GEORGIA BOARD OF PHARMACY
Conference Call Agenda
2 Peachtree Street, NW, 6th Floor
Atlanta, GA 30303
February 17, 2021
9:00 a.m.

The following Board members were present:
Michael Brinson, Vice-President
Carrie Ashbee
Michael Azzolin
Cecil Cordle
Chuck Page
Bill Prather
Dean Stone

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

Visitors:
Becca Hallum, GHA
Emily Yona, Impact Public Affairs
Travis Clark
John Rocchio, CVS Health
Stephanie Kirkland
Carla Winkles
John Finley, Bond Pharmacy
Chuck Bell, Bond Pharmacy

Open Session

Vice-President Brinson established that a quorum was present and called the meeting to order at 9:04 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. Stone made a motion to approve the January 13, 2021 Public and Executive Session Conference Call minutes. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Correspondence from Aneet Patel, Navicent Health
The Board considered this correspondence regarding informed consent and immunization certification. In response to Mr. Patel's inquiry regarding informed consent, the Board directed staff to respond to Mr. Patel by stating that Georgia Pharmacy law and rules are silent as to a requirement for an immunization consent form when immunizations are being administered based on patient-specific prescription orders from an authorized practitioner. In regards to the certification course, for immunization under the federal PREP Act, the U.S. Department of Health and Human Services requires all pharmacists, interns, and technicians engaging in the immunization process to have a current basic CPR certification, complete a ACPE practical training program, and complete a minimum of two hours of ACPE-approved immunization related continuing education for each licensing period. Lastly, it is the Board's understanding that the current APhA immunization training course is ACPE and CDC approved. Based on the language in the Board's

2015 post and the language in O.C.G.A. § 43-34-26.1, there is a requirement for an additional immunization-related ACPE approved course.

Georgia Drugs and Narcotics Agency – Dennis Troughton
Director Troughton reported that GDNA has conducted 1607 inspections and 195 investigations for FY2021.

Attorney General's Report – Max Changus
No report.

Executive Director's Report – Eric Lacefield
Continuing Education Report: No report for February.

March and June 2021 Meetings: Mr. Lacefield stated that discussion was held by the Board at its January meeting in regards to moving the March and June meetings to later in the month. He stated that the March meeting is currently scheduled for March 3rd. He inquired as to whether or not the Board was interested in moving it to later in the month. Mr. Prather made a motion to reschedule the March 3rd meeting to March 10th. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Vice-President Brinson inquired as to whether or not the Board would like to hold a 2 day meeting in June. Mr. Azzolin responded by stating that the Board had reserved that 2nd day for the practical; however, since the Board is not administering the practical in June, he thinks the 2nd day can be a working day for the Board to discuss re-evaluating rules, especially after looking at today's lengthy agenda. Vice-President Brinson agreed with Mr. Azzolin in terms of holding a 2 day meeting. He stated, however, that he does not think the Board should be changing a lot of rules at this time and sending them to the Governor's office due to the pandemic. Mr. Azzolin suggested having a two day meeting in October instead. The Board agreed.

NABP Examination Program Changes: Mr. Lacefield reported that beginning in January 2021, NABP will only report a result of "Pass" or "Fail" in lieu of a numeric score for the MPJE and NAPLEX. Vice-President Brinson inquired as to whether or not a rule change would be necessary to reflect this information. Mr. Lacefield responded that this would not affect the rule as the criteria is still the same. He stated the passing score still remains at 75 for both the NAPLEX and MPJE.

Temporary Pharmacy Technicians: Mr. Lacefield reported that 293 temporary permits expire at the end of this month. He explained that at the beginning of the pandemic, it was difficult for applicants to get the fingerprints done. He asked if the Board would like to extend the expiration date. Mr. Lacefield stated there no longer seems to be any issue with the applicants getting the permanent license. Vice-President Brinson agreed. He asked what timeframe should the permits be extended. Mr. Azzolin commented that, for continuity purposes, the expiration date should be until the end of the State of Emergency, plus 120 days thereafter. Ms. Emm inquired as to whether or not 120 extra days would be needed as there are no issues with obtaining the fingerprints. Mr. Azzolin stated that Ms. Emm was correct; however, if the Board ties everything to the State of Emergency, it is less likely to have to keep up with end dates. Mr. Prather asked if applicants who apply for the temporary permits are being told he/she needs to obtain the fingerprints as soon as possible. Mr. Lacefield responded that board staff would be happy to send an email to all temporary permit holders encouraging them to get fingerprinting completed. After further discussion was held, Mr. Stone made a motion to extend the expiration date for temporary pharmacy technician permits to June 30, 2021 and encourage the permit holder to obtain the fingerprints as soon as possible. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Michelle Lincoln: Mr. Lacefield discussed this correspondence received regarding PharmScript of Georgia looking to repackage medications for nursing homes. Mr. Lacefield responded that board staff has responded with the applicable rules that should be followed regarding such, but he just wanted to inquire as to whether or not there was any further information staff should respond with. Director Troughton responded by stating the individual could be referred to Rule 480-9-.04 because it gives information on repacking medications from another pharmacy. Mr. Lacefield commented that Ms. Lincoln has been provided information on Rule 480-9-.04

Election of Officers: Mr. Lacefield reported that Mr. Faulk has resigned. He stated that in light of Mr. Faulk's resignation, the Board should elect a President and Cognizant member for the remainder of the year. Mr. Stone made a motion for Mr. Brinson to serve as President. Mr. Page seconded and the Board voted unanimously in favor of the motion. Mr. Prather made a motion for Mr. Stone to serve as Cognizant and Vice-President. Mr. Page seconded and the Board voted unanimously in favor of the motion. President Brinson thanked Mr. Faulk for his many years of service and stated that the members of the Board of Pharmacy, Pharmacists, Technicians, and the citizens of the State of Georgia are very privileged to have had Mr. Faulk serve as a member of the Georgia Board of Pharmacy.

