GEORGIA BOARD OF PHARMACY
Conference Call
2 Peachtree Street, NW, 6th Floor
Atlanta, GA 30303
October 13, 2021
9:00 a.m.

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

Staff present:
Eric Lacefield, Executive Director
Dennis Troughton, Director, GDNA
Alec Mathis, Special Agent, GDNA
Nicholas Aderibigbe, Special Agent, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst

Visitors:
Mark Johnston, RPh
Heather Tally
Ashley Woodhouse
Becca Hallum, Georgia Hospital Association
Diane Sanders
Leigh Anne Jacobson

Open Session

President Brinson established that a quorum was present and called the meeting to order at 9:02 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.

President Brinson thanked the board staff and GDNA for the great job they do.

Mr. Cordle stated that pharmacists play a critical role in all that they do. He stated that the Board would like to recognize that October is American Pharmacist Month. He added that the Board appreciates all of the hard work he/she does every day.

Approval of Minutes
Mr. Page made a motion to approve the Public and Executive Session minutes from the September 15, 2021, Conference Call. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

Report of Licenses Issued
Vice-President Stone made a motion to ratify the list of licenses issued. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

Rule Waiver Petition from Ashish Shah: Vice-President Stone made a motion to deny the petition as O.C.G.A. § 26-4-42 requires a pharmacist who is a graduate of a pharmacy school or college located in another country to complete all requirements of the Foreign Pharmacy Equivalency Certification Program administered by the National Association of Boards of Pharmacy. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Express Pharmacy, PHRE010056: Mr. Azzolin made a motion to grant the petition. Vice-President Stone seconded, and the Board voted unanimously in favor of the motion.

Correspondence from N. Christopher Doll, Navicent Health Oconee

The Board considered this correspondence regarding providing non-patient specific, compounded IV products under the FDA temporary policy dated April 2020. Director Troughton commented that two (2) of the guidances from Health and Human Services (HHS) come into play. He stated that the one referenced in the letter is from April 2020; however, additional guidance released in October 2021 allows for 503A facilities under certain circumstances, which includes within the hospital/health system. He added that the hospitals are still responsible for proper compounding storage, etc. After further discussion, the Board viewed this correspondence as informational purposes only.

Correspondence from Corie Hawks, Political Capital, LLC

The Board considered this correspondence regarding 503B outsourcing facilities. Ms. Hawks' letter states that in April 2021, the Board addressed a question from the company regarding the dispensing of outsourcing facility products by veterinarians. At that time, the Board indicated that it did not have an issue with veterinarians dispensing outsourcing facility products when medically necessary in accordance with federal law; however, Ms. Hawks stated that the position statement did not make it into the Board minutes. She added that the minutes only reflected that the Board considered a question from Political Capital, LLC, for informational purposes.

Ms. Emm commented that Ms. Hawks inquired about a veterinarian's ability to dispense products that have been purchased from a 503B. Ms. Emm stated that a 503B does not really cover vets, it only covers human drugs. Director Troughton agreed and stated that Rule 480-11-.02(1)(d) reads, *"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."*

Director Troughton commented that it seemed 503B does not apply to veterinarian compounded drugs, and Ms. Hawks was asking for that statement. Ms. Emm stated that, at that point, they would have to follow the practitioner dispensing regulations. Mr. Changus commented that the Board can refer them to the rule, but did not know if he saw anything all that objective. President Brinson inquired if the Board should say veterinarians were excluded. Mr. Changus responded that Ms. Hawks requested the Board's position be reflected in the minutes and that it is his understanding Ms. Howell will put that information into the minutes and that will be sufficient.

Correspondence from Linda Stevens, PipelineRx

The Board considered this correspondence regarding medication reconciliation services. Ms. Stevens inquired if medication reconciliation services were allowed by the Board as PipelineRx would like to utilize pharmacy technicians to assist with the medication reconciliation process. Ms. Emm commented that PipelineRx provided a breakdown of the services they provide and what they were looking to do. She added that it is a drugless pharmacy and they are supposed to only do remote processing for hospitals, but they are looking to expand their services.

Mr. Azzolin commented that he could offer insight into what he believes they are trying to accomplish. He stated that the assumption is they are referring mostly to hospital pharmacies. He further stated that when a patient comes to the emergency room or is directly admitted at the hospital, the patient will bring his/her medications, and the nurse will write those down. Mr. Azzolin explained that those will be evaluated by a medication reconciliation staff member, which could be a nurse or pharmacist, to determine if those medications should be continued or discontinued. He added that whether the reconciliation is done by a pharmacy technician, a pharmacist, or a nurse, it will be reviewed by a physician and the physician orders it before the patient receives the medications. When discussing medication reconciliation, if in a hospital setting, they are saying the pharmacy technician is helping to identify everything that patient could be taking and indicating what is relevant. Mr. Azzolin explained that he is not saying the Board should not allow a technician to do it. He stated that he wanted to give what he thought the process was.

Mr. Chang commented that he thinks the confusion comes from them talking about medication reconciliation being the primary service; however, in the documentation provided by PipelineRx, it talks about remote entry based on an order that is given. Mr. Azzolin commented that when a pharmacist does a review and approve a medication order, the physician has to sign off on it and then it goes to the pharmacist for verification. President Brinson agreed with Mr. Azzolin and stated they are supposed to have a physician sign off on it.

