GEORGIA BOARD OF PHARMACY
Conference Call
2 Peachtree St., NW, 6th Floor
Atlanta, GA 30303
May 11, 2022
9:00 a.m.

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

Staff present:
Eric Lacefield, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Max Changus, Assistant Attorney General
Brandi Howell, Business Support Analyst I

Visitors:
Travis Clark
Jonathan Marquess, GPhA
Dr. Keri Riddick
Keri Conly, Georgia Hospital Association

Public Hearing

President Stone called the public hearing to order at 9:00 a.m.

Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security

President Stone stated that the purpose of the rule amendment is to aid in the prevention of the diversion of controlled substances. He stated the main features of the rule amendment is to require the pharmacist on duty to sign the invoice(s) for all controlled substances upon receipt and verification.

President Stone noted that the written comments from Lauren Paul, CVS Health, were received. He stated Ms. Paul suggested additional language be included under 480-10-.01(1)(b) stating, "A pharmacist may use an electronic system to generate and record these elements." He asked if there were any comments from the Board members. Mr. Brinson commented by stating that he does not mind that part of it as long as it is done at the time the order is received and checked in. Additionally, he stated he would not have a problem if the electronic means was not done seven days later, or something along those lines. Mr. Brinson stated if the Board feels the intent of this is it could be electronically signed at time the order is checked in, he does not have an issue with that. He asked for Mr. Cordle's thoughts.

Mr. Cordle stated he believed Ms. Paul was on the conference call. Ms. Paul, Executive Director, Pharmacy Regulatory Affairs, CVS Health, was on the call and spoke to the Board. Ms. Paul stated that this is not a current functionality, but is something they are building within their invoice and checking in system. She added that while it is not available, it would be real time when the invoice is checked in. She stated this data will be captured at that time and will not be recorded days later. She added that it will be retrievable immediately at the store level once it is checked in.

President Stone discussed the worries he has when talking about an electronic system to generate or record these elements. He stated that the Board has seen with some of its cases that it can be a

technician, who may say they checked it in for the pharmacist. He further stated that he is not sure if he is comfortable opening that up. President Stone expressed his concern over someone not actually looking at the bottles when checking those items in. He commented that he was not comfortable adding that language, and asked what the other board members thought.

Director Troughton commented, that as the Board's investigators, if the current rule amendment is adopted, it is not going to matter whether it is electronic or on paper. He stated that the rule as written covers that. Director Troughton continued by stating that there is nothing to say it cannot be signed for electronically or recorded electronically. He explained that the key for GDNA is the pharmacy being able to produce it, and as Ms. Paul stated, with CVS Health's new system, it would be immediately retrievable. Additionally, Director Troughton stated that when one says they are using an electronic system, that may open it up more broadly because there are different electronic systems used. For GDNA, Director Troughton stated the key is the pharmacist producing proof showing who signed the invoice, whether electronic or paper, and who is responsible for those drugs coming into the store. He stated that he does not feel that additional language is needed from GDNA's standpoint.

President Stone inquired if the Board's proposed amendment was sufficient. Mr. Changus responded by stating that he thinks it is a matter of interpretation but had the same thought when reviewing it as Director Troughton. He stated that it is a signature, and the code section offered by Ms. Paul in her letter suggests some equivalency. He stated one could certainly read it that way, but the important reason for this rule is to ensure the pharmacist takes these and makes the notation so it could be checked. He further stated that he does not think the language needs to be changed. Mr. Brinson agreed. President Stone stated that the Board would leave the rule amendments as proposed, and not add anything further.

No additional public comments or written responses were received.

Mr. Brinson made a motion to adopt Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Mr. Azzolin inquired as to where the information was the Board members were discussing. Ms. Howell stated it was in the Public Hearing folder on Sharepoint.

Rule 480-13-.06 Drug Distribution Control

President Stone stated that the purpose of the rule amendment(s) is to remove an out-of-date regulation and aid in the prevention of the diversion of controlled substances. He stated the main features of the rule amendment(s) are to assist in preventing diversion of controlled substances and to remove a regulation deemed no longer necessary.

No public comments or written responses were received.

Mr. Brinson made a motion to adopt Rule 480-13-.06 Drug Distribution Control. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Prescription Drug Orders

President Stone stated the purpose of the rule amendment(s) is to make minor clean up edits and allow for the maintenance of controlled substances III, IV, and V prescriptions in hardcopy or electronic format. He stated the main features of the rule amendment(s) are to make minor

grammatical changes, remove unnecessary language, and clarify that C_III, IV, and V prescription drug orders can be maintained in hard copy or electronic format.

No public comments or written responses were received.

Mr. Brinson made a motion to adopt Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Prescription Drug Orders. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule 480-31-.01 Patient Counseling

President Stone stated the purpose of the rule amendment is to clarify the personal offer to discuss prescription related matters when a prescription is being delivered. He stated the main feature of the rule amendment adds guidance language permitting a personal offer to counsel to be made in written format for prescriptions being delivered.

No public comments or written responses were received.

Mr. Brinson made a motion to adopt Rule 480-31-.01 Patient Counseling. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

The public hearing concluded at 9:15 a.m.

Open Session

President Stone established that a quorum was present and called the meeting to order at 9:16 a.m.

Mr. Lacefield asked the visitors on the call to send an email via the "Contact Us" portal on the website if he/she would like his/her name reflected as being in attendance in the minutes.

Approval of Minutes

Mr. Page made a motion to approve the Public Session minutes from the April 13, 2022, Conference Call as amended. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Mr. Prather made a motion to approve the Executive Session minutes from the April 13, 2022, Conference Call. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Mr. Brinson made a motion to ratify the list of licenses issued. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion. Mr. Brinson commented that he reviews the report each month and stated that it was amazing how much work Mr. Lacefield and his staff do. He added that there were close to 600 licenses issued for the month. Mr. Brinson thanked Mr. Lacefield and his staff for doing a great job. President Stone commented that staff also work with the Board of Dentistry as well and do a great job. He added that he feels the amount of information staff has to handle is overlooked at times.

Petition for Rule Waiver or Variance

Rule Waiver Petition from Piedmont Mountainside Hospital-Ellijay, PHCL000035: The Board considered this request for a waiver of Rule 480-13-.06 and the requirement for a laminar flow hood. Mr. Prather made a motion to deny the rule waiver petition as the rule cited in the request pertains to hospital pharmacy regulations. Additionally, the requirement of a laminar flow hood is not required for a clinic pharmacy. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Publix Pharmacy, PHRE009573, PHRE009792, PHRE010176: The Board discussed this request for a waiver of Rules 480-15-.03(d)(2), 480-36-.02(2) and 480-36-.03(2). President Stone inquired if a representative from Publix Pharmacy was on the call. Ms. Laura Churns, Pharmacy Regulatory Affairs, and Mr. Adam Mango were on the call and spoke to the Board regarding the request.