President Brinson inquired as to how the Board has handled elections in the past when a member leaves. Mr. Prather responded by stating that the Board would elect whomever the sitting Vice-President was for the position of President and the next person in line would be elected as the Cognizant member.

Director Troughton stated that from GDNA and his personal standpoint, he got to know Mr. Faulk over the last few years. Director Troughton stated that he is a consummate professional. Director Troughton further stated that he is a better employee, person and director because of Mr. Faulk. On behalf of GDNA, Director Troughton thanked Mr. Faulk for the tremendous job he did.

Renewals: President Brinson asked Mr. Lacefield if many pharmacists had renewed. Mr. Lacefield responded by stating that the renewal rate was over 70% at the first of the year. He stated that he will get the exact number and report back to the Board. He added that the renewal cycle is over now, so if a pharmacist has not paid for a renewal, he/she must submit an application for reinstatement.

Legal Services – Kimberly Emm

No report.

Discussion Topics

Addiction Program Criteria: The Board discussed its addiction program criteria. President Brinson commented that he did not see anything that needs to be changed at this time. Mr. Page agreed. Mr. Prather commented that the Board previously had Dr. Bartling review program submissions to see if the facility would meet the Board's requirements. Mr. Azzolin stated he would defer to whomever is an expert in that particular area. Mr. Changus commented to Mr. Prather's point that what the Board has in terms of the criteria touches on everything it needs. He added that, while Dr. Bartling was familiar with this area, other individuals have spoken to the Board. He stated that the Board needs to be mindful of that person's qualifications and rely on his/her judgement in terms of whether or not an individual is safe to practice. With no further discussion, the Board agreed no changes were necessary to the addiction program criteria.

Practical Exam in March and June: Mr. Lacefield stated that the Board previously cancelled the January practical, but it has not formally cancelled the March and June practical examinations.

President Brinson stated he thought the Board decided last year that it was postponing the exam for 2021. Mr. Prather commented that he does think the Board or anyone else knows as to when the Board could resume giving the test. Mr. Prather made a motion to cancel the practical examination for the remainder of 2021. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

Number of MPJE Attempts: Discussion was held by the Board regarding the number of attempts allowed for the NAPLEX and MPJE. Mr. Prather asked about the maximum number of attempts NABP allows for the NAPLEX. Mr. Lacefield responded by stating that NABP allows for five attempts, but it will not allow the individual to take it without Board approval. Mr. Lacefield added that in regards to the MPJE, the Board can allow the individual to attempt it as many times as the Board would like. President Brinson stated he felt the Board should follow NABP's policy of allowing the candidate to attempt both exams five times. He added that the Board should consider a rule change to allow for such. Ms. Emm commented that the Board's law states that the individual shall not take the examination more than three times without permission from the Board. She stated that the Board has previously discussed this matter. She further stated that it comes down to whether or not the Board wants correspondence requesting additional attempts to retake the MPJE or petitions for rule waivers. Ms. Emm explained that if the Board amends its rule to limit the number of MPJE attempts to five times, the Board will be receiving rule waiver petitions from anyone that wants to exceed five times. She stated that it is the same way as approving or denying correspondence received requesting another attempt to retake the exam. With no further discussion, the Board agreed not to amend its rule and continue to receive written requests for attempts to retake the exam via correspondence.

Pharmacy Technician Continuing Education: President Brinson suggested the Board table this matter until its June meeting so it can decide how it would like to handle pharmacy technician continuing education. He stated that it is the consensus that everyone feels a technician, whether certified or not, completes some form of continuing education.

Remote Prescription Drug Order Processing: Vice-President Stone commented that the technician should be able to enter data and the pharmacist should not need to be directly over them. Mr. Cordle agreed and stated that having to personally supervise the individual is the part that needs to be clarified. He asked if that meant the supervisor has to be in same building or the same room as that data entry person who has nothing to do with the preparation of the product. He stated that the supervision could be done electronically when that order gets sent in to the pharmacy. Mr. Azzolin responded by stating that he agreed with Vice-President Stone and Mr. Cordle. He stated that O.C.G.A. § 46-4-82(c)(1) states that in the dispensing of all prescription drug orders, *"The pharmacist shall be responsible for all activities of the pharmacy technician in the preparation of the drug for delivery to the patient;"* Mr. Azzolin commented that data entry does not constitute preparation of the drug. He added that, to him, it does seem the law offers the opportunity for a rule to support the technician doing data entry from an offsite location not under direct supervision or being personally supervised. President Brinson agreed. Ms. Emm stated that O.C.G.A. § 46-4-82(c)(2) states, *"The pharmacist shall be present and personally supervising the activities of the pharmacy technician at all times;"* Mr. Azzolin responded by stating that he sees that it says the pharmacist shall be present, but does not see that it requires a technician to be in the same room. He added that he thinks there is room for this to be more practical. He stated that to Ms. Emm's comments, referencing the fact it is relative to the preparation and dispensing of the drug, to him, data entry does not constitute preparation of the drug.

