribed by the PA is a drug approved by the supervising physician in the PA's job description and that the drug prescribed by an APRN is a drug authorized by the delegating physician in the APRN's nurse protocol agreement, unless the pharmacist has actual or constructive knowledge to the contrary.

(4) Any prescription drug order form containing less information than that described in this Rule shall not be offered to or accepted by any pharmacist.

Rule 480-36-.01 Definitions

No public comments were received.

Written responses were received from Brent Hudson and Lauren Paul, CVS Health.

President Page asked if there were any board member comments. Mr. Farmer stated that he reviewed the October 2023 minutes where the Board discussed this rule. He stated that the concept of remote order entry can be fantastic and great for efficiency. He explained that his concern comes from the fact of it going from one pharmacist to potentially limitless. President Page inquired if the concern was regarding being able to

track that information. Mr. Farmer responded by stating that his concern was regarding being able to track every pharmacist that may be involved with that particular transaction and workflow in the pharmacy. He stated that there are some positives, but with the number being limitless, his perception is there are possibilities of things that may come up.

In response to Mr. Farmer's comments, Mr. Azzolin stated that there are really positive things that can come out of it from a clinical perspective. He stated that if there is a prescription that goes to a primary pharmacist, then flows to the secondary pharmacist, who reviews part of that prescription, it moves to a DUR pharmacist and then to an insurance specialist in that flow because they specialize in those areas. Mr. Azzolin provided an analogy that occurs across practice types. He explained that it is similar in terms of sending the prescription to the best person who is best suited to solve the problem. Mr. Farmer agreed.

Mr. Stone stated that the Board wants to ensure that patients and citizens are protected. He further stated that as technology changes it can be used to verify things and go through and increasing patient care. He continued by stating that Rule 480-36-.05(2) states, "In addition to any other required records, the primary dispensing pharmacy shall maintain retrievable records which show, for each prescription remotely processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function." Mr. Stone stated that he felt comfortable with the prescription coming back to the dispensing pharmacy and the dispensing pharmacist verifying what is going to the patient. He further stated that he was in support of the rule amendment. He added that he read Mr. Hudson's written comments. Mr. Stone stated that this will keep the patients safe, but also advance patient care. He continued by stating that he felt this was something that would help alleviate workload issues and conditions. Mr. Brinson agreed with Mr. Stone. He stated that as long as GDNA was happy with it and could go into a pharmacy and track the prescription in that moment in time, he does not have any concerns.

No further comments were received.

Mr. Stone made a motion to adopt Rule 480-36-.01 Definitions. Vice-President Cordle seconded, and the Board voted in favor of the motion, with the exception of Mr. Farmer, who opposed.

Rule 480-36-.07 Notification to Patients

No public comments were received. A written response was received from Lauren Paul, CVS Health.

Mr. Azzolin made a motion to adopt Rule 480-36-.07 Notification to Patients. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

In regards to the Board's vote to post 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 as amended, Mr. Stone made a motion and Vice-President Cordle seconded that the formulation and adoption of the proposed rule amendment does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule amendment cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board also votes that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed in O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of the proposed rule amendment will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

The public hearing concluded at 9:26 a.m.

Open Session

President Page established that a quorum was present and called the meeting to order at 9:06 a.m.

President Page commented that Mr. Changus recently took a position with another organization. He stated that Mr. Changus was an integral part of the Board for a while. He further stated that Mr. Changus will do a great job in his new position.

President Page welcomed Mr. Cotton to the Board as the new representative from the Attorney General's office.

President Page stated that Mr. Lacefield has accepted another position. He added that Mr. Lacefield did a fantastic job for the Board. He continued by stating that Mr. Lacefield will do well in his new position.

President Page stated that Mr. Joiner has been appointed as the new Executive Director for the Board as of April 1st. He further stated that Mr. Joiner has done a great job for the Board.

President Page noted that this will be Ms. Howell's last meeting as she has accepted another position elsewhere. The Board wished her well and thanked her for the job well done.

Approval of Minutes

Mr. Stone made a motion to approve the Public and Executive Session minutes from the March 6, 2024, meeting as amended. Mr. Farmer 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. Mr. Brinson noted the amount of licenses issued and thanked staff for a job well done.