Mr. Azzolin commented that sometimes it may be good having a tech gather the information. He added that the literature supports the technician doing it because of his/her knowledge of drugs and he/she may have a better idea of what the patient is taking better than a nurse. Mr. Azzolin discussed order of operations. He commented that whether it is a nurse, technician, or a pharmacist doing the reconciliation, it will still flow up to the physician and back to the pharmacist. Ms. Emm stated that the correspondence does not speak to the physician's piece in this. She stated that it talks about the technician gathering all of the information and then it is the pharmacist who does the drug utilization review. Mr. Azzolin commented that if they do that, it still has to flow to the physician. He added that while it may not have been mentioned, he feels they did not anticipate the level of scrutiny this would receive and that is the reason why he wanted to give an overview of the process. He stated that once it is entered, it still goes up to the physician for approval and back to the pharmacist for verification.

Mr. Page agreed with Mr. Azzolin and stated that it seems like a three (3) step process. He stated the pharmacy technician gathers the information and then the pharmacist verifies it. He further stated that the correspondence states that if the pharmacist has a clinical concern, he/she contacts the prescribing or admitting physician as appropriate to address the concern. Mr. Page stated that he does not see any issue with the process.

Vice-President Stone commented that he agrees, but the only issue he has is when talking about pharmacies licensed in Georgia and the pharmacist or technicians are outside of Georgia, how does the Board police that or take action if something were to go wrong. Ms. Emm responded by stating that Pipeline Rx is registered as a non-resident pharmacy. She added that Pipeline Rx obtained the license specifically for the purpose of remote order entry for a pharmacist for hospitals. Ms. Emm stated that Pipeline Rx is aware that the pharmacist doing the remote order entry does have to be a Georgia licensed pharmacist per Georgia law. Ms. Emm explained that since they are registered as a non-resident pharmacy, their pharmacy technicians would have to follow the rules of his/her home state.

Mr. Prather stated that what he heard Ms. Emm say was that in an out of state situation, the pharmacist has to be licensed in Georgia, but the technician did not have to be registered. He asked Ms. Emm if that was correct. Ms. Emm stated that was correct for remote order entry for hospitals.

Mr. Prather inquired as to whether the Board should require the technicians doing this type of work be registered in Georgia. Mr. Azzolin responded by stating that Mr. Prather did have a point. He stated that when the Board discusses technicians doing any sort of remote work from home such as data entry, he believes if the technician is just transcribing and not making any clinical decisions, he/she should be able to do so. He added that through the pandemic when the Board allowed that in a retail setting, the technician had to be licensed. He continued by stating that there is nothing in the law requiring a technician working out of state to be licensed for hospital remote order entry. Mr. Azzolin stated that if the Board requires it for retail, then it should be required as well for hospital remote order entry. Vice-President Stone commented by stating that he believes if you are going to be working on Georgia patients, he thinks that individual should be registered or licensed in Georgia to do so. Ms. Emm stated that in a non-resident pharmacy situation, they are required to abide by Rule 480-6-.02. She added that the rule requires the permit holder to follow the shipping and compounding regulations of Georgia and also requires the permit holder to comply with the laws, rules, and regulations of the state where the pharmacy is located. Ms. Emm stated that Georgia's pharmacy technician ratio requirement does not apply to the non-resident pharmacy permit holder as they have to abide by their home state requirement.

Mr. Azzolin stated that the reason why PipelineRx has a non-resident pharmacy permit is because it is the only thing available to companies that provide remote based services. He added that the law requires a remote service provider in a hospital to be licensed in Georgia as a pharmacy. Mr. Azzolin stated that they are not shipping drugs into the state, which was the intent of the non-resident pharmacy permit. He continued by stating that they are doing clinical drug order processing.

Mr. Cordle commented that one counterpoint is ultimately the work being done by the technician has to go through a Georgia licensed pharmacist. Mr. Changus stated that the struggle with this conversation is we are beyond what the idea was in setting up technicians and registrations. He further stated that the Board is being asked to comment on what specialized services a technician may offer and there is not anything in the law or rules that would specifically address that. Mr. Changus stated that when the non-resident pharmacy aspect is added, it makes it more difficult. He explained that technicians cannot render judgement and to the extent these are tasks that do not involve judgement, it may not be much of a concern for the Board to address.

Mr. Chang inquired as to whether or not the Board had the ability to hold the non-resident permit holder accountable for any misfill or other issues that may occur. Ms. Emm responded by stating that the Board does have the ability to investigate and discipline non-resident pharmacy permit holders. She stated the non-resident pharmacy permit holder would be held responsible for any errors that occur within their facility.

There being no further discussion, Mr. Azzolin made a motion to direct staff to respond to Ms. Stevens by stating that the Board has no issue with pharmacy technicians performing the functions outlined in the document provided. Additionally, to please be aware the hospital pharmacy must abide with all rules and regulations. Vice-President Stone seconded, and the Board voted unanimously in favor of the motion.

Correspondence from Laura Churns, Publix Super Markets, Inc.

The Board considered this correspondence requesting consideration of rule changes allowing remote order entry. Mr. Azzolin added that Ms. Churns' correspondence requests changes to Chapter 480-36. Specifically, Publix requests the Board consider:

- *Allowing all "appropriately licensed pharmacy staff members" to engage in remote order processing, with the term "appropriately licensed pharmacy staff members" to include*

both Georgia licensed professionals and those licensed in the staff member's state of residence, provided such out of state staff would be assigned to a Georgia licensed retail pharmacy for supervision and ratio purposes.