Vice-President Stone stated that the pandemic has made him view things differently. He commented that the technician is not in any secure location with drugs. Mr. Cordle commented that the emergency rule that referenced the Executive Order clearly defines what remote prescription

drug order processing shall mean. President Brinson stated that he agrees with everything that has been said; however, he believes it is more of an interpretation. He asked if anything needed to be changed. Mr. Azzolin responded by stating that if interpretation allows for it, the Board needs to make sure that is how it is being enforced. He further stated that if it is not being enforced and the technician is offsite doing data entry, that would be a violation of direct supervision rules. Director Troughton responded that, from the enforcement standpoint, and until the pandemic started, the pharmacist direct supervision meant the pharmacist is in the same area as the technician. He stated that once the pandemic is over, the Board will need to advise GDNA of the Board interpretation abd GDNA will enforce. Mr. Azzolin suggested amendments to the rule that reflects the Board's interpretation. Ms. Emm responded by stating that if this interpretation is agreed upon by the Board, the rule would need to be further reviewed as the Board's permanent rule expressly states, *"Remote prescription drug processing from any location other than a retail pharmacy licensed in this State is prohibited."* She stated that a technician can help other pharmacies with this process, but the individual must be physically located in a Georgia licensed pharmacy. Mr. Azzolin responded by stating Ms. Emm was correct; however, at the Board's November meeting it waived that rule for a pharmacy in Omaha. Mr. Azzolin commented that with just data processing, he sees no reason to limit that to the four walls of a prescription shop. Director Troughton requested the Board consider if the person is a data entry person or technician and would this count against the ratio. He stated that is a question that is important from the enforcement side. After further discussion, Mr. Prather stated that he is a believer in the saying "if it ain't broke, you don't fix it". He further stated that what the Board is doing right now is not broken. Mr. Prather stated that, until this pandemic is over and the Board can get a better handle on it, the rule needs to be left alone. President Brinson agreed and suggested the Board revisit this matter again in several months.

Collaborative Practice Agreement vs. Protocol Agreement vs. Drug Therapy Modification: Vice-President Stone stated that he has brought this subject up previously. He stated that he could not find anything in the Pharmacy Practice Act regarding collaborative practice agreements, but there are protocols and the Board has drug therapy modification law and rules. Vice-President Stone stated that Rule 480-35-.01(2) defines "Drug Therapy Modification" as *"the adjustment of dosages, dosage schedules, and/or medications by a pharmacist under authority delegated and supervised by a physician. Such medications need not be pharmaceutically or therapeutically equivalent to the initial prescription issued to the patient by the prescribing physician."* He further stated that Rule 480-35-.02 discusses the application for certification being submitted to the Board and that evidence of completion of a course of study and evidence of continuing education are required. He inquired how does this play in with a collaborative practice agreement and are they the same thing. Mr. Azzolin responded by stating that the laws themselves are not very restrictive. He further stated that the rules are not very restrictive either except for the record keeping piece of it. Mr. Azzolin commented that the Board has previously been approving the protocols at its meetings, and there is nothing in the law or rules that requires the Board to approve the protocols. He stated that the Board has also denied some applications because of the protocol submitted. Mr. Azzolin explained that the application requires a copy of the protocol be submitted; however, there is nothing in the law or rule that requires a protocol be approved by the Board. Mr. Azzolin requested the Board amend its application to remove the language stating the protocol needs to be submitted with the application.

Mr. Changus stated that Drug Therapy Modification Certification is assigned to the Board under O.C.G.A. § 26-4-50. He stated this code section requires the pharmacist to be licensed to practice as a pharmacist in this state, has successfully completed a course of study regarding modification of drug therapy, completed a continuing education program, and is certified by the Board as meeting the requirements of this section. He further stated that the rules go beyond what is in the statute and seem to imply more in terms of requirements of the protocol. Mr. Changus stated the Board has been reviewing the protocol with the application, which does not seem to flow from the statute

themselves. Ms. Emm commented that she believes some of those requirements flow from O.C.G.A. § 43-34-24. Mr. Azzolin asked if O.C.G.A. § 43-34-24 required the Board to approve the protocol. He stated that a sub-committee was previously formed with Mr. Henderson and Mr. Azzolin regarding this matter. Mr. Azzolin stated that Mr. Henderson kept saying the law required the Board to list every patient in the protocol and Mr. Azzolin could not find anywhere that stated that information. He stated that he guesses it is because it was in the Medical Practice Act and not in the Pharmacy Practice Act. Mr. Azzolin further stated that is part of what is cumbersome about the practicality of a protocol. He stated patients come in and out of a physician's practice monthly and are on and off of a collaborative practice agreement within a month. He further stated that he is unaware if it is required to go back and list those patients and provide that information to the Board. Mr. Azzolin stated that having to do that would cause an administrative blockage. After further discussion, Mr. Azzolin made a motion to amend the Application for Pharmacist Certification of Drug Therapy Modification Protocol by removing the language that requires a copy of the proposed protocol, signed by the supervising physician, be submitted to the Board with the application. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

Change in Ownership/Location: Vice-President Stone discussed when a change in ownership or location occurs. He stated that O.C.G.A. § 26-4-111(c) states, *"Pharmacy licenses issued by the board pursuant to this chapter shall not be transferable or assignable."* Vice-President Stone commented that he argues that moving locations is not transferring or assigning. Mr. Azzolin responded by stating that he believes the issue is with Rule 480-10.-06(1)(c), which states, *"Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business."* He stated the Board would need to modify the rule to remove "location".