Ms. Churns explained that Publix Pharmacy was requesting a rule waiver for three of their pharmacy locations in the state and applying to 11 of Publix Pharmacy's licensees in order to allow them to complete remote order entry from other locations outside of the four walls of the designated pharmacy site, including from the individual's home. Ms. Churns stated that through the pandemic, Publix Pharmacy recruited and hired 11 licensees that were trained to perform remote order entry in Georgia. She further stated that this was allowed through the Governor's Executive Order and the Board's Emergency Rule; however, both of those have expired. Ms. Churns stated that transitioning the employees into his/her specific retail cites would pose a hardship. She explained that the hardship would be that employees were hired for this particular remote role and many are unable to commute from his/her site to a pharmacy. She added that there is a lack of physical space bringing these 11 personnel into the pharmacy. Ms. Churns stated that Publix Pharmacy did assign these remote employees to preserve the Georgia ratio requirement. She added that it would be impossible to bring those employees into the pharmacy at once. She explained that she believes the hardships are severe enough that Publix Pharmacy may have to sever ties with these employees after much training and they do not want to see that happen. She further explained that Publix Pharmacy is requesting a waiver in order to serve Georgia patients. Ms. Churns stated that through the pandemic remote order entry has been proven to be safe and effective. She further stated that since the Board is considering amendments to Chapter 480-36 Retail Pharmacy Requirements for Remote Prescription Drug Order Processing, Publix Pharmacy feels this is the perfect time to request a waiver.

President Stone commented that even with the proposed changes to Chapter 480-36, it would require technicians to be in the pharmacy doing remote order entry. He stated that he was unsure about granting the waiver now since the Board was still working on the rule amendments. Mr. Brinson agreed with President Stone. He stated that what Publix Pharmacy was requesting is not being considered in the proposed rule amendments.

Mr. Prather and Mr. Page agreed with President Stone and Mr. Brinson. Mr. Page stated that regardless of whether or not the Board would was looking to make changes to the rule, he did not think the petition presented a unique hardship. Mr. Cordle inquired if the Board was not granting the petition, or would it wait until after conversation was held regarding the proposed amendments to Chapter 480-36. He stated there have been instances where the Board has granted the petition with the anticipation that the rule would be addressed. President Stone responded by stating that Publix Pharmacy was requesting the Board grant a waiver to allow pharmacy technicians to do remote order entry outside of the pharmacy. He continued by stating that this was not in line with what the Board was considering in terms of changes to Chapter 480-36.

Mr. Azzolin commented that from a personal level he agreed with Publix. He added that in the future he hoped this would be something that was permitted by the Board. Mr. Azzolin stated that when looking at the proposed rules, Ms. Emm previously pointed out that O.C.G.A. § 26-4-5 states that the pharmacy technician must be under the direct supervision of the pharmacist which would prevent the Board from allowing pharmacy technicians to work in a remote environment.

Mr. Bracewell agreed on denying the petition.

Mr. Mango stated that he understood what the Board was stating and requested to verbally withdraw the petition. He stated this would allow the Board time to work on the rules and Publix Pharmacy would resubmit the petition for reconsideration at a later time. The Board accepted Mr. Mango's request to withdraw the petition.

Correspondences

Correspondence from John R. Caughman: The Board considered this correspondence regarding licensure in Georgia. The Board directed staff to respond by stating that based on the information provided, a wholesaler permit would be required if Mr. Caughman was engaged in the activities described in his letter.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA conducted 2059 inspections and received 441 complaints for FY2022.

Attorney General's Report – Max Changus

No report.

Executive Director's Report – Eric Lacefield

Continuing Education Report: Mr. Cordle made a motion to ratify the below continuing education programs approved since the previous meeting. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
05/05/2022	1	Atrium Health-Navicent	Shock	2022-0006

Rules Discussion

Chapter 480-36 Retail Pharmacy Requirements for Remote Prescription Drug Order Processing: President Stone stated that this topic was discussed at the Board's April meeting and was tabled to allow time for staff to add the requested changes. He commented that in thinking about what the Board did during the pandemic and some of the changes in trying to adapt to such, the Board has been discussing allowing a pharmacist to do remote entry from anywhere in the United States. He explained that only technicians could help in the pharmacy with a licensed pharmacist overseeing the work. President Stone stated the Board had previously discussed discipline and how it would protect the public and serve the population better. He stated that he had received calls from pharmacists concerning workloads. He inquired as to how the Board could alleviate some of that. President Stone stated that he felt remote order entry would help pharmacists and pharmacies with workload issues while also keeping patients safe.

Mr. Page inquired if the suggested language to Rule 480-36-.05(3) was sufficient for GDNA. Mr. Page read the amendment as follows:

(3) ~~The primary dispensing pharmacy and the secondary remote entry pharmacy may maintain records separately at each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.~~ <u>These prescription records must also be sortable and retrievable from other records by the designation that they were remotely processed.</u>

Mr. Page inquired if the pharmacy would have to have the appropriate software to track records that have the designation stating the prescriptions were remotely processed. Director Troughton

responded by stating that the suggested language was satisfactory for GDNA. He stated that the computer system has to be able to sort controlled drugs from non-controlled drugs. He further stated that it is important for GDNA to ask what prescriptions were remotely processed and for GDNA to be able to obtain those prescriptions. He stated that it may require some sort of designation in the pharmacy's software to be able to track that information. Mr. Page commented that it was very important and wanted to be able to satisfy what GDNA needed when it conducts an inspection. Director Troughton stated that the wording may need to be tweaked. He further stated that when conducting an inspection, if GDNA were to look at schedule II's, the rule requires the system in the pharmacy to be able to retrieve that information by designating parameters of that report. Director Troughton explained that not being able to readily retrieve that information is what lengthens the investigation. He stated that the purpose of the suggested language to Rule 480-36-.05(3) is for the pharmacy to be able to provide a report that can only show remotely processed prescriptions.