Petitions for Rule Waiver or Variance

Rule Waiver Petition from Walgreens Co.: The Board discussed this request for a waiver of Rule 480-36-.01(4). Mr. Jeenu Philip was present and spoke to the Board regarding his request. He stated that Walgreens uses dynamic workload balancing in Georgia. He explained that their systems cannot combine data review and DUR to the same pharmacist they design it as a one to one location. He added that the pharmacies in other states are able to help each other based on the amount of work that is coming in, such as slower pharmacies helping busier pharmacies. Mr. Philip stated that it is very beneficial from a patient care standpoint. He further stated that if Georgia grants it, they can utilize it as soon as it is effective.

Mr. Stone stated that, based on the spirit of what the Board had discussed, he would be in support of the request.

Mr. Azzolin stated to Mr. Philip that this would be an excellent opportunity to monitor prescription accuracy and the change in medication related events that occurred if the stores were busy. Mr. Azzolin also suggested Walgreens monitor workload satisfaction with pharmacists. He added that it would be an excellent case study. Mr. Stone agreed with Mr. Azzolin.

Mr. Farmer inquired if the rule that was adopted during the Board's public hearing still had to be approved by the Governor's office. Mr. Azzolin responded by stating that if the Governor approves the rule amendment, the submission of a rule petition will not be necessary.

Mr. Farmer commented that it was going from one additional pharmacist to an unknown number is the way he read it. Mr. Philip responded by stating that it will be one person checking the data and one person checking the DUR. He added that it will still be two (2) people involved with each prescription. He continued by stating that in terms of the number of potential pharmacists that could be checking, it could be any pharmacist in the state. Mr. Farmer inquired if the petition included information about there being a set number. Mr. Philip stated that the way it works is prescription data and the DUR goes into a cloud based function. He explained that the pharmacist checks it and a record is kept of who is checking it. Mr. Stone commented that each pharmacist can do it differently, but the workflow is basically the same.

Mr. Azzolin mentioned that there are many possibilities of how this process can be beneficial.

There being no further discussion, Mr. Stone made a motion to grant the petition. Vice-President Cordle seconded, and the Board voted in favor of the motion, with the exception of Mr. Chang and Mr. Farmer, who abstained from the vote.

Correspondences

Correspondence from Savannah Cunningham, Alliance for Pharmacy Compounding: The Board viewed this correspondence for informational purposes only.

Correspondence from Jordan T. Vogel, Brown & Fortunato: The Board discussed this correspondence seeking guidance on behalf of Senior Life Pharmacy, LLC, a pharmacy that intends to obtain a non-resident pharmacy permit in Georgia. The correspondence requested guidance with regard to the applicability of O.C.G.A. § 26-4-119. Mr. Casey Knight was present and discussed the request with the Board. President Page commented that the insurance agent mentioning the pharmacy specifically is possibly perspective patient advertising, and inquired if that is done specifically with that one patient, or is there a broadcast medium that is advertising this service to everyone that comes in contact with the company. Mr. Knight responded by stating that the idea is when the agent is selling the insurance policy and they offer Senior Life Rx that could fill the prescription for the patient, would the patient be interested in that pharmacy contacting them. President Page inquired if there was an agreement with the two (2) sides in order to provide that interaction with those patients. Mr. Knight responded affirmatively. He stated there is mutual ownership between Senior Life Rx and Senior Life Insurance. Mr. Knight provided a breakdown of the ownership between the two. He stated there is no financial benefit to the agent.

Mr. Azzolin inquired if the agent speaking to the potential patient was an independent insurance broker or an employee of the insurance company. Mr. Knight responded by stating that they are an employee of the insurance company. He stated that the idea is to ask the patient if he/she would be interested in this pharmacy contacting them. Mr. Azzolin stated that this traverses two (2) different sections of the law. He explained that the Board is only able to enforce Title 26; however, the matter at hand traverses into Title 33, which pertains to the Insurance Commission. He stated that the definitions for affiliates are located in Title 33. He encouraged Mr. Knight to review Title 33 relative to the company's practices. He continued by stating that it appears if they are going to do this and are a defined affiliate by statute, they would have to mention other pharmacies that are capable of filling prescriptions, not just their own. Mr. Azzolin stated that the Board could not offer an opinion or provide advice since the matter traverses into Title 33.