- *Revising the definition of Secondary Remote Order Entry Pharmacy under Ga. Comp. R. & Regs. 480-36-.01 to remove the limitation that "[only] one secondary pharmacy [may] assist the primary dispensing pharmacy with [Remote Order Entry] per prescription."*

- *Allowing Pharmacist supervision of relevant staff to be accomplished by technological means, as permitted in Florida since 2014 under Fla. Admin. Code. R. 64B16-27.4001 since 2014.*

Mr. Azzolin stated that remote drug order processing is what we do in a covid environment. The writer of the correspondence knew the Board would be discussing it at the meeting. He added that Ms. Churns is requesting the rule be made permanent.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA conducted 648 inspections and received 123 complaints for FY2022.

Attorney General's Report – Max Changus

Wellness Pharmacy, Inc. Memorandum of Opinion: Mr. Changus reported that an opinion from the United District of Columbia regarding the FDA Memorandum of Understanding (MOU) was received. He stated that the Board has discussed the difficulties of signing the MOU. Mr. Changus stated the Board was recently informed that the FDA was extending additional time for Boards to consider the MOU. In regard to the opinion, Mr. Changus explained that the judge stated the FDA did not follow the requirements for rolling out the MOU and directed the FDA to follow those requirements before proceeding. Mr. Changus stated that he assumes the FDA will address some of the concerns and that will buy the Boards more time for consideration; however, thinks some of the same issues will still be present. Mr. Changus further stated that this had been brought to his attention by Mr. Steven Snow. Mr. Changus stated this does not require any action by the Board at the moment.

Executive Director's Report – Eric Lacefield

Continuing Education Report: Report presented. Vice-President Stone made a motion to ratify the below continuing education programs approved since the previous meeting. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
10/05/2021	1	Kaiser Permanente	Breaking the Scale: Weight Management Treatment Options	2021-0014

Legal Services – Kimberly Emm

No report.

Discussion/Rules Topics

Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security: Mr. Azzolin made a motion to post 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.

Rule 480-13-.06 Drug Distribution Control: Vice-President Stone made a motion to post Rule 480-13-.06 Drug Distribution Control. Mr. Azzolin 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: Vice-President Stone made a motion to post Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Prescription Drug Orders. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Rule 480-31-.01 Patient Counseling: Vice President Stone made a motion to post Rule 480-31-.01 Patient Counseling. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Low THC Oil Dispensing Rules: Mr. Prather stated the law states, *"The State Board of Pharmacy shall develop an annual, nontransferable specialty dispensing license for a pharmacy to dispense low THC oil to registered patients. The State Board of Pharmacy shall develop rules and regulations regarding dispensing pharmacies in this state."* Mr. Prather further stated that he and Mr. Reybold previously submitted a draft of the rule and to his knowledge, it was left with Ms. Emm and Mr. Changus to review.

Ms. Emm stated that O.C.G.A. § 16-12-206(b) states, *"The State Board of Pharmacy and the commission shall separately adopt rules relating to the dispensing of low THC oil and products, with the State Board of Pharmacy promulgating rules and regulations for pharmacies that dispense low THC oil and products and the commission promulgating rules and regulations for other retail outlets that dispense low THC oil and products. Such rules shall include but not be limited to:*

> *(1) Standards, procedures, and protocols for the effective use of low THC oil and products as authorized by state law and related rules and regulations;*
> *(2) Standards, procedures, and protocols for the dispensing of low THC oil and products by a pharmacy with a dispensing license and by retail dispensing licensees and for the utilization of a tracking system;*
> *(3) Procedures and protocols to provide that no low THC oil or products may be sold to or transferred to a location outside of this state;*
> *(4) The establishment of standards, procedures, and protocols for determining the amount of usable low THC oil and products that is necessary to constitute an adequate supply for registered patients in this state to ensure uninterrupted availability for a period of one month, including amounts for topical treatments;*
> *(5) The establishment of standards, procedures, and protocols to ensure that all low THC oil and products dispensed are consistently pharmaceutical grade;*
> *(6) The establishment of standards and procedures for the revocation, suspension, and nonrenewal of dispensing licenses;*
> *(7) The establishment of other licensing, renewal, and operational standards which are deemed necessary by the State Board of Pharmacy and the commission;*
> *(8) The establishment of standards and procedures for testing low THC oil and products for levels of tetrahydrocannabinol or other testing parameters deemed appropriate by the State Board of Pharmacy and the commission;*
> *(9) The establishment of health, safety, and security requirements for pharmacies and retail dispensing licensees dispensing low THC oil and products; and*
> *(10) Requirements for the issuance of dispensing licenses to pharmacies and Class 1 and Class 2 production licensees.*

Mr. Prather commented that the law previously stated the Board and the Commission "shall jointly adopt" rules. Ms. Emm responded that the language was changed this past session to read, *"The*

State Board of Pharmacy and the commission shall separately adopt rules relating to the dispensing of low THC oil and products, with the State Board of Pharmacy promulgating rules and regulations for pharmacies that dispense low THC oil and products and the commission promulgating rules and regulations for other retail outlets that dispense low THC oil and products."