President Stone inquired if the suggested language was sufficient. Mr. Changus responded by stating that the use of remote order entry processing is not a requirement, but more of being engaged in a practice that is optional. He stated that in order to use that processing, the Board could prescribe the necessary requirements in order to ensure quality control and the investigation of that could be performed without difficulty. Mr. Changus stated that "sortable" was a strange term and he was unsure if there was a better term that could be used. He further stated that he thought it was something that could be imposed as a requirement. Mr. Changus commented that how the individual entities that use this system are able to configure their own personal system would be up to those individual entities.

Mr. Azzolin commented that from last month's meeting, the spirit of what GDNA was trying to accomplish is requiring the pharmacy to be able to retrieve only those prescriptions that are remotely processed and be able to get those without GDNA having to sort through a list of all the prescriptions processed. He added that GDNA wants to be able to get that information upon request. He explained that one way he knows to currently do that without any software changes is to pull up every prescription processed by the pharmacist that is processing prescriptions remotely. Mr. Azzolin asked Director Troughton if it pulling the information by the remote pharmacist's initials or identification was acceptable for GDNA. Director Troughton responded by stating that it would be acceptable as long as the information is "immediately retrievable". Mr. Azzolin commented that he believed the language satisfied what GDNA needed, but because it states "sortable and retrievable", he suggested alternative language that states, "The prescriptions that are processed remotely are identifiable by the pharmacy and can be presented independent upon inspection".

Director Troughton stated that what it would boil down to is the pharmacist-in-charge and the pharmacy owner would be held responsible if he/she could not provide the records, which is a violation of the rule. He added that if the pharmacist can provide the information and articulate to GDNA as to how he/she got there, it would be sufficient. President Stone commented that based on Mr. Changus's comments, the language added by Director Troughton was adequate.

Mr. Prather asked Director Troughton if in getting the information needed was specific to the pharmacy in Georgia. Director Troughton responded affirmatively and stated it is required that the primary dispensing pharmacy have all of the records of where the prescription went, who filled it, and which prescriptions were remotely filled. Director Troughton stated that if primary pharmacy is using a non-resident pharmacy, then GDNA would follow investigation to that non-resident pharmacy as well. He further stated that if there was a problem, GDNA would speak to the pharmacist that did the remote entry. Additionally, he stated that the key is the pharmacist be able to provide as much information as possible as to who touched the prescription.

Mr. Prather expressed his concerns about the Board's limited ability to conduct investigations outside of Georgia. Director Troughton stated that GDNA has not done many investigations on non-resident pharmacies. He further stated that Mr. Prather was correct in that GDNA would not likely jump on a plane and travel to that non-resident pharmacy to lay eyes on their records. He stated GDNA would have to depend on the non-resident pharmacy to be truthful and work with GDNA on the investigation and if the pharmacy was not cooperative or providing GDNA with what it needed, GDNA would contact the state board for assistance with the investigation. Mr. Prather stated that as far as remote order entry is concerned, that would have not been an issue in the past because remote order entry could not be done outside of Georgia. He continued by stating that the way the proposed amendments were written, remote order entry would be allowed anywhere in the United States. Mr. Prather stated that he understands the problems with border counties better than any other member does. He further stated that he was born in a border county and practiced pharmacy in a border county. Mr. Prather continued by stating that he is familiar with the issues that one runs into when trying to fill prescriptions for patients that come from other states. He stated that he is 11 miles from Tennessee and 15 miles from North Carolina. He further stated that his comments on this matter are that when he drives from Blue Ridge to North Carolina, he is subject to the laws of North Carolina.

President Stone commented that the Board currently licenses non-resident pharmacies. Director Troughton answered affirmatively that it does. President Stone stated there are prescription drugs coming into Georgia from other states or countries. He further stated that he understood Mr. Prather's concerns; however, this has been happening for a while. He added that he has patients that ask him questions about medications received via mail by a non-resident pharmacy. President Stone stated that he is aware of Mr. Prather's concerns regarding discipline, but the Board would continue to discipline how it does currently.

President Stone inquired if hospital pharmacies are able to do remote order entry from other places outside of Georgia. Mr. Azzolin responded by stating that O.C.G.A. § 26-4-80(7)(b) states that the hospital pharmacist can process orders remotely from anywhere in United States. Additionally, he stated that Rule 480-13-.04 mirrors the law. Mr. Azzolin stated that he appreciated Mr. Prather's comments on the matter. He further stated that mail order prescriptions come into Georgia now. Mr. Azzolin continued by stating that the pharmacist may be anywhere in the United States due to the nature of their business. He explained that the Board previously granted three rule waivers, and had they not been granted, patients would probably get those prescriptions through mail order in another state instead of a pharmacy in Georgia. He added that this actually increases the utilization of Georgia pharmacies. Mr. Azzolin stated that the remote order pharmacist is not touching the drug and he/she does not access to controlled substances. He further stated this is a Georgia licensed pharmacist approved by the Board to process and ensure the medication being chosen is correct and checking to make sure there are no adverse drug reactions before processing. Mr. Azzolin stated that the only issue at hand seems to be if that individual is qualified to be a pharmacist in Georgia that can interpret the data. He stated that the pharmacist is only doing a clinical review of that drug.

Mr. Prather commented that the Board is talking about retail pharmacy rules versus hospital pharmacy rules and there are differences between the two. Additionally, he stated the Board is also talking about mail order and retail pharmacy rules. He stated that it was "apples and oranges". He requested a member of the Board to explain to him how allowing someone in Idaho or another state working on a prescription that would be filled in Georgia, was protecting the citizens of Georgia. President Stone responded by stating that each of those pharmacy settings mentioned by Mr. Prather all deliver prescriptions to patients. He explained that when Mr. Prather states it is "apples and oranges", the end result is the same, which is the patient is receiving a medication from a pharmacy.

Mr. Bracewell commented that when this rule was enacted the request came from a current pharmacy that asked for this to be allowed. He stated that he thought it was a great idea and would help with balancing the workload. He inquired as to who or what group brought this matter back to the Board for additional changes. Mr. Bracewell stated that prior to his most recent term with the Board, he was on a subcommittee with NABP, and they looked at this topic nationally and researched how other states handled it. He commented that in regard to having pharmacists working outside the state of Georgia, the Board has to depend on the pharmacist's honor as it would be difficult to conduct an inspection on someone outside of the state. He inquired as to why should the Board send GDNA to inspect pharmacists in Georgia as it is a dual system. Mr. Bracewell stated that he thinks the concept has a lot of merit, but a lot of work needs to be done on the proposed amendments before the Board proceeds.