Vice-President Stone thanked Mr. Azzolin for the clarification. He stated he would be in favor of removing "location" from the rule. Vice-President Stone discussed various situations such as ownership within a corporation changing. He inquired as to how the Board looks at these certain situations. Mr. Greg Reybold, GPhA, commented that this is an issue GPhA receives many calls on. He stated that there is some ambiguity the Board could weigh in on in terms of what constitutes a change of ownership. He further stated that he thinks this is an issue worth more scrutiny and worth looking at because it has caused some confusion over the years.

Mr. Azzolin asked Mr. Changus what the term "assignable" means under O.C.G.A. § 26-4-111(c). Mr. Changus responded by stating there is a process of submitting an application. He stated that the Board requests information about the people who are behind the issuance of license, such as partners, owners, etc. He further stated there is an inspection by GDNA that goes along with it as well. Mr. Changus explained that the purpose of this code section is to say "this is not your property right" that can be sold without the Board weighing in and making a determination as to whether or not the new ownership satisfies the Board. He further explained that this is an opportunity for the Board to make sure the people coming in and looking to purchase the pharmacy are vetted. Mr. Changus stated that with the term "assignability", one cannot give the property away and the license still be in effect with the new owner having the same rights as the previous owner. He further stated that the Board should be able to weigh in when there is going to be a change in ownership prior to that sale being acceptable. Mr. Azzolin asked if this could be done through an application of transfer to which the Board is notified a transfer is occurring. He stated the key point of the matter is the license number getting rescinded and a new license number being issued. Vice-President Stone responded by stating that, based on what Mr. Changus said, it does not mean a new license number should be issued. He stated it just means the Board needs to be notified and the people are vetted. He further stated that as long as the Board is notified that a change of ownership is occurring and the Board is approving the new owners, it should not mean a new license number is issued. Mr. Changus responded that there may be administrative concerns that Mr. Lacefield and Ms. Emm may have in terms of the license number, which would appear it is

being transferred. He stated that the law says the license shall not be transferrable. Mr. Changus stated that the change in location would be a different analysis because administratively at a minimum, that it signifies a break. He explained that when this statute was written, it did not contemplate all the modern ways of financing. He stated that the change in license number signifies the company just has not been handed over. Mr. Azzolin asked if the change in location could be modified. Mr. Changus responded that he views the change in location as being different from the change in ownership; however, he does not know if there are any caveats that may raise. President Brinson requested Ms. Emm review Rule 480-10.-.06 and report back to the board.

Point of Care Testing: Vice-President Stone requested to table discussion on this subject as it seems House Bill 93 may cover this. President Brinson asked Ms. Emm how the Board of Dentistry viewed this matter. Ms. Emm responded that the Board of Dentistry deemed that this type of testing does fall within the scope of practice for a dentist if he/she should choose to offer the testing. She added if a practitioner is using an FDA approved, CLIA waived, Point-of-Care test, then a CLIA waiver is required.

Mr. Reybold stated that, up until 2018, the Clinical Lab Act had a provision that only allowed pharmacists to do capillary blood test thats were approved for home use. He added that in 2018 that provision was changed so a pharmacist can conduct any home use test. Mr. Reybold stated that a substitute bill has been submitted.

Role of Technicians in Pandemic: Vice-President Stone requested to table this matter and discuss at a later time.

Remote Data Entry: Mr. Cordle stated the Board did talk about issues that would be of concern. He stated when the Executive Order ends, the Board would be taking a step back from where it is today and that it may be prudent for the Board to be prepared instead of waiting for the Executive Order to expire. Mr. Azzolin responded by stating that he would be happy to assist Mr. Cordle on this topic and come up with recommendations relative to technicians inside or outside the prescription area that would make the continuation of remote data processing appropriate post pandemic. Mr. Cordle agreed.

Electronic Record Keeping: Mr. Cordle discussed electronic record keeping procedures. He stated that if a prescription comes in via hard copy, telephone or facsimile, it has to be retained for two years in that hard copy manner; however, if it comes in an electronic manner, it can be maintained electronically. Mr. Cordle stated that as the Board moves forward, it is not a system that is broken, but he can see some issues that would present problems such as the safety and security of those records that are kept on site. He asked if the Board should consider the possibility of retaining all dangerous drugs electronically. President Brinson asked for Director Troughton's thoughts. Director Troughton responded by stating that if the prescription comes in as a paper copy, that is what GDNA looks for. He added that in terms of electronic records, it is already in place where those records must be able to be seen immediately. Director Troughton stated that in whatever form the prescription comes, whether it is scanned or hard copy, GDNA will deal with that. He further stated that the records must be immediately retrievable and not sent somewhere else where GDNA is unable to get to them. Mr. Cordle commented that the DEA mandates hardcopy storage, but he is thinking in terms of dangerous drugs and the retention of those paper copies. He stated that right now the Board has a set of rules and then the DEA has its rules. Mr. Cordle suggested the Board remove this rule around dangerous drugs and follow the DEA rule and still provide the information that GDNA needs. Director Troughton responded that, as board members, the Board is not just hearing cases about diversion. He stated that there are also cases on misfills where those dangerous drug prescriptions are still important and having the original paper document is better for the

investigation. Director Troughton stated that he understood Mr. Cordle's point; however, GDNA does a lot more investigations than just on the control substances.