Mr. Prather responded by stating that he was looking at the original bill. He added that he could confirm the Medical Cannabis Commission had not developed any rules thus far. Ms. Emm responded by stating that is why she and Mr. Changus were concerned and stuck in regard to this matter. Ms. Emm added that when this issue was previously discussed, she inquired as to how a pharmacist who never had any training in low THC oil, because it is not an FDA approved product, would determine what is an adequate amount for a 30-day supply. She inquired as to how the Board would determine if the products the pharmacies receive are pharmaceutical grade. She asked do the products come with a certificate from the producer and would they come with a tracking system from seed to sale. Ms. Emm explained that Alabama recently passed its rules and regulations in regard to its program and there is no product coming in or going out of Alabama. Mr. Prather responded by stating that Georgia is the same as Alabama in that nothing can be brought in or shipped out. Mr. Azzolin asked if pharmacists would be held accountable to the Commission's rules or the Board of Pharmacy's rules. Ms. Emm responded by stating that the pharmacies will follow pharmacy rules and the retail outlets will have to follow the Commission's regulations.

Mr. Azzolin stated that the Board previously held discussion regarding "independent pharmacy" and inquired as to whether or not that meant an independent pharmacy, such as an individual Kroger or CVS, or a single entity. Mr. Prather stated that he understood what Mr. Azzolin was stating; however, that would be up to the legislature to define "independent".

Ms. Emm commented that it was another topic that came up during the last legislative session. O.C.G.A. § 16-12-206(a)(1) was changed to read, *"Upon request by a licensed pharmacy in this state, the State Board of Pharmacy shall be authorized to develop an annual, nontransferable specialty dispensing license for an independent pharmacy with a registered office located within this state to dispense low THC oil and products to registered patients."* She stated that the word "independent" was added; however, it was not defined which has created the confusion.

Mr. Changus commented that there are two (2) questions here. The first being, what is legal under federal law, and stated that there is a lack of clarity on that subject. He added that it seemed like most of the states have moved forward with rolling out its statutes and rules. Mr. Changus stated that the second question is concerning "independent pharmacy" and does "independent" means what the Board thinks it means in pharmacy, and is there an equal protections issue. He added that there may be a potential question from a chain pharmacy as to why they cannot do it. Mr. Changus stated that he thought it would be reasonable to ask the General Assembly to consider this question. After further discussion, the Board recommended tabling this matter until clarification could be sought from the General Assembly.

Change in Ownership: President Brinson stated this has been an issue for many pharmacies through the years. He stated that if the pharmacy moved, you would need to get a new license number. Mr. Prather inquired with Director Troughton as to whether or not there was a reason past members of the board wanted it done this way. Director Troughton responded by stating that he recalled the Attorney General's interpretation was the license was "non-transferrable" which included a change in name, change in location, or change in ownership. He added that it seemed lately in discussions with Ms. Emm and Mr. Changus, the Board viewed a change of ownership as transferring. Director Troughton stated that recently it seemed the Board agreed that if the facility had a change in name or change in location, the facility would need to submit a rule waiver request because the Board had been granting those. Director Troughton stated that this particular discussion

was concerning a change in ownership, which would require a new license number, and should be further discussed with Mr. Changus or Ms. Emm.

Mr. Changus 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."* He stated that this comes down to ownership. He added that the Board would want to make sure someone who owns a pharmacy does not have a violation that would disqualify him/her from being issued a license. Mr. Changus stated that the change in name and change in location seemed to be subordinate concerns that could be addressed by notification and inspection. Mr. Changus stated that GDNA conducts an inspection if an application for a change in location was received. Director Troughton affirmed that was correct and stated that before the facility could move, GDNA would conduct an inspection prior to them being able to set up any business.

Mr. Reybold commented that this has been an issue for years. He stated that the law reads, "shall not be transferrable or assignable". He further stated that pharmacy licenses are issued to the pharmacy, not the shareholders. Mr. Reybold added that this does have impact on patient care. He stated that , at a minimum, the regulations seem to go further than the statutory language. He continued by stating that if the Board went further than the law and if the Board interpreted that aggressively, to include shareholders, he thinks it would be worthy to have some sort of threshold such as the Board being notified when there is a certain percentage of ownership change.

Mr. Page commented that, from what he understood, if there was an ownership change, it does not prevent the patient from receiving care or prescriptions he/she needs. He stated that delays could occur with other aspects such as the Medicare/Medicaid claims. Vice-President Stone disagreed and stated there could be potential problems such as billing, for example. He added that it has taken 3-6 months to get contracted with some of the stores he has opened. Vice-President Stone stated that as a brand new startup store, he had to personally deliver the medication to the patient because it took him six (6) months to get contracts dealt with.

Mr. Azzolin asked if the license becomes null and void immediately upon sale if a change in ownership occurred. If so, he asked if it could become null and void on the date of the sale. Ms. Emm responded by stating that is taken into consideration as there is a section on the application that asks for the date the change of ownership becomes effective. She further stated that staff advise pharmacies that have a change to apply in advance of such change based on application processing times. Mr. Azzolin responded that the board office may have a pathway; however, in terms of practicality, supplies will not be shipped until they know the pharmacy is licensed. He added that the pharmacy cannot get a DEA license until it has a pharmacy license. He stated that it is critical for the pharmacy to continue to operate, as Vice-President Stone stated, because it is detrimental to patient care.

Mr. Azzolin inquired if the language in the statute needed to be changed. Mr. Changus responded by stating these are commonly understood terms and thinks the rule as promulgated was designed to clarify the law. He further stated that the Board was acknowledging in its discussion that it does not need to be read as broad as previously. Mr. Changus stated that the issue with the license number and the difficulties imposed on pharmacies at the time of sale were probably not envisioned by the General Assembly when the law was passed. He stated that it may be helpful for staff, GDNA, and Attorney General's office to look at this more closely in terms of what the practical effects are. Mr. Changus stated that trying to decouple the license from the ownership is something that everyone needs to be comfortable with.