In response to Mr. Bracewell's comments, President Stone stated that he did not think it was a particular group that brought this matter before the Board. He further stated that the Board has been discussing this topic for a while. He explained that things are happening now. He stated that there are medications being filled outside of the state coming into Georgia for patients.

President Stone stated that at the Board's last meeting, Director Troughton had comments related to the security of information. He inquired if that was addressed. Mr. Azzolin responded by stating that the Board discussed if that piece was necessary to add based on federal laws and HIPAA as these locations could be subject to penalties based on how it was handled. He further stated the Board recommended not adding any further language.

Mr. Bracewell stated that a chain pharmacy came before the Board regarding the current rule. He inquired as to who or what group brought this matter back to the Board for additional changes. Mr. Azzolin responded by stating that the Board received several rule waiver requests from pharmacies requesting to use out of state pharmacists to provide remote order processing. He added that the Board has granted three waiver requests in the last year and after considering those requests, coupled with the pandemic and the need for this, it seemed appropriate for the Board to look at the rule now relative to the way it was written. He stated that the Board is proposing amending the rule from reflecting the pharmacy processing the order to a Georgia licensed pharmacist processing the order. He explained that if the rule is not changed, it could be a non-Georgia licensed pharmacist processing the orders. He stated the idea is to get away from the pharmacy processing the order from a remote location and to allow a pharmacist to do that remotely in a more applicable location where there may not be as many distractions. Mr. Azzolin stated that the spirit behind the changes was to allow different ways for the processing to occur.

Mr. Bracewell commented that he was not opposed to the changes, but had questions. He stated that he was ultimately concerned about going outside the state and saying the Board was going to take a pharmacist's word on his/her honor. Mr. Azzolin inquired as to what Mr. Bracewell meant by stating the Board would take the pharmacist on his/her honor. Mr. Bracewell responded by stating that the Board would not be able to inspect or visit the pharmacist. Mr. Azzolin stated the Board could inspect the primary pharmacy, which is located in Georgia and if an adverse event occurred that was committed by a secondary pharmacist in another location, the Board would have authority to discipline the licensee and report them to the appropriate board of pharmacy. Mr. Prather commented that would help someone who has already suffered a problem. Mr. Azzolin inquired as to how many issues the Board has seen with Georgia licensed pharmacists. He stated that the Board could not deny allowing a Georgia licensed pharmacist from doing a job because the Board was scared, he/she would hurt someone. He asked how allowing the pharmacist to do the same thing as a Georgia licensed pharmacist across state lines, that they can do inside state lines, increase his/her propensity for error. Mr. Prather stated he had previously asked this question and wanted to know exactly how doing this outside of Georgia protects Georgia patients?

Mr. Brinson commented that he had been contacted by many pharmacists who have independent retail stores and would like to have opportunity to fill or verify prescriptions from his/her home. He stated that he would like for the Board to move forward with this as he is looking out for the independent pharmacies as well as the chain pharmacies. He further stated that Mr. Azzolin has done a lot of work and research on this matter. Mr. Brinson stated that the proposed change to section (2) of Rule 480-36-.03 states that if a pharmacy technician or pharmacy intern/extern is assisting the secondary remote entry pharmacist, he/she must be located within the licensed pharmacy. Additionally, Mr. Brinson stated that this is in line with Mr. Azzolin's previous comments regarding O.C.G.A. § 26-4-5(32).

Mr. Cordle commented that he appreciated everyone's opinions and thoughts on the matter. To address Mr. Prather's concerns about how it makes it safer for patients, Mr. Cordle stated that he thinks there have been examples of that already provided. Mr. Cordle stated that in an independent situation, they are very constrained with payroll. He explained that having two key people out and not being able to function at his/her highest capacity would put a strain on those who are able to work. He stated that if he has two to five staff out, he has to keep the pharmacy open, but now the workload has increased beyond the capacity of the people he has. Mr. Cordle stated that having a safeguard in place where he can shift that work over will provide safer pharmacy services with accountability. He further stated that it is a safety concern when the pharmacy does not have its key personnel in the pharmacy. He explained that being able to shift the work over to a remote location and having someone who is trained to do that work keeps public safety in mind.

Mr. Chang commented that he understands everyone's thoughts and concerns. He stated that Mr. Bracewell had inquired as to how this matter was brought up. Mr. Chang stated that the genesis is what the profession has done in the last few years. He further stated that the pandemic really elevated what pharmacists can do and in order to do that the Board has to enable some of these services that are important, while keeping patient safety in mind. Mr. Chang stated that President Stone commented there are drugs coming in from other states. He stated that it is about holding that non-resident pharmacy accountable. Mr. Chang asked Director Troughton about the kind of errors that occur with non-resident pharmacies. Director Troughton responded by stating that the most common complaint the Board has received on non-resident pharmacies concern the prescription not getting delivered. Additionally, he stated that poor customer service was another complaint. He continued by stating that part of the rule requires the non-resident pharmacy to cooperate with investigations. He further stated that he could not recall where a pharmacy did not cooperate with an investigation. Director Troughton explained that he has subpoena powers to obtain information, if needed, and the case would be handled like it would for any other pharmacy.

Mr. Chang commented that when talking about medication errors or data errors, there appears to be a fear that the Board does not have the power to address those matters, but if it is a non-resident pharmacy, the Board could impose discipline. He stated that he just wanted to make sure all of the members think about that piece.

Mr. Page commented that the need has been established for this process and he is comfortable with that. He stated the main issue is the investigative process and how follow up will occur. Mr. Page stated that based on the discussion by the Board, he was satisfied with how that would occur. He continued by stating that the biggest issue he sees is the concern for public safety and he is comfortable with how that is addressed as well. Lastly, Mr. Page stated that he understood the concerns and appreciated all comments, but has no issues with the proposed changes to Chapter 480-36 Retail Pharmacy Requirements for Remote Prescription Drug Order Processing.

Mr. Brinson commented that he went to a grocery store type pharmacy and the pharmacy was closed. He stated that he inquired as to why the pharmacy was closed and was told that the

pharmacist could not come in until later. Mr. Brinson continued by stating that if remote entry inside the state was permitted, another pharmacist from another store could process the prescriptions. He stated he wanted to give that as an example as to how remote order processing would be beneficial.

In regard to the suggested language to Rule 480-36-.05(3), Mr. Azzolin offered the following language as an alternative:
(3) ~~The primary dispensing pharmacy and the secondary remote entry pharmacy may maintain records separately at each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.~~ Prescriptions processed by a secondary pharmacist must be separately identifiable and retrievable upon request by a GDNA agent during inspection.