To Director Troughton's point, Mr. Changus stated that it does come down to what was the actual evidence. He stated that any time you take a step away from what the original evidence was, you have introduced a questionable document. He further stated that GDNA would want to see the most accurate evidence there. Director Troughton commented that when a case goes to a hearing type of setting, he is responsible for maintaining that chain of custody of evidence. He stated that GDNA treats every case as if it were a criminal case and collects and maintains evidence as if they are doing it for a court of law. Director Troughton stated that GDNA does this so it is prepared from the beginning to walk into that hearing or courtroom.

FDA Memorandum of Understanding (MOU): Mr. Azzolin commented that the Board previously discussed this matter and indicated that it needed to be addressed by 10/26/2021. He stated that it may not need to be addressed now; however, he does not want to forget about it. Mr. Changus responded by stating that this mandate comes from the FDA who have indicated that in order for compounders to do business the way they would like, the Board has to sign off on the MOU. He stated the MOU will impose additional requirements on the Board and GDNA. Director Troughton commented that this matter has been put off because the questions being raised cannot be answered yet. Mr. Changus stated that it may be helpful to assign this to the Board's April agenda and get input from compounding pharmacies that may be effected by this. President Brinson requested Mr. Reybold reach out to the compounding pharmacies for their input. Mr. Reybold responded that he would be happy to assist with such.

Mr. John Finley, General Counsel, AIS Healthcare, spoke to the Board regarding this matter. He stated that he welcomes the opportunity to work with the Board and provide input on the MOU and how it would impact pharmacies and patients.

Rules Review:

Rule 480-16-.02 Receipt of Prescription Drug Order by a Non-Pharmacy: President Brinson stated this matter is related to correspondence received by the Board and discussed at its November 2020 meeting. Mr. Snow's correspondence is a follow up to a previous correspondence submitted in the Spring of 2018 and requested the Board strike the requirement in Rule 480-16-.02(03) for written authorization from the patient in order for a pharmacy to deliver the patient's drugs to a medical practitioner. The Board had previously stated it was not inclined to strike the rule altogether, but suggested Mr. Snow provide proposed language for revising the rule. Mr. Snow's letter states the reason for the request is because of a number of difficulties that render it impossible or impractical for a patient to get written authorization before the prescription is provided to the patient's doctor. President Brinson asked for comments on the matter. Director Troughton responded by stating that from GDNA's perspective, it would be very difficult to prove that a patient verbally authorized something. Mr. Page commented that if the Board were to say that verbal authorization is permissible, should it at least ask for documentation. Director Troughton responded by stating that GDNA would need to have more than just the verbal authorization. Mr. Prather commented that he has always been told that if it is not written down, it did not happen. Mr. Changus commented on Director Troughton's point. Mr. Changus stated that he thinks the proposal was made to address situations that may not happen all that often. He further stated that if there needs to be an exception, they could ask for a waiver. Vice-President Stone made a motion to not make any changes to the rule. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Rule 480-18-.05 Physical Requirements and Equipment: President Brinson stated that subsection (1) requires floor space to be at a minimum of 150 square feet. Director Troughton

commented that this matter was brought up at the Board's November 2020 meeting when discussing a rule petition. He stated that it was a case that had been established before and GDNA made an error in measuring the first time. He further stated the Board granted the waiver. There being no further discussion, the Board agreed to not make any changes to the rule.

Rule 480-11-.02 Compounded Drug Preparations: The Board discussed correspondence from the Georgia Veterinary Medical Association (GVMA) that was tabled at the Board's January 2021 meeting. The correspondence requested the Board reconsider Rule 480-11-.02 Compounded Drug Preparations due to the unprecedented impact of the pandemic. President Brinson explained that the language agreed upon previously by GPhA and GVMA was 96 hours for emergency dispensing. Mr. Prather commented that he spoke with some veterinarians in the Blue Ridge area and they stated they are not having any issues. Ms. Emm stated that representatives from GPhA and GVMA were on the call and could provide some insight to the Board.

Dr. Justin Toth, GVMA, spoke to the Board regarding this matter. Dr. Toth explained the issue came about when the pandemic started. He stated that, due to the pandemic, shipping delays have become a real problem. Dr. Toth explained that if a patient comes in on Friday at 5:00 p.m. and the veterinarian diagnoses congestive heart failure and a 96 hour supply is prescribed, the veterinarian cannot get in touch with the compounding pharmacy until Monday. He stated that if the product is shipped Monday, the best case scenario is the product would be received Wednesday; however, due to shipping delays, it could be at least seven days before the client receives the medicine. Dr. Toth explained there are pharmacies in Georgia that do compounding and most of the time they have the product available and can mix and dispense within 24 hours. Dr. Toth stated that GVMA understands why the Board wants to restrict the amount of office stock that is dispensed; however, GVMA is trying to come up with a happy medium where they can get something more reasonable, but it is still restricted to protect the public. He further stated that is the reason why GVMA came up with "14 days". Dr. Toth stated it can more than allow for shipping times and cover shorter treatment plans.