President Brinson asked if there was any further discussion. Mr. Page responded by stating that they do change license numbers. He added that it was an issue for the patients in terms of the payment option. He stated that it is a hit to the company when reimbursement cannot be applied for in a certain amount of time. Mr. Page stated that he does not see it as much as Vice-President Stone, but can see from Vice-President Stone's comments that it would be a burden for the patients.

Mr. Cordle stated that it has not been an issue for him with previous store openings; however, it may limited some contracts. He further stated that he understood the issue and would support making the necessary adjustments so all of the hoops would not have to be jumped through.

Mr. Chang commented that he does see where there are delays; however, the transition of care is pretty quick and there is no delay from that aspect. President Brinson stated that the Board should make some changes as a new license should not be required to move down the street. Ms. Emm responded that the Board previously agreed what it wanted to do in terms of a change in location. She added that this was held up because of the change of ownership piece and whether or not the Board had the right to define what a change in ownership was. Mr. Azzolin commented that the law itself states that the pharmacy license shall not be transferrable or assignable; it does not say anything about pharmacy license numbers. Discussion ensued. Ms. Emm stated that when staff receive inquiries regarding a change in ownership, the response has been "any addition of a new person to the ownership is considered a change of ownership" because a portion of that pharmacy has been transferred to another person. She continued by stating that if a person was being removed, staff have not considered that as being a change. Ms. Emm explained that the Board does have the ability to reject an application based on ownership.

Mr. Reybold stated that this has been an issue he has dealt with for several years and believes it can be changed by going to the General Assembly. He further stated that the Board has broadly interpreted the statute. He explained that he has seen several boards of pharmacy draw distinction via regulation between license transfers and the company being sold and transferred. Mr. Reybold stated that when he was in private practice, he had independent pharmacy clients and the Board's interpretation was a barrier to the pharmacies getting the capital they needed because of going through the whole process. He stated that he felt this would fall within the Board's authority.

Mr. Scott Bass was on the call and spoke to the Board. He stated that his understanding of the statute says that the license shall not be transferrable. He further stated that the public policy behind that is the Board not wanting one pharmacy to sell to a second party behind closed doors and the Board not be aware of such. He added that the way he interprets the statute is when it says "not transferrable", it means not transferrable by the Board of Pharmacy. Mr. Bass stated that there should be no reason for the Board to not be able to expire a license and reuse a license number to be given to a new entity or the same entity that had a 10% ownership change.

Mr. Azzolin responded by stating that he agrees and understands the concept; however, he does not see anywhere in the rule or law that specifies the number. Vice-President Stone discussed corporations selling stock. He stated that this happens all the time and pharmacies are not changing numbers. He stated that he is having trouble understanding that. Mr. Azzolin explained that the way the law is implied, if locations are doing that, it just has not been enforced and the Board has not been made aware that a change in ownership occurred. Mr. Azzolin continued by stating that he did not think the law required the license number to change. He stated that he believed that could be done procedurally with an application.

Mr. Changus commented that the license number can be viewed as being the representation of ownership and the parties matching up with that. He stated that there may be some administrative or enforcement concerns, and as such, thinks it would be helpful for the staff, GDNA and Attorney

General's office to review this matter more closely. He further stated that the rule has been in place before he came on the Board. Mr. Changus stated that making any changes and decoupling the license number from ownership interest seems like a change everyone should be comfortable with on all fronts to determine if that is the best route.

Vice-President Stone asked if the Board could do anything in regard to a change in name and location. Ms. Emm responded that the rule had been tabled. Vice-President Stone stated that if it is in the rule, the Board does not need to be doing double work and should continue to address through the rule waiver process. Mr. Azzolin suggested the Board continue to be liberal about the application of the waivers and make sure this topic stays on the agenda to address in the event members of the board or staff members change. There being no further discussion, the Board agreed to further discuss this matter at its December meeting to allow time for Ms. Emm and Mr. Changus to research.

Pharmacist Practical Examination: President Brinson stated that it was too late in the year for the Board to consider a practical examination in January or March. He further stated there is the potential of another surge and did not see how the Board could do an exam mid-year. He explained that with the exam not given in 2022, it would be two years of not administering the practical exam. President Brinson inquired if there were any issues with not giving the exam on any level for any pharmacist. Mr. Page responded that he was not aware of such. President Brinson stated that he thoroughly enjoyed doing the practical, not only to meet the staff, but also meet the students.

Mr. Azzolin commented that based on previous discussions regarding statistics, the Board had seen that it was not detrimental to not administer the practical exam. He stated that he does not see the need for the Board to continue such and recommended the Board discontinue administering the practical exam for 2022. Additionally, Mr. Azzolin requested the Board amend its rules to not require the practical for licensure in Georgia.

Ms. Emm stated that it is up to the Board whether or not to keep the practical examination. She stated that the Board's current emergency rules expire on October 29th. She explained that the Board did have grounds to readopt the emergency rules to continue to postpone the practical based on the current executive order because the state is still under a state of emergency based off of a public health emergency. Ms. Emm explained if another surge were to occur, there would be the need for pharmacists in the field to assist with such.