After further discussion, the Board agreed to have Mr. Knight consult his own legal counsel regarding the matter.

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

Director Troughton introduced Special Agent Nick Aderigbe to the Board. Director Troughton stated that Special Agent Aderigbe currently covers three (3) counties. Director Troughton also introduced Special Agent Alec Mathis. Director Troughton stated that both agents to a great job for GDNA.

Director Troughton stated that GDNA would miss Ms. Howell thanked her for a job well done. He welcomed Mr. Cotton as the Attorney General representative and Mr. Joiner as the new Executive Director for the Board.

Director Troughton reported that GDNA conducted 2535 inspections and received 428 investigations for FY2024.

Attorney General's Report – Mr. Justin Cotton
No report.

Executive Director's Report – Mr. James Joiner
Continuing Education Report: Mr. Farmer made a motion to ratify the below continuing education program approved since the previous meeting. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
03/16/2024	5.25	Northside Hospital Cancer Institute	Clinical Strategies for Immunotherapy in Daily Practice	2024-0003

NABP Delegate for Annual Meeting: Mr. Brinson made a motion to appoint Vice-President Cordle as the voting delegate for the Board. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Miscellaneous: Mr. Joiner reported that the board office is continuing its cross training initiative and introduced Ms. Itovia Evans, Business Operations Manager, to the Board. Additionally, he thanked Ms. Howell for her many years of service to the Board.

Legal Services – Mr. James Joiner
Mr. Joiner reported that the Board was currently without a dedicated legal officer. He stated that he is continuing to do those functions at this time. He added that there are staffing options in the works and would continue to update the Board regarding such.

Miscellaneous/Discussion Topics
Rule 480-13-.08 Drugs from Outside Sources: President Page commented that the Board last discussed this matter at its February meeting. He explained the discussion arose from correspondence from Sarah Mattmuller, HCA Healthcare South Atlantic Division (HCA). He stated that Director Troughton went to inspect the locations and requested Director Troughton provide an update. Director Troughton stated that the discussion previously held was that HCA was asking if the security department could store patient owned medications outside of the licensed area of the pharmacy and the Board determined that was not an acceptable method of storage. He further stated that at that meeting GDNA would go inspect all of HCA facilities. He explained that Rule 480-13-.08 states in part, "…Medications received from an outside source, but not to be administered, may not be stored on the patient care unit. Nothing in this section shall prohibit another method of accomplishing the intent of this section provided such method is approved by an agent of the Board of Pharmacy." Director Troughton stated that has allowed GDNA to see what facilities were doing when conducting inspections. He further stated that if they ran across a situation where the facility was storing the medications in the security department, GDNA would instruct them to send a letter to the Board to see if the Board would approve that. He added that previous suggestions have been to store the medications in a locked safe in the patient's room or have the pharmacy store it. Director Troughton stated that with HCA, he was of the understanding that GDNA would inspect the facilities to see if their

procedures met the Board's requirements. President Page inquired if the inspection was satisfactory. Director Troughton responded by stating that it would be discussed in Executive Session.

Mr. Azzolin stated that the DEA regulation seems to imply that when a controlled substance is in the possession of a patient, who is not a licensed practitioner or pharmacy, and is in a hospital and they hand the drug to anyone in the hospital, that is considered illegal distribution of a controlled substance. He further stated that if a nurse or the pharmacy department receives the medication, which is what the rule allows for with exceptions, then that has caused the patient to illegally distribute a controlled substance. He added that what the DEA is saying is that the controlled substance should not leave the patient's possession or go to a nurse to put it in a locked cabinet. Mr. Azzolin stated that according to the DEA, the controlled substance can never leave the possession of the patient. He continued by stating that the DEA regulations provide examples of what can be done. He stated that if the patient cannot send the controlled substance home with a family member, then the patient has to be provided with a locked safe that only the patient has access to. He further stated that it would seem to him that GDNA could do what it wanted relative to telling them it is permissible to do anything with anything other than controlled substances, but for HCA to be in compliance with DEA regulations, they have to do that.