Director Troughton stated as long as there is language that provides GDNA with an avenue to obtain the prescriptions processed remotely, the language proposed by Mr. Azzolin would be sufficient. President Stone asked if Mr. Changus had any comments. Mr. Changus agreed with Director Troughton's comments and stated that this is a matter of trying to retain some control over a system that is designed to disperse authority to some extent. He continued by stating that the idea of remote order processing allows the pharmacist to farm some of this stuff out and retain the records for investigative purposes.

President Stone inquired if there were any further comments. Mr. Bracewell commented that Rule 480-36-.07(1)(a) discusses use of a sign in the pharmacy which states, "Remote Order Processing Utilized Here". He stated that he doubted that a general layperson would know what that meant. He suggested there being a better way to disclose this information to patients. Mr. Prather stated that the original rule as written by himself and Mr. Laird Miller stated that prior to the use of remote order processing, the pharmacist had to obtain written consent from the patient stating he/she would allow the prescription to be remotely processed or the patient had the option to opt out if he/she desired. Mr. Azzolin agreed that was correct. Mr. Azzolin stated the whole concept and modifications to the rules are to make it more practical. He stated in a pharmacy now, the pharmacist is already having trouble getting things done due to various reasons. He further stated that the purpose of utilizing remote order processing could assist with that, as several members previously stated.

Mr. Page made a motion to post Chapter 480-36 Retail Pharmacy Requirements for Remote Prescription Drug Order Processing. Mr. Brinson seconded. Discussion was held by Mr. Bracewell who stated that this was the first time he had seen the draft and thought it could be better. There being no further discussion, the Board voted in favor of the motion, with the exception of Mr. Bracewell and Mr. Prather, who opposed.

480-36-.01. Definitions
As used in this chapter, the following terms:
(1) "Board" shall mean the Georgia Board of Pharmacy.
(2) "Remote prescription drug order processing" shall mean the processing of prescription or patient information from a location other than the location from which the prescription medication is received and dispensed. It shall not include the dispensing of a drug, but may include:
    (a) Receiving the prescription order from the primary dispensing pharmacy
    (b) Interpreting, analyzing, or clarifying prescriptions;
    (c) Entering prescription or patient data into a data processing system;
    (d) Transferring prescription information;

(e) Performing a drug regimen review;
(f) Performing a drug allergy review;
(g) Performing therapeutic interventions; or
(h) Any combination of these order processing functions.

(3) Primary dispensing pharmacy. A primary dispensing pharmacy shall be defined as the retail pharmacy located in this State from which a prescription is physically received and dispensed to the patient or the patient's caregiver.

(4) Secondary remote entry pharmac~~y~~ist. A secondary remote entry pharmac~~y~~ist shall be defined as ~~the retail pharmacy which~~ a pharmacist licensed in this state and located anywhere in the United States who performs remote prescription drug order processing but does not dispense the medication to the patient or the patient's caregiver. There shall only be one secondary remote entry pharmac~~y~~ist to assist the primary dispensing pharmacy with remote prescription drug order processing per prescription.

480-36-.02. Licensing

(1) Secondary remote entry ~~P~~pharmaci~~e~~sts who ~~which~~ perform remote prescription drug order processing shall be ~~independently~~ licensed ~~as a retail pharmacy~~ by the Board ~~and physically located within the State of Georgia~~.

(2) When a secondary remote entry pharmacist performs ~~R~~remote prescription drug processing from any ~~location other than a retail~~ pharmacy, the pharmacy must be licensed in this State ~~is prohibited~~.

(3) Secondary remote entry ~~P~~pharmaci~~e~~sts who ~~which~~ perform remote prescription drug order processing shall either ~~have the same owner~~ be employed by or contracted with the primary dispensing pharmacy or be employed by an organization that has~~ve~~ a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy and the contractor. Such contract shall be available for review by the Board or its representative.

480-36-.03. Personnel and Supervision

(1) The primary dispensing pharmacy shall have a licensed pharmacist on site during business hours and his/her ~~shall~~ duties shall include the verification of the validity of all prescriptions. Such pharmacist shall be responsible for obtaining and recording all information needed. This shall include but not be limited to the following patient information: biographical information, medication history, drug allergies, and other information as required. Pharmacy technicians and pharmacy interns/externs may assist a pharmacist located at the primary dispensing pharmacy with remote prescription drug order processing. Such pharmacies shall comply with Georgia laws and rules set forth pertaining to ratios and the supervision of pharmacy technicians and pharmacy interns/externs.

~~(2) The secondary remote entry pharmacy shall have a pharmacist on duty, licensed in this State, who is physically present and personally supervising all pharmacy activities. Remote prescription drug order processing in a retail pharmacy without the direct supervision of a pharmacist is prohibited.~~

(~~3~~2) If the secondary remote entry pharmacist is engaging in the remote services listed in rule 480-36-.01 from a Georgia Board of Pharmacy licensed pharmacy, then ~~P~~pharmacy technicians and pharmacy interns/externs may assist ~~a~~ the secondary remote entry pharmacist ~~located at the secondary remote entry pharmacy~~ with remote prescription drug order processing. If a pharmacy technician or pharmacy intern/extern is assisting the secondary remote entry pharmacist, he/she must be located within the licensed pharmacy. ~~Such~~ Secondary remote entry pharmaci~~e~~sts shall comply with Georgia laws and rules set forth pertaining to ratios and the supervision of pharmacy technicians and pharmacy interns/externs.

(43) The secondary remote entry pharmacist ~~on duty at the secondary remote entry pharmacy~~ shall be responsible for assuring the accuracy of prescriptions for which he/she performed or supervised remote prescription drug order processing. This responsibility shall exclude the compounding, preparation, dispensing, and counseling for prescriptions for which he/she has performed remote prescription drug order processing. The pharmacist shall verify the data entered into the computer system is consistent with the prescription. The pharmacist shall conduct a drug regimen review for each prescription. Any activity requiring the exercise of professional judgment shall be performed by the secondary remote entry pharmacist ~~on duty~~ and shall not be delegated to pharmacy technicians. The secondary remote entry pharmacist ~~on duty at the secondary remote entry pharmacy~~ shall be responsible for verification of all activities performed by pharmacy technicians, or pharmacy interns/externs.