Vice-President Stone commented that he and Mr. Azzolin did research and worked with staff on obtaining statistics. He stated that, as Mr. Prather has always said, the Board is charged with protecting the health, safety, and welfare of the citizens of Georgia. He further stated that Mr. Azzolin previously commented that statistics showed the practical did not prohibit anyone from becoming licensed in Georgia. It was always the NAPLEX or MPJE. Vice-President Stone stated that the Board did not foresee a pandemic happening, but the pandemic has changed many things and it has been almost two years of not requiring a practical examination. He commented that he believes there are other ways for the Board to utilize its time. Lastly, he stated that he would be inclined to not require the practical exam and believes the Board should look at other ways to move forward.

Mr. Page and Mr. Chang agreed. Mr. Chang commented that Georgia would be the only state that would have a practical in place. Mr. Prather commented by stating he thinks a case can be made for the practical as being a basic entry level test and would like for the Board to continue it. Mr. Page commented that, in terms of public safety, he did not see it being a hurdle to not require the exam. He stated that, as times are changing, the Board may not need to require it in the future.

Mr. Cordle stated that he appreciates the progressive, objective nature of the Board and would also like to recognize how the pharmacy profession is changing. He further stated that he did not see a reason for the Board to continue with the exam. Mr. Cordle commented that the Board would retain the ability to take disciplinary action on a pharmacist if need be. Additionally, Mr. Cordle stated he was very comfortable supporting the permanent suspension of the practical examination.

Mr. Azzolin inquired as to whether or not the Board needed to modify its rules. Ms. Emm responded by stating there were several rules that would need to be amended. Mr. Lacefield commented that the Board's emergency rule expires at the end of the month and as such, the Board could adopt new emergency rules under the executive order that postpones the requirement of the practical and then vote to amend the rules that contain the requirement of the practical for licensure.

Mr. Cordle made a motion to adopt Emergency Rules 480-2-0.49-.05. Reciprocity and 480-2-0.48-.04 Examinations, and to direct Ms. Emm to amend Rules 480-2.-03 Experience Requirements, 480-2-.04 Examinations, 480-2-.05 Reciprocity, and 480-2-.06 Temporary Licenses, and bring back to the Board for review and approval. Mr. Azzolin seconded and the Board voted in favor of the motion, with the exception of Mr. Prather, who opposed. Those in favor of the motion were Mr. Azzolin, Vice-President Stone, Mr. Page, Mr. Chang, Ms. Ashbee, and Mr. Cordle.

Rule 480-2-0.49-.05. Reciprocity

(1) As a response to the current state of emergency as declared by the Governor, the Georgia State Board of Pharmacy finds the potential for imminent peril to the public health, safety, or welfare of Georgia citizens. This emergency rule shall go into effect based on O.C.G.A. 50-13-4(b) and shall be effective for the duration of the emergency and for a period of not more than 120 days thereafter. During the time this rule is effective, it shall replace Georgia State Board of Pharmacy Rule 480-2-.05.

(2) In order for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist from the Board, an applicant shall:

(a) Complete an applicant form supplied by the National Association of Boards of Pharmacy (NABP) to apply for licensure with the Georgia State Board of Pharmacy. This application should be filed with NABP, and then with the Board for further review by the Board and an investigation by the Georgia Drugs and Narcotics Agency (GDNA), if necessary. If so requested, an applicant must produce evidence satisfactory to the Board or the GDNA which shows the applicant has the age, moral character, background, education, and experience demanded of applicants for registration by examination under O.C.G.A. 26-4 and by this chapter.

(b) Have attained the age of majority;

(c) Be of good moral character;

(d) Have possessed at the time of initial licensure as a pharmacist, all qualifications necessary to have been eligible for licensure at that time in this state;

(e) Have presented to the Board proof of initial licensure by examination and proof that such license is in good standing;

(f) Have presented to the board proof that any other license granted to the applicant by any other state is not currently suspended, revoked, or otherwise restricted for any reason except nonrenewal or for the failure to obtain the required continuing education credits in any state where the applicant is currently licensed, but not engaged in the practice of pharmacy;

(g) Have successfully passed a jurisprudence examination approved by the Board on Georgia's pharmacy laws and Board regulations;

(h) If requested by the Board, have personally appeared for an interview with a member of the Board;

(i) Have paid the fees specified by the Board.

(3) No applicant shall be eligible for reciprocity unless the state in which the applicant is licensed as a pharmacist also grants license reciprocity to pharmacist duly licensed by examination in this state under like circumstances.

Rule 480-2-0.48-.04 Examinations.
(1) As a response to the current state of emergency as declared by the Governor, the Georgia State Board of Pharmacy finds the potential for imminent peril to the public health, safety, or welfare of Georgia citizens. This emergency rule shall go into effect based on O.C.G.A. 50-13-4(b) and shall be effective for the duration of the emergency and for a period of not more than 120 days thereafter. During the time this rule is effective, it shall replace Georgia State Board of Pharmacy Rule 480-2-.04.

(2) For licensure, an individual must successfully pass the NAPLEX and a jurisprudence examination approved by the Board.

(a) An individual is not eligible to take the examinations for licensure until such individual has graduated from an approved college or school of pharmacy and has completed all internship requirements.

(3) The NAPLEX examination is made available throughout the year and the jurisprudence is given at specified times.

(a) Candidates for a Georgia license are required to make a minimum score of 75 on both the NAPLEX examination and the jurisprudence examination.

(4) The Board will provide reasonable accommodation to a qualified applicant with a disability in accordance with the Americans with Disabilities Act (ADA). The request for an accommodation by an individual with a disability must be made in writing and received in the Board's office by the application deadline along with appropriate documentation, as indicated in the Request for Disability Accommodation Guidelines.