Director Troughton commented that he understood that part of HCA's questions; however, GDNA does not work for the DEA. He stated that GDNA works for the State of Georgia. He added that most hospitals do not have a locked safe in individual rooms. He continued by stating that from the state's perspective and as the Board's enforcement agency, he is telling them what is permissible by law and rule.

Mr. Azzolin suggested the Board direct staff to respond to HCA and state that in response to their request for feedback, relative to Georgia law and the enforcement thereof, whatever the GDNA agents accept as the protocol they have in place is acceptable to the Board of Pharmacy; however, the Board encourages them to be in compliance with DEA standards and regulations. The Board agreed with directing staff to send this response.

Policy Manual Update: President Page stated that the policy manual update was still a work in progress. He added that the Board was still working with getting updated revisions in place and would discuss this topic at a future meeting.

USP 800: President Page commented that the Board had asked Mr. Changus and Mr. Cotton to provide it with an interpretation or clarity regarding the way the law stands on following USP guidelines. He stated that there have been many questions and a lot of confusion regarding this topic. He further stated that the response was the law is clear, and the guidelines need to be abided by. He continued by stating that the Board should decide if it would like GDNA to follow their normal procedures and when they have inspections and come across something that needs to come to the Board, GDNA would bring it to the Board's attention. Mr. Azzolin agreed and stated that is all the Board could do. He stated that several of the board's members were members of GPhA and other associations. He explained that the board members could not interact directly with legislators, but stated that if the associations felt this was an important issue as a profession to consider this as something to address with the legislators. Mr. Azzolin stated that the language in the law specifying a single organization or entity such as USP was too broad. He explained that the language should be more specific or should say "an institution approved by the Board". He added that it would allow the Board to choose a more appropriate regulatory body or oversight mechanism of compounding.

Mr. Scott Bass, GPhA, spoke to the Board. He stated that he looked heavily into this matter. He stated the law around the non-delegation doctrine is pretty clear and states that if the legislature says that another body is given the authority to either enforce or makes judicial decisions that delegation has to be clear and within their purview. He explained that it is almost a delegation to a non-governmental agency. Mr. Bass stated

that the Georgia Supreme Court is more wary of that type of delegation. He further stated that the legislature has asked for the Board to monitor the profession and do so by using standards not set by the Board. He requested the Attorney General's office look at that closely and stated he could provide a letter of opinion if the Board would like. Mr. Bass stated that, unless the legislation is very clear, the outside body and their guidelines are to be currently accepted and enforced. He further stated that when the legislature says they require the Board to follow USP guidelines, they are saying they have reviewed the guidelines of USP as current in 2014 and those are the regulations they want the Board to follow. He added that unless legislation adopts any current updates by USP, then they are locked in. He discussed cases with sentencing guidelines. After discussion, President Page requested Mr. Cottom follow up with Mr. Bass regarding this matter.

Mr. Bass stated that it was his understanding that the Board's request to GDNA was to allow them to continue to educate and monitor the situation. He requested that continue to happen. He stated that it would be nice to make it clear what the Board was asking GDNA to do when they visit a pharmacy. Mr. Azzolin asked if the Attorney General's office could look into the matter. Mr. Joiner responded by stating that the Board could direct staff to send a referral to the Attorney General's office.

Director Troughton expressed his concerns with the Board directing GDNA to only enforce the 2014 USP guidelines. He suggested the Board continue to absorb the information and allow GDNA to provide their prospective. He stated that GDNA does not enforce best practices as there is not a law or rule behind that. He further stated that GDNA has to follow what the legislators set out for them to enforce. President Page stated that it was his understanding not to tell GDNA to do it in the scenario that was just laid out, but only to continue what they were currently doing and if they saw things that needed the Board's attention to bring those to the Board, and on the back end, let Mr. Cotton and Mr. Bass research the matter and bring back to the Board in the future.

Director Troughton directed the Board to the information that was posted on Sharepoint related to USP <800>. He referenced a document titled "Role and Applicability of USP General Chapter <800> Related to Safe Handling of Hazardous Drugs". He read the following portion from the document:
"Where the revised USP <795> and <797> contain references to USP <800>, <800> is applicable and compendially required **only to the extent to which USP General Chapters <795> and <797> apply.**"
Director Troughton explained that this means if you are not compounding and not responsible for <795> and <797>, then you do not have to be responsible for <800> as it is not compendially applicable. He stated that in reading the opening of USP, it sounds like everyone has to do it such as wholesalers, suppliers, pharmacies, etc.