480-36-.04. Policy and Procedures

The primary dispensing pharmacy ~~and the secondary remote entry pharmacy~~ shall have a written policy and procedure that relates to the remote processing ~~at each pharmacy involved in the processing~~ of ~~a~~ prescriptions and such policy shall be available for inspection by the Board or its representative. The policy shall at a minimum include the following:

(a) The responsibilities of ~~each~~ the primary dispensing pharmacy and secondary remote entry pharmacist;
(b) A list of the name, address, telephone numbers, and permit/registration/license numbers of all pharmacies and pharmacists involved in remote processing;
(c) Procedures for protecting the confidentiality and integrity of patient information;
(d) Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
(e) Procedures for maintaining required records;
(f) Procedures for complying with all applicable laws and regulations to include counseling.

480-36-.05. Record Keeping

(1) The primary dispensing pharmacy and the secondary remote entry pharmac~~y~~ist shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.
(2) In addition to any other required records, the primary dispensing pharmacy ~~and the secondary remote entry 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.
(3) ~~The primary dispensing pharmacy and the secondary remote entry pharmacy may maintain records separately at each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.~~ Prescriptions processed by a secondary pharmacist must be separately identifiable and retrievable upon request by a GDNA agent during inspection.
(4) These records maintained by the primary dispensing pharmacy ~~and the secondary remote entry pharmacy~~ shall be readily retrievable for at least two years through the primary dispensing pharmacy, and shall be available for inspection by the Board or its representative.
(5) The record keeping required by this rule is in addition to the record keeping required under Rule Chapter 480-10 and any other Board rules and state and federal laws.

Rule 480-36-.06. Patient Counseling

(1) It shall be the responsibility of the pharmacist on duty at the primary dispensing pharmacy to perform patient counseling of all prescriptions, as required, including those assisted by remote processing.

(2) The secondary remote entry pharmac~~y~~ist shall not perform patient counseling on behalf of the primary dispensing pharmacy.

480-36-.07. Notification to Patients

(1) Prior to utilizing remote prescription drug order processing, the primary dispensing pharmacy shall:

(a) Notify patients their prescription drug order may be processed in part by an~~other~~ offsite pharmacist or pharmacy. Such notification may be provided ~~through a one time written consent from the patient or the patient's authorized representative and~~ through use of a sign in the pharmacy which states: "Remote Order Processing Utilized Here." Such sign must be clear and legible with letters at least three (3) inches in size, and the sign shall be free from obstruction and visible to patients at the time the prescription is presented to the pharmacy.

~~(b) Give the name of that pharmacy, or if the pharmacy is part of a network of pharmacies under a common ownership and any of the network pharmacies may process the prescription order, the patient shall be notified of this fact. Such notification may be provided through a one time written consent from the patient or the patient's authorized representative and through use of a sign in the pharmacy which states: "Remote Order Processing Utilized Here." Such sign must be clear and legible with letters at least three (3) inches in size, and the sign shall be free from obstruction and visible to patients at the time the prescription is presented to the pharmacy.~~

~~(2) Prior to utilizing remote prescription drug order processing, written consent from the patient or the patient's authorized representative shall be obtained by the primary dispensing pharmacy when the primary dispensing pharmacy and the secondary remote entry pharmacy do not share the same owner.~~

Mr. Page made a motion and Mr. Brinson seconded that the formulation and adoption of these rule amendments does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule amendments 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 voted 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 at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rule amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Rule 480-11-.02 Compounded Drug Preparations: President Stone stated the Board discussed changes to section (d)(1) of this rule at its April meeting. He asked if there was any discussion. Dr. Heather Talley was on the call and spoke to the Board. She stated that the federal government recently provided guidance related to compounding for animals. She explained the guidance opens up consumer choice and the federal government's thinking is the consumer has the choice to get office stock from veterinarian or another compounding pharmacy of his/her choice. Dr. Talley stated she attended a GPhA meeting and many of those members were not aware of this and were not opposed to consumer choice.

Mr. Brinson made a motion to post Rule 480-11-.02 Compounded Drug Preparations. Mr. Chang seconded, and the Board voted in favor of the motion, with the exception of Mr. Prather and Mr. Page, who opposed.

Rule 480-11-.02. Compounded Drug Preparations

(1) Compounded drug preparations - Pharmacist/Patient/Prescriber Relationship.

(a) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations that are not commercially available in the marketplace or commercially available in the place as outlined by the restrictions under 12(b). Dispensing of pharmaceutical products shall be consistent with the provisions of O.C.G.A. T. 16, Ch. 13 and T. 26, Ch. 4 relating to the issuance of prescriptions and the dispensing of drugs.

(b) Pharmacists shall receive, store, or use pharmaceuticals that have been manufactured or repackaged in a FDA-registered facility. Pharmacists shall also receive, store, or use pharmaceuticals in compounding preparations that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.

(c) Pharmacists may compound pharmaceuticals prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such preparations compounded at the pharmacy. Preparations compounded in anticipation of a valid prescription drug order shall be properly labeled to include the name of the compounded pharmaceutical, date of compounding, and beyond-use date.

(d) The distribution of non-patient specific compounded preparations for office use by a practitioner, excluding veterinarians, is prohibited. This subsection shall not affect 503b outsourcing facilities ability to provide non-patient specific compounded preparations for office use by a practitioner. The distribution of compounded preparations, for office administration or emergency dispensing, to a veterinarian shall not exceed 5% of production of compounded preparation in a calendar year by that pharmacy. Amounts produced greater than 5% shall be considered manufacturing and will require separate licensure as a manufacturer.

1. "Emergency Dispensing" shall mean no more than a ~~96 hour~~ 10-day supply dispensed for an urgent condition to an animal patient by a licensed veterinarian with a valid veterinarian-client-patient relationship when timely access to a compounding pharmacy is not available.

(e) Pharmacists must maintain a separate compounding log for each compounded preparation that includes the quantity and amount of each pharmaceutical that is compounded. Pharmacists shall label all compounded preparations that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. T. 16, Ch. 13 and O.C.G.A. T. 26, Chs. 3 and 4, and Board rules and regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

(f) All compounded preparations labeled in accordance with Board rules and regulations regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of O.C.G.A. T. 16, Ch. 13, and T. 26, Chs. 3 and 4.

(2) Compounded drug preparations - Pharmacist for Distribution to Veterinarian.

(a) Only a pharmacy licensed or registered by the Board may distribute compounded preparations to veterinarians licensed in this state for administration or emergency dispensing to their patients in the course of their professional practice, either personally or by an authorized person under their direct and immediate supervision.

(b) A veterinarian shall make a request to the pharmacy for a compounded preparation in the same manner as ordering products from a wholesale pharmaceutical distributor or manufacturer and not by using a prescription drug order.