Pharmacy Technician Continuing Education: President Brinson stated that the Board has discussed this matter previously. Mr. Azzolin made a motion to require all pharmacy technicians to obtain ten (10) hours of continuing education credits prior to the next renewal on 6/30/2023. Thereafter, as a requirement for the biennial renewal of his/her license, a pharmacy technician must complete no less than twenty (20) hours of approved continuing education, either A.C.P.E., P.T.C.B. or other education as approved by the Georgia Board of Pharmacy, prior to each renewal. Mr. Cordle seconded and the Board voted unanimously in favor of the motion. The Board directed Ms. Emm to make the necessary changes to Rule 480-15-.02 and bring back to the Board in November for consideration.

Mr. Lacefield discussed correspondence from Yogesh Gala requesting the Board recognize CTSP (Certified Technician in Specialty Pharmacy) as an approved provider. Ms. Emm stated that O.C.G.A. § 26-4-82(d) states that in order to be certified, pharmacy technicians must:

(1) *Have successfully passed a certification program approved by the board of pharmacy;*
(2) *Have successfully passed an employer's training and assessment program which has been approved by the board of pharmacy; or*
(3) *Have been certified by either the Pharmacy Technician Certification Board or any other nationally recognized certifying body approved by the board of pharmacy.*

After further discussion, the Board directed staff to request additional information from Mr. Gala concerning his request.

At this point in the meeting, the Board recessed for lunch 12:15 p.m.

The meeting resumed at 12:45 p.m.

Newsletter: Vice-President Stone stated that in the past, he knows there was concern about cost and the time involved to produce a newsletter. He suggested putting out a newsletter quarterly and stated that he would be willing to spearhead it. He stated the newsletter would be to inform pharmacists or make sure them aware of certain things. President Brinson agreed and stated something could be emailed strictly to Georgia pharmacists. Vice-President Stone stated that he was aware that the board office may not have a valid email address for each pharmacist on file and suggested the updates be posted to the Board's website. Mr. Azzolin stated that Twitter or Facebook would be good platforms to post information as there are many agencies that communicate through those platforms. Ms. Emm responded by stating that the Board does not have any social media pages. Mr. Lacefield commented by stating that staff cannot manage a social media website; however, if Vice-President Stone wanted to spearhead the newsletter and the Board wanted to post it to the Board's website or have one of the associations share the information, he sees no issue with that. Vice-President Stone stated that he would gather the information and would consult with Mr. Lacefield and Director Troughton. He added that he would share the information with the Board prior having it posted on the Board's website. Vice-President Stone also stated that he would speak with the associations and pharmacy schools to see if they would be willing to include the newsletter on their website.

Melissa Reybold, Georgia Pharmacy Association (GPhA), was on the call and spoke to the Board. She stated that GPhA would be happy to share the newsletter with its members. There being no further discussion, Mr. Lacefield stated that once Vice-President Stone puts the newsletter together, it would be provided to the Board for review. Mr. Page and Mr. Cordle volunteered to assist Vice-President Stone.

Responsibility to verify reverse distributors and wholesalers hold an active permit: Vice-President Stone stated that he feels the newsletter would be a good tool to use to inform licensees of this matter.

Point of Care Testing: Vice-President Stone discussed O.C.G.A. § 26-4-5(31). He also provided information from the North Carolina Board of Pharmacy concerning CLIA-waived tests. He stated that most of his concerns were addressed when discussing with Mr. Lacefield; however, he suggested the Board discuss at a later date when appropriate.

Number of times an individual is permitted to take both the NAPLEX and MPJE exams and the process of exceptions by the Board: Mr. Page stated that this topic comes up at every meeting. He commented that O.C.G.A. § 26-4-41(b)(3) states that a person shall not take the examination more than three (3) times without written permission from the Board. Mr. Page stated that the Board had been denying an applicant's request for a fourth attempt. He explained that the Board has granted the applicant an appearance to explain his/her situation to the Board, and afterwards, the Board granted an additional attempt. He stated that he feels the Board should be consistent and does not feel it is fair to deny requests, but only grant the additional attempt if the individual appeared before the Board. Mr. Page suggested the Board allow the same number of attempts for both the NAPLEX and MPJE. President Brinson agreed and stated that NABP allows five (5) attempts at the NAPLEX per jurisdiction. Mr. Prather commented that the law states three (3) times and it has been that way for a long time. He added that if the Board suggested allowing five (5) attempts, he hopes

the Board sticks with that. Mr. Page responded by stating that whatever the number the Board decided on, that should be the hard stop. President Brinson inquired as to what the rule stated regarding this matter. Ms. Emm stated that O.C.G.A. § 26-4-41(b)(3) states in part that a person shall not take the examination more than three (3) times without written permission from the Board. Discussion was held regarding changing the law. Ms. Emm explained that the individual must request permission from the Board for any further attempts. She continued by stating that the law also states that a person who has taken the board approved examination and failed the examination for the third time shall not practice as a pharmacy intern. The Board discussed contacting GPhA for assistance with changing the law.