Mr. Reybold commented that, at this point, it is something GPhA is still looking at. He stated that when this issue initially came up, GPhA did not oppose it and the agreement of 72 hours in an emergency situation was reached. He further stated at the board meeting it was changed from 72 hours to 96 hours and GPhA still did not take issue with it. Mr. Reybold stated that it seems the veterinarians just want to dispense for 14 days. He stated there may be some members from both sides that that have concerns and others that do not. He explained that to the extent of this matter being COVID related, he is not sure if there had been any requests for an emergency rule in that regard. Mr. Reybold stated when this matter was previously discussed at the board meeting two years ago, it seemed clear it was related to the ability to dispense for emergencies. He stated that if the Board decides to promulgate a rule, he would expect GPhA to provide input on such, but at this time, GPhA does not have a stance of being for or against it. President Brinson inquired as to whether or not the Board could come up with an emergency rule that would allow veterinarians to dispense a 14 day supply of a compounded preparation. Vice-President Stone commented that since COVID-19 is an issue, he is not sure if the Board should permanently change the rule; however, if the Board could assist in the interim due to the pandemic, he feels it should. Mr. Azzolin commented that the emergency rules are in place and are effective for the duration of the State of Emergency and for a period of not more than 120 days thereafter. He continued by stating that would give time for GVMA and GPhA to present their cases to the Board. President Brinson inquired as to what should be done regarding the rule. Ms. Emm responded by stating the Board would need to vote on an emergency rule for 480-11-.02(1)(d)(1) that would need to go to the Governor's Office for review. President Brinson asked if any board members were opposed to doing such. Mr. Prather asked if this would just be during the pandemic only. Mr. Azzolin responded by stating that is his suggestion. There was not any opposition from the Board. Ms.

Emm stated that she would work on the language of the emergency rule and would present it to the Board for consideration.

Correspondence from Dr. Lois J. Lassiter: Mr. Lacefield discussed this correspondence from Dr. Lassiter regarding compounded buprenorphine to dispense for use for cats. In her letter, she states that she "cannot even legally dispense postoperative pain control that is safe in cats according to the current law." Director Troughton responded by stating that he is not aware of a law that would prevent them of dispensing and that the issue sounds more logistical. Mr. Changus suggested the Board respond by stating that before it can provide a response, the Board requests she provide further information regarding what she sees as the legal barrier that would prevent her from compounding and dispensing patient-specific prescriptions.

Rules 480-27-.09 Patient Records and 480-31-.01 Patient Counseling: Mr. Azzolin pointed out the conflict between the two rules regarding record keeping. Ms. Emm commented that the Board agreed Rule 480-27-.09(3) should be amended to be consistent with Rule 480-31-.01. Mr. Azzolin inquired as to what needs to happen in order for the change to occur. Ms. Emm stated that the amended rule needs to be drafted. She further stated that once the Board votes to post it, a public hearing would need to be held, and once the rule is adopted, it must be sent to the Governor's office for review. Mr. Azzolin asked if there was a reason this matter should be delayed or could the Board act on it now. Mr. Lacefield responded that it will be added to the list of rules that need to be amended and Ms. Emm will bring it back to the Board.

Rule 480-24-.01 Definitions: Mr. Azzolin stated the Board previously discussed this matter at its June meeting. He further stated that discussion was held concerning there being no definition of a practitioner drug order. Mr. Azzolin stated the question was concerning if there was a need to have the prescription in the nursing home or could a drug order be used similar to what one would see in a hospital. He stated that Mr. Prather recommended not creating a definition for practitioner drug order, but instead have a different definition for prescriptions in nursing homes. Mr. Azzolin stated that Mr. Henderson thought it would be good for the nursing home environment and indicated he would work with Ms. Emm. Ms. Emm responded that she and Mr. Henderson did come up with a few barriers in regards to this matter. She stated the first issue is nursing home prescriptions are filled by retail pharmacies and retail pharmacies are bound by retail laws and rules. She added that there is no separate licensure for a pharmacy that only services nursing homes.

Mr. Azzolin made a motion to amend Rule 480-27-.01 by removing the definition of "Practitioner Drug Order". Discussion was held. Director Troughton stated that it seems as though this rule applies to all pharmacies and requested researching the matter to ensure it does not impact other rules before the definition is removed. Ms. Emm responded by stating she previously researched it when she was addressing the rule with Mr. Henderson. She stated that "Practitioner Drug Order" is only defined in Rule 480-27-.01 and that is the only place where "Practitioner Drug Order" is mentioned. Vice-President Stone inquired as to why it should be removed. Mr. Azzolin responded by stating that the issue was that Mr. Henderson requested nursing homes be able to fill prescriptions from paper orders; however, because of how the law is written, the Board cannot create a separate definition for a nursing order prescription because it has to be filled by a retail pharmacy. He stated that the definition of "Practitioner Drug Order" is being removed to prevent any confusion. With no further discussion, Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

At this point in the meeting, the Board recessed for lunch at 12:24 p.m.

The meeting resumed at 1:00 p.m.

Rule 480-31-.01 Patient Counseling: Mr. Azzolin commented that the Board previously discussed this matter. The Board voted to amend Rule 480-31-.01(c)(1) to read, *"Upon receipt of a Prescription Drug Order and following a review of the patient's record, the dispensing Pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. The personal offer to counsel may be made verbally or in written format; a written offer must provide a telephone number and business hours during which the dispensing pharmacist can be reached."* Mr. Azzolin requested the status of this amendment. Ms. Emm responded by stating that it is on the list to be processed.

Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Orders: Mr. Azzolin discussed corrections that need to be made to section (3). Mr. Azzolin made a motion to amend Rule 480-22-.07(3) to read, *"A pharmacy must either file the original prescription drug order or generate a hard copy prescription drug order to be ~~filled~~ filed, both of which are required to contain all of the information required by this chapter."*
Mr. Page seconded and the Board voted unanimously in favor of the motion.