Director Troughton discussed training the GDNA agents attended and directed the board members to a document on Sharepoint that was a slide that states that if the activity being performed is not within the scope of <795> or <797>, then <800> is not compendially applicable. He stated that based on the comments from Mr. Bass, USP is not applicable as they are an outside non-governmental source who had no authority to enforce anything. He stated that <800> became applicable when the revisions to <795> and <797> became applicable in November. He further stated that GDNA made sure the revised changes of <795> and <797> were what they focused on first. He added that in the last six (6) months they have been doing inspections based on the revised changes to <795> and <797>. Director Troughton stated that GDNA has its <800> hazardous inspection ready to go. He explained that GDNA made sure they put it together based on the revised <795> and <797> that was incorporated. He continued by stating that GDNA will go to the pharmacies and do assessments. He added that the agents will go over that information with the pharmacists as to how to make corrections and request they provide an action plan. Director Troughton stated that if there is an issue, they will bring it the case to the Board.

President Page suggested GDNA continue to keep doing what they are doing and the Board will follow up with the Attorney General's office. The Board agreed.

Mr. Stone made a motion and Mr. Brinson 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, Michael Brinson, Young Chang, Cecil Cordle, Michael Farmer, Chuck Page, and Dean Stone.

Executive Session

Georgia Drugs and Narcotics Agency

- D.H.

Cognizant's Report – Mr. Cecil Cordle

- GDNA Case #A35136
- GDNA Case #A35176
- GDNA Case #A35104
- GDNA Case #A35062
- GDNA Case #A35059
- GDNA Case #A35103
- GDNA Case #A35100
- GDNA Case #A35041
- GDNA Case #A35040
- GDNA Case #B35110
- GDNA Case #B35209
- GDNA Case #B35203
- GDNA Case #B35132
- GDNA Case #B34645
- GDNA Case #B35125
- GDNA Case #B35145
- GDNA Case #B35210
- GDNA Case #B35152
- GDNA Case #B35182
- GDNA Case #B35211
- GDNA Case #B35157
- GDNA Case #B35131
- GDNA Case #B35113
- GDNA Case #B34953
- GDNA Case #B34974

Additionally, Mr. Cordle discussed the Board's complaint response letters, and his intention to review them with Board staff to potentially streamline this part of the Board's complaint response process.

Attorney General's Report – Mr. Justin Cotton

Mr. Cotton presented the following consent orders for acceptance:

- C.P.
- C.P.
- F.F.
- W.P.
- K.P.
- M.D.C.
- W.P.
- N.C.A.
- I.K.
- C.P.
- S.D.C.
- C.H.P.
- H.P.

Mr. Cotton discussed the following:

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

Executive Director's Report – Mr. James Joiner

Mr. Joiner updated the Board on administrative personnel matters.

Legal Services – Mr. James Joiner

No report.

Applications

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

Correspondences/Requests

- M.M.T.
- E.P.
- E.I.
- V.P.
- P.P.A.P.
- P.I.
- Q.I.
- W.P.
- A.M.M.
- T.M.T.
- L.P.U.
- J.F.M.
- D.O.O.
- E.A.O.
- T.T.N.
- Z.A.
- K.H.D.
- K.O.A.
- Y.S.J.
- W.C.M.

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

Open Session

Vice-President Cordle made a motion for the Board to take the following actions:

Georgia Drugs and Narcotics Agency

- D.H. GDNA to conduct follow-up inspection.