(c) A pharmacy receiving an order from a veterinarian for a compounded preparation shall maintain such order with its compounding records as required in Rule 480-11-.08 and other rules and regulations of the Board.

(d) Pharmacists shall label all compounded preparations distributed to veterinarian for administration or emergency dispensing to their patients with the following:

1. "By purchase order, Not by prescription",

2. "For Office Use Administration or Emergency Dispensing by a Veterinarian Only - Not for resale",

3. The name of the active ingredients and strengths contained in the compounded preparation,

4. The lot number or identification of the compounded preparation,

5. The pharmacy's name, address and telephone number,

6. The initials of the pharmacist verifying the finished compounded preparation and the date verified,

7. The quantity, amount, size, or weight of the compounded preparation in the container,

8. An appropriate beyond-use (expiration) date of the compounded preparation as determined by the pharmacist in compliance with Board rule and USP-NF standards for pharmacy compounding, and

9. Appropriate ancillary instructions such as storage instructions or cautionary statements, and where appropriate, hazardous drug warning labels.

(e) Pharmacists shall enter into a written agreement with a veterinarian for the veterinarian's use and emergency dispensing of the compounded preparation before providing any compounded preparation to the veterinarian. The written agreement shall provide the following information:

1. The name and address of the veterinarian, license number and contact information.

2. An agreement by the veterinarian that the compounded preparation may only

be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except for a case in which emergency dispensing is required.

3. An agreement by the veterinarian to include on the patient's chart, or medication administration record the lot number and beyond-use date of the compounded preparation administered or dispensed to the patient.

4. The procedures for a patient to report an adverse reaction or to submit a complaint about a compounded preparation.

5. The procedure to be used when the pharmacy has to recall a batch of compounded preparation.

(f) When pharmacists are compounding preparations to be provided to veterinarians for use in patient care or when pharmacists are altering or repackaging such products for veterinarians to use in patient care in the veterinarian's office, the compounding shall be conducted as allowed by applicable federal law and Board rules and shall be in compliance with USP-NF standards for compounding.

(g) Pharmacists may not compound Schedule II, III, IV or V controlled substances, as defined in Article 2 of Chapter 13 of Title 16 without a patient specific prescription drug order.

(h) Nothing in this paragraph shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners employed by an institution or its affiliated entities; provided, however, pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to the other rules and regulations of the Board governing the compounding of pharmaceuticals.

(3) Pharmacists must maintain documentation of proof that the beyond-use date on compounded pharmaceuticals is valid.

(4) Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final verification check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

(5) Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

(6) Pharmacists may use prescription bulk substances in compounding when such bulk substances:

(a) Comply with the standards of an applicable USP-NF monograph, if such monograph exists, including the testing requirements, and the Board rules on pharmaceutical compounding; or are substances that are components of pharmaceuticals approved by the FDA for use in the United States; or otherwise approved by the FDA;

(b) Are manufactured by an establishment that is registered by the FDA; and

(c) Are distributed by a wholesale distributor licensed by the Board and registered by the FDA to distribute bulk substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

(7) Pharmacists shall maintain records of all compounded pharmaceutical products. Pharmacist shall maintain a complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail when such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

(a) This record-keeping requirement does not apply when FDA-approved and labeled sterile injectable drug products, produced by registered pharmaceutical manufacturers, are reconstituted under conditions as allowed by USP 797, and each such sterile drug product must be administered within 24 hours of being reconstituted.

(8) Pharmacists engaged in the compounding of pharmaceuticals shall operate in conformance with Georgia laws and regulations. Non-sterile compounded preparations shall be subject to USP 795. All sterile compounded preparations shall be subject to USP 797.

(9) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.

(10) Special precaution preparations. If drug preparations with special precautions for contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

(11) Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved.

(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet or an appropriate barrier isolator. Other preparations should not be compounded in this cabinet.

(b) Personnel compounding cytotoxic drugs shall wear protective apparel as outlined in the National Institute of Occupation Hazards (NIOSH.) in addition to appropriate compounding attire as described in USP 797.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations.

(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and delivered in a manner to minimize the risk of accidental rupture of the primary container.

(g) Disposal of cytotoxic and/or hazardous wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of cytotoxic and/or infectious waste in a manner so as not to endanger the public health.

(12) Pharmacists shall not engage in the following:

(a) The compounding for human use of a pharmaceutical product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe.

(b) The compounding of any pharmaceutical products that are essentially copies of commercially available pharmaceutical products. However, this prohibition shall not include:

1. The compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,

2. The compounding of a commercially available manufactured pharmaceutical during times when the product is not available from the manufacturer or wholesale distributor,

3. The compounding of a commercially manufactured pharmaceutical that appears on the drug shortages list, or

4. The mixing of two or more commercially available products of which the end product is a commercially available product.

(13) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. Section 26-4-130 shall comply with all the provisions of this rule and other applicable Board laws, rules and regulations.

Mr. Brinson made a motion and Mr. Azzolin seconded that the formulation and adoption of this 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 voted 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 at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this 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.

Miscellaneous

Mr. Lacefield reported that the Board's June 15th meeting would be in-person only and would be held at the University of Georgia College of Pharmacy.

Mr. Page 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, Jim Bracewell, Michael Brinson, Young Chang, Cecil Cordle, Chuck Page, Bill Prather, and Dean Stone.

Executive Session

Appearances

- M.E.M.
- D.W.

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Cognizant's Report – Michael Azzolin

- GDNA Case # A33920
- GDNA Case # B34131
- GDNA Case # B34226
- GDNA Case # A34230
- GDNA Case # A34209
- GDNA Case # B34204
- GDNA Case # A34154
- GDNA Case # A34184
- GDNA Case # B33993
- GDNA Case # B34109
- GDNA Case # B34040
- GDNA Case # B34158
- GDNA Case # A34023
- GDNA Case # A34213
- GDNA Case # A34190
- GDNA Case # A34162
- GDNA Case # B34219
- GDNA Case # B34183
- GDNA Case # B34111
- GDNA Case # B34132
- GDNA Case # B34182
- GDNA Case # B34092
- GDNA Case # B34140
- GDNA Case # B34153
- GDNA Case # B34216

Attorney General's Report – Max Changus

Mr. Changus presented the following Consent Orders for acceptance:

- C.V.S.P.
- J.S.H.C.
- R.C.P.

Mr. Changus presented the following Voluntary Surrender for acceptance:

- A.P.