Rule 480-37-.03 Minimum Requirements: Mr. Azzolin stated that Rule 480-37-.03 needs to be amended to mirror O.C.G.A. § 26-4-28(12.1)(B). He stated that O.C.G.A. § 26-4-28 allows for the pharmacy technician to restock a RAM. Ms. Emm stated that the law supersedes what is currently in the rule. She stated Rule 480-37-.03(l) states, *"The stocking or restocking of a dangerous drug or controlled substances shall only be completed by a Georgia pharmacist or a pharmacy intern/extern under the direct on-site supervision of a Georgia licensed pharmacist."* Ms. Emm stated that this matter had not been addressed because what is in the law supersedes the rule; however, she stated that the rule does need to be amended to mirror what is in the law. She further stated that this request will be added to the list of items to process.

Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Orders: Director Troughton requested to circle back to this topic. He stated that section (3) conflicts with section (2). He asked if section (3) needed to be removed completely. Mr. Azzolin agreed. Discussion was held concerning removing the language regarding "or generate a hard copy". Mr. Azzolin made a motion to amend Rule 480-22-.07(3) to read, "*A pharmacy must ~~either~~ file the original prescription drug order ~~or generate a hard copy prescription drug order to be filled, both of~~ which is ~~are~~ required to contain all of the information required by this chapter."*
Mr. Page seconded and the Board voted unanimously in favor of the motion.

Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security: Mr. Azzolin commented that this goes back to a question from a pharmacist at Walgreens. Mr. Azzolin stated that the pharmacist felt the way the language was written would create an issue with regards to signing off the invoices for controlled substances. Mr. Azzolin stated that the Board discussed the issue and Ms. Emm and Mr. Changus indicated they would suggest amendments to the rule and would report back to the Board. Mr. Azzolin requested the status of the matter. Ms. Emm stated this request was added to the list of items to process. She further stated the Board will receive updates to Rule 480-13-.06 Drug Distribution Control as well.

Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed: Mr. Azzolin stated that this is just a reminder that when the Board is reviewing the rule, House Bill 918 went into effect as of January 2021. He stated that comments were received at the Board's September meeting from GPhA regarding such. He further stated that the Board needs to revisit this rule to remove the exceptions for PBM retail pharmacies. Ms. Emm responded by stating that there are three rules that will need to be addressed. She added that she will review them to see what might need to be altered.

Rules 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances and 480-28-.10 Loss or Theft of Controlled Substances: Mr. Azzolin commented that the DEA does not necessarily want to know every time an insignificant loss occurs. He stated that the rule requires the DEA and GDNA be notified. He further stated the proposal would do away with reporting to the DEA under certain circumstances and losses. Mr. Changus responded by stating that this was related to correspondence submitted to the Board by Josh Belinfante. He stated that Mr. Belinfante's proposal made sense. Mr. Changus stated that the DEA is not looking for certain forms to be submitted to them, whereby the Board's rule mandated it be reported to the DEA. He further stated that he and Director Troughton discussed this matter. He stated that he thought the language proposed would be sufficient. Director Troughton commented that he will get with Ms. Emm and review so this can be brought back to the Board for review.

Low THC: Vice-President Stone stated that he wanted to follow up on this matter. He further stated that Mr. Prather has discussed this with the Board in the past. Mr. Prather responded by stating that the Board needs to formulate rules. Mr. Lacefield stated that the Board is supposed to work in conjunction with the Medical Cannabis Commission. He further stated that he will contact the Executive Director of the commission. Mr. Reybold commented that the Board of Pharmacy has authority to promulgate rules for licensure and has to collaborate with the commission on dispensing rules.

Rule 480-48-.02 Conditions for Use of Delivery by Mail: Mr. Cordle stated that the current rule requires signature upon delivery for all CIIs, CIIIs, CIVs and CVs. He commented that he understands the preventative nature of having those requirements, but his concern is regarding continuation of care. Mr. Cordle stated that a patient may not be able to provide a signature and it might be a flag to the courier that there is something different in the package worth stealing. Mr. Prather responded by stating that, prior to the rule, there was a history of kids on bicycles following the delivery vans and stealing the medications off of porches after the courier had dropped of packages. He stated that after the Board discussed this matter, the signature was required due to the amount of theft and the Board needing to protect the public. He further stated that he understands Mr. Cordle's concerns; however, he did not recall patients stating that he/she could not get his/her medications because he/she was collapsed or incapacitated. Mr. Prather commented that he is not saying that type of situation does not occur, however. Mr. Cordle inquired as to whether or not there are issues with thefts on control substances. Mr. Prather stated that when this rule was written, the Board had evidence of individuals stealing narcotics off of porches. Mr. Cordle stated that his overall concern is the inconvenience it causes because of the restrictions around it. Mr. Page commented that he understands Mr. Cordle's concerns, but agrees with Mr. Prather's points.