Cognizant's Report – Mr. Cecil Cordle

- GDNA Case #A35136 Refer to the Department of Law
- GDNA Case #A35176 Refer to the Department of Law
- GDNA Case #A35104 Refer to the Department of Law
- GDNA Case #A35062 Refer to the Department of Law
- GDNA Case #A35059 Change license status to "Null and Void"
- GDNA Case #A35103 Close with Letter of Concern
- GDNA Case #A35100 Refer to the Department of Law
- GDNA Case #A35041 Refer to the Department of Law
- GDNA Case #A35040 Refer to the Department of Law
- GDNA Case #B35110 Misfill Guidance #1A
- GDNA Case #B35209 Misfill Guidance #1A
- GDNA Case #B35203 Close with Letter of Concern
- GDNA Case #B35132 Close with Letter of Concern
- GDNA Case #B35125 Close with Letter of Concern
- GDNA Case #B35145 Close with Letter of Concern
- GDNA Case #B35210 Refer to the Department of Law
- GDNA Case #B35152 Close with no action

- GDNA Case #B35182 Close with no action
- GDNA Case #B35211 Close with no action
- GDNA Case #B35157 Close with no action
- GDNA Case #B35131 Close with no action
- GDNA Case #B35113 Close with no action
- GDNA Case #B34953 Close with no action
- GDNA Case #B34974 Close with no action

Attorney General's Report – Mr. Justin Cotton

Mr. Cotton presented the following consent orders for acceptance:

- C.P. Accept Private Consent Order
- C.P. Board provided supplemental direction to AG's office to clarify prior referral
- F.F. Board directed staff to send letter to Respondent
- W.P. Accept Public Consent Order
- K.P. Accept Private Consent Order
- M.D.C. Accept Public Consent Order
- W.P. Close with no action
- N.C.A. Accept Voluntary Surrender
- I.K. Accept Consent Order counterproposal
- C.P. Accept Consent Order counterproposal
- S.D.C. Accept Consent Order counterproposal
- C.H.P. Deny Consent Order counterproposal
- H.P. Accept Private Consent Order

Mr. Cotton discussed the following:

- A.M.C. Close with no action
- C.H.A. Close with no action
- E.F.P. Board provided supplemental direction to AG's office to clarify prior referral
- J.M. Board provided supplemental direction to AG's office to clarify prior referral

Executive Director's Report – Mr. James Joiner

No Board action required.

Legal Services – Mr. James Joiner

No report.

Applications

- A.N.S. Pharmacy Technician Approved for registration
- E.I.J. Pharmacy Technician Tabled, pending receipt of additional information.
- A.S.N. Pharmacy Technician Approved for registration
- K.A.M. Pharmacy Technician Approved for registration
- T.L.W. Pharmacy Technician Approved for registration
- J.S.M. Pharmacy Technician Approved for registration
- A.S.M. Pharmacy Technician Denied
- M.K.D. Pharmacist Approved application
- C.A.P. Pharmacist Denied application
- B.F.F. Pharmacist Approved application
- J.T.H. Pharmacist Tabled, pending receipt of additional information.
- K.A.W. Pharmacist Approved application
- M.M. Pharmacist Approved application

- S.M.C. Pharmacist Approved application
- H.P.R. RPh Certification of DTM Approved application
- S.F.T. RPh Certification of DTM Approved application
- Y.M.A. RPh Certification of DTM Approved application
- M.J.C. RPh Certification of DTM Approved application

Correspondences/Requests

• M.M.T.	Notice of Discipline	No action
• E.P.	Notice of Discipline	No action
• W.P.	Notice of Discipline	No action
• E.I.	Notice of Discipline	No action
• V.P.	Notice of Discipline	No action
• P.P.A.P.	Notice of Discipline	No action
• P.I.	Notice of Discipline	No action
• Q.I.	Notice of Discipline	No action
• W.P.	Notice of Discipline	No action
• A.M.M.	Request to terminate probation	Approved request
• T.M.T.	Request to terminate probation	Approved request
• L.P.U.	Self-report	No action
• J.F.M.	Request for Appearance	Approved request
• D.O.O.	Request for 4th MPJE attempt	Approved request
• E.A.O.	Request for 6th NAPLEX attempt	Denied request
• T.T.N.	Request for 4th NAPLEX attempt	Approved request
• Z.A.	Request for 4th NAPLEX attempt	Approved request
• K.H.D.	Request to extend NAPLEX date	Approved request
• K.O.A.	Request to extend intern license	Approved request
• Y.S.J.	Request to extend intern license	Approved request
• W.C.M.	Request to terminate probation	Approved request

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 2:19 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, May 8, 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 J. Clinton Joiner, II, Executive Director