Mr. Changus discussed the following cases:

- GDNA Case # B34131
- GDNA Case # B33565
- GDNA Case #B33991
- M.C.

Executive Director's Report – Eric Lacefield

- G.D.

Applications

- J.A.M.W.
- T.M.S.M.
- L.B.
- A.S.
- K.L.R.
- T.J.M.
- K.G.W.
- S.C.S.
- M.I.U.
- C.U.M.
- R.J.M.
- S.Z.S.

Correspondences/Requests

- P.I.
- C.P.
- W.P.N.
- A.P.
- C.P.
- H.V.
- H.V.
- H.V.
- I.P.
- C.R.B.I.
- P.M.S.
- V.C.P.
- T.R.H.P.S.
- T.S.Q.
- B.D.F.
- B.Z.A.
- E.M.T.
- E.J.K.
- A.A.A.
- S.D.G.
- G.S.R.
- P.A.
- T.A.S.

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

Mr. Page reminded the board members that the next installment of the newsletter would come out in July. He asked each member to provide suggestions on topics or content by June 1st. Mr. Page stated that it is his hope that the Board can review and discuss at the June meeting.

Mr. Brinson commented that the GPhA Convention is June 9th through June 12th. He stated he believed the board panel would be held on Friday, June 10th. President Stone reminded the members that information regarding registration was discussed at the April meeting.

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

Appearances

• M.E.M.	Pharmacist Examination	Approved to sit for examination and refer to the Department of Law
• D.W.	Denied Pharmacy Technician	Denial Upheld

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Cognizant's Report – Michael Azzolin

- GDNA Case # A33920 Refer to the Department of Law
- GDNA Case # B34131 Refer to the Department of Law
- GDNA Case # B34226 Close with letter of concern
- GDNA Case # A34230 Refer to the Department of Law
- GDNA Case # A34209 Refer to the Department of Law
- GDNA Case # B34204 Misfill Policy #1
- GDNA Case # A34154 Refer to the Department of Law
- GDNA Case # A34184 Refer to the Department of Law
- GDNA Case # B33993 Close with letter of concern
- GDNA Case # B34109 Misfill Policy #1
- GDNA Case # B34040 Close with letter of concern
- GDNA Case # B34158 Misfill Policy #1 for RPh #2/Misfill Policy #2 for pharmacy and RPh #1
- GDNA Case # A34023 Refer to the Department of Law
- GDNA Case # A34213 Refer to the Department of Law
- GDNA Case # A34190 Close with letter of concern
- GDNA Case # A34162 Misfill Policy #1
- GDNA Case # B34219 Close with letter of concern
- GDNA Case # B34183 Close with no action
- GDNA Case # B34111 Close with no action
- GDNA Case # B34132 Close with no action
- GDNA Case # B34182 Close with no action
- GDNA Case # B34092 Close with no action
- GDNA Case # B34140 Close with no action
- GDNA Case # B34153 Close with no action
- GDNA Case # B34216 Misfill Policy #1 to pharmacists/Refer to the Department of Law for pharmacy

Attorney General's Report – Max Changus

Mr. Changus presented the following Consent Orders for acceptance:

- C.V.S.P. Public Consent Order accepted
- J.S.H.C. Private Consent Order accepted
- R.C.P. Private Consent Order accepted

Mr. Changus presented the following Voluntary Surrender for acceptance:

- A.P. Voluntary Surrender accepted

Mr. Changus discussed the following cases:

- GDNA Case # B34131 Rescind referral
- GDNA Case # B33565 Deny counterproposal
- GDNA Case # B33991 Deny counterproposal
- M.C. Close with no action

Executive Director's Report – Eric Lacefield

• G.D.	Appearance request	Denied request

Applications

• J.A.M.W.	Pharmacy Technician	Denied registration
• T.M.S.M.	Pharmacy Technician	Approved for registration
• L.B.	Pharmacy Technician	Denied registration
• A.S.	Pharmacy Technician	Approved for registration
• K.L.R.	Pharmacy Technician	Approved for registration
• T.J.M.	Pharmacy Technician	Denied registration
• K.G.W.	Pharmacy Technician	Approved for registration
• S.C.S.	Pharmacist Intern	Approved application
• M.I.U.	Pharmacist Intern	Approved extension thru 12/2023
• C.U.M.	Pharmacist Reinstatement	Policy 3A
• R.J.M.	Pharmacist Reciprocity	Approved application
• S.Z.S.	Pharmacist Examination	Approved application

Correspondences/Requests

• P.I.	Notice of Discipline	No action
• C.P.	Notice of Discipline	No action
• W.P.N.	Notice of Discipline	No action
• A.P.	Notice of Discipline	No action
• C.P.	Notice of Discipline	No action
• H.V.	Notice of Discipline	No action
• H.V.	Notice of Discipline	No action
• H.V.	Notice of Discipline	No action
• I.P.	Notice of Discipline	No action
• C.R.B.I.	Notice of Discipline	No action
• P.M.S.	Notice of Discipline	No action
• V.C.P.	Notice of Discipline	No action
• T.R.H.P.S.	Manufacturing Pharmacy Applicant	Board directed staff to respond by stating that, based on the information provided, the Board concluded that a wholesaler

		permit would be required if the facility sends it product into Georgia, or if it provides brokering services for products entering Georgia.
• T.S.Q.	Request to terminate supervised practice requirement	Approved request
• B.D.F.	Request to terminate probation	Approved as of 06/19/2022
• B.Z.A.	Request to terminate probation	Approved as of 06/19/2022
• E.M.T.	Request for extension of application	Approved extension thru 09/30/2022
• E.J.K.	Correspondence	Table pending receipt of additional information
• A.A.A.	Request for 4th attempt to retake MPJE	Approved request
• S.D.G.	Request for 4th attempt to retake MPJE	Approved request
• G.S.R.	Request for 5th attempt to retake NAPLEX	Approved request
• P.A.	Request for 5th attempt to retake NAPLEX	Approved request
• T.A.S.	Request for 4th attempt to retake NAPLEX	Approved request

Mr. Azzolin seconded, and the Board voted in favor of the motion, with the exception of Mr. Cordle, who abstained from the vote regarding C.V.S.P.

There being no further business to discuss, the meeting was adjourned at 3:37 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, June 15, at 9:00 a.m., at the University of Georgia, College of Pharmacy, located at 250 W. Green St., Athens, Georgia 30602.

Minutes recorded by Brandi Howell, Business Support Analyst I
Minutes edited by Eric Lacefield, Executive Director