Rule 480-36-.03 Personnel and Supervision: Mr. Azzolin stated he wanted to discuss this relative to remote data processing. He stated the Board came across this issue months ago with the facility in Omaha that was wanting to process orders using a Georgia licensed pharmacist remotely. Mr. Azzolin stated that the Board waived the rule to allow them to do this. Ms. Emm responded by stating that Rule 480-36-.02 requires the pharmacy to be licensed and located in Georgia. Additionally, Ms. Emm stated that 480-36-.03(2) states, *"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."* Discussion was held. Mr. Prather commented that the Board did not want the transferring of prescriptions between more than two pharmacies. He stated that the purpose of the rule was to provide some sort of relief to a store that was busy. He added that Store A could transfer the patient's prescription to Store B for all of the adjudication that goes along with filling. Mr. Azzolin commented that the idea was to allow a Georgia licensed pharmacy to be able to do secondary responsibilities from any location, not just from a location in Georgia. Ms. Emm commented that Rule 480-36-.02(2) states, *"Remote*

prescription drug processing from any location other than a retail pharmacy licensed in this State is prohibited." She added that the processing has to be done from a location in Georgia. Mr. Azzolin asked if it could be done by an out of state non-resident pharmacy. Ms. Emm responded by stating that Rule 480-36-.02(1) states, *"Pharmacies 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."* Mr. Azzolin stated that the point he would like to bring up for consideration is concerning the language stating, *"physically located within the State of Georgia"*. He further stated that he feels this language is not necessary if the pharmacy and pharmacist are licensed and are doing the secondary processing. Mr. Azzolin stated that he feels it should be permissible whether they are located in or out of state.

Director Troughton commented that the Board discussed this matter previously. He stated that what Mr. Azzolin is suggesting would make an investigation much more difficult if something were to happen. He added that GDNA would not have any authority in another state. Director Troughton stated that the only repercussion would be whether or not to revoke the license. Mr. Prather commented that he understands Mr. Azzolin's point, and is not opposed to technology; however, he believes there are instances when it may not be a good idea. Mr. Azzolin responded by stating that he understands and respects the comments made; however, he just wanted to make sure the Board is taking the matter into consideration. After further discussion was held, Mr. Azzolin commented that the facility could present a rule petition and show why it would be a hardship. Ms. Emm responded by stating that the pharmacy would have to demonstrate why it would be a unique hardship.

Laws for Discussion

O.C.G.A. § 26-4-113(b): Mr. Azzolin stated that the Board previously discussed an issue where nursing homes were having to get a pharmacy to come out to retrieve drugs or controlled substances that were out of date or could no longer use. He stated this is creating an administrative burden on pharmacies. Mr. Azzolin stated that the law says the reverse distributor is not allowed to pick up from anyone not licensed in this chapter with nursing homes licensed in another chapter. He further stated that, as a result, this prevents the reverse distributor from going out and taking those medications. He stated that he does not know if there is anyway to communicate this to GPhA. President Brinson commented that he agrees with Mr. Azzolin. He added that the reverse distributor should be allowed to go in nursing homes and take back any unwanted drugs, or destroy the drugs. He suggested the Board get with GPA or GPhA members to address this law.

O.C.G.A. § 26-4-114.1 and § 26-4-5(10): Mr. Azzolin commented that the Board discussed this matter several months ago. The issue related to an out of state pharmacy that held a non-resident permit in Georgia. He stated that the facility was providing medications to nursing homes in Georgia, but they were not allowed to provide an e-kit. He further stated that he sees this as a patient care issue. Mr. Azzolin stated O.C.G.A. § 26-4-5(10) states, *'"Dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient, patient's caregiver, or patient's agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient."* Mr. Azzolin stated that an e-kit is not an unlawful order from the practitioner. He suggested either modifying O.C.G.A. § 26-4-114 to include floor stock items or modify O.C.G.A. § 26-4-5 to provide for an e-kit to be provided to the nursing homes. President Brinson agreed with Mr. Azzolin. Mr. Azzolin inquired as to whether or not this issue could be communicated to the associations. President Brinson stated that perhaps, GPA or GPhA can bring this matter before the legislature.

Mr. John Rocchio spoke to the Board regarding this matter. He stated that he believes the issue was that the e-kit does dispense a prescription. He added that it is really how the e-kit is being perceived. He understood the Board previously viwed the e-kit is not dispensing prescriptions. Mr.

Rocchio stated the drug has not been delivered to the patient until the pharmacy dispenses the drug, the nurse removes the drug and gives it to the patient. Discussion was held by the Board. President Brinson requested Mr. Rocchio provide further information to the Board in writing. Mr. Rocchio stated he would be happy to assist as he believes everyone is on the same page to help the patients. Mr. Changus commented that the Board can wait to see what information Mr. Rocchio is able to provide, but it seems like an expansion on e-kits and what their uses are for. He stated that the idea that the pharmacist retains control is a bit of an extension.

O.C.G.A. § 26-4-82(b) and O.C.G.A. § 26-4-85: Mr. Azzolin stated that at the Board's October meeting Mr. Changus and Ms. Emm were going to review what a pharmacist intern/extern could do from a remote environment. He stated this matter came up because pharmacy schools inquired as to what was appropriate in this current environment. He asked if Ms. Emm or Mr. Changus had reviewed this topic. Mr. Changus responded by stating he has not had the opportunity to confer with Ms. Emm on this matter; however, he thinks the way the law was written was meant to have more of a "hands on" direct supervision environment than what is being contemplated in the remote entry order scenario.

House Bill 316: President Brinson stated that this bill deals with raising the technician ratio from three to four. He stated he just wanted to make the Board aware of this bill.

There being no further business to discuss, the meeting was adjourned at 2:22 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Thursday, February 18, 2021 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6th floor, Atlanta, GA 30303.

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