Mr. Changus stated that the statute was designed to give the Board some discretion over this process. He further stated the Board could vote to allow an individual to take the examination up to five (5) times as the statute gives the Board discretion for such after three (3). Mr. Lacefield inquired about the portion of the law that states that a person who has taken the exam and failed three times shall not practice as a pharmacy intern. Mr. Azzolin responded by stating that the individual could not practice as an intern. He asked if that was a matter that would be brought to the Board's attention. Mr. Changus commented that the individual could not practice as a pharmacy intern immediately. He stated that he understands how the two (2) are connected, but when the issue of the individual asking permission to take the exam again comes up, he does not recall it being tied to a discussion of whether or not the individual could practice as an intern. He stated the requestor has just asked if he/she can have the Board's permission to retake the examination. Mr. Changus explained that if the Board felt the aspect of whether or not someone could practice as an intern needed to be changed, a legislative change would be needed. Mr. Page asked if the intern license was revoked or suspended, could the individual work as a technician. Ms. Emm responded by stating the individual could if he/she is registered. Mr. Page stated that being registered as a pharmacy technician could limit what he/she does intern wise, but still give the individual the needed experience.

Mr. Prather stated that he felt the best way to address this situation was to ask Ms. Emm to review what needed to be changed in the law and address it all at once. Mr. Azzolin responded by stating that the Board does not have a direct mode of correcting things through the legislature, and suggested the Board directly communicate the request to one of the associations. Ms. Reybold stated that she would discuss the Board's request with Mr. Greg Reybold. She added that GPhA will be meeting later in the week and she can further discuss it with the members of legislative policy. Mr. Prather made a motion to amend the rule to allow up to five (5) attempts at the NAPLEX and MPJE. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule 480-22-.04 Requirements of a Schedule II (C-II) Controlled Substance Prescription Drug Order: Ms. Emm discussed correspondence received from a licensed pharmacist regarding this rule. She stated that the inquiry was regarding subsection (8)(a)(3). She explained that subsection (8)(a)(3) expressly allows for adjustment in strength, but only implies a change in directions. Ms. Emm explained that when a pharmacist receives a prescription for a C-II controlled substance and if the quantity or strength has not been included by the prescriber, the pharmacist must speak directly with the practitioner to determine the quantity of the drug intended to be dispensed, or determine the strength of the drug intended to be dispensed, or inform the practitioner the drug in the strength prescribed is not immediately available, but another strength is available.

Director Troughton commented that this question comes up frequently and GDNA always points the individual to the law or rule. He stated that what is most important is the patient getting the correct dose. He stated that it is intended that the prescription is verified by the physician to make sure the patient gets the correct drug. After further discussion, the Board agreed to not make any changes to the rule.

Rule 480-10-.15 Requirements of a Prescription Drug Order, Rule 480-22-.12(1)(d) & (2)(d) Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia, Rule 480-27-.02 Prescription Drug Order Requirements: Ms. Emm stated that the rules pertaining to what is required of a prescription drug order are not in harmony. She explained the most common question the board office receives is in regard to the NPI number. Specifically, she stated that the NPI number is not required in the electronic section, but it is under the PA and APRN prescribing requirements for both hard copy and electronic requirements. Ms. Heather Tally requested a line be added stating "except for veterinarians" as they are not required to have an NPI number. After further discussion, the Board agreed to remove the requirement of an NPI number all together. Vice-President Stone made a motion direct Ms. Emm to remove the NPI number requirement from the effected rules and bring back to the Board for consideration. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Rule 480-11-0.47-.11 Veterinarian Emergency Dispensing of Non-Patient Specific Compounded Preparations for Office Use: Ms. Emm explained this was the Board's current emergency rule for veterinary emergency dispensing of non-patient specific medication received from a 503A. Mr. Azzolin commented this topic was mentioned due to previous discussion by the Board pertaining to emergency dispensing in section (2). Mr. Page asked if there was any comment from a veterinarian on the call. Ms. Tally stated that she has a veterinary clinic in Northwest Georgia. She commented that having something on hand is much better for the client in order to treat the animal in a timely manner. She stated that if the Board kept it at 14 days, that would be sufficient. She stated that if the Board were to shorten the timeframe, many veterinarians would go out of state, which is not what they want to happen for local pharmacies. She further stated that she would like to get the medication from a local pharmacy in Georgia. President Brinson responded that a veterinarian could compounding whatever they needed to. Ms. Tally agreed. Mr. Azzolin made a motion to keep the language in section (2) at 14 days. Discussion was held by the Board regarding the language of the rule. Ms. Emm stated that Rule 480-11-.02(1)(d) states:
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 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.*

Mr. Azzolin stated that the latter piece is what he was referring to the whole time because of geographical issues and the ability to get to a legitimate compounding pharmacy. Discussion was held concerning whether or not to amend the permanent rule. Mr. Prather commented that the last time this matter was brought up, the Board came to an agreement with the veterinarians that 14 days was sufficient. Ms. Emm responded that the 14 days was in the emergency rule and only permitted due to Covid-19. She continued by stating that when this was originally discussed, the agreement was a 96 hour supply. After further discussion, the Board agreed to table this topic for the time being.

Rule 480-36-0.42-.08 Remote Order Verification for Retail Pharmacy Permits and Rule 480-36-.02 Licensing and Rule 480-36-.03 Personnel and Supervision: Mr. Azzolin stated that during the pandemic the Board authorized remote prescription drug order processing for retail pharmacies.

He further stated that the Board previously had a discussion concerning the primary and secondary pharmacy. Mr. Azzolin explained that the primary is the dispensing pharmacy, whereas the secondary is the one licensed in Georgia that is processing the prescription in support of the primary pharmacy. He added that the primary pharmacy is responsible for the counseling, oversight and supervising of technicians. Mr. Azzolin stated that some of the issues discussed were concerning requirements that make it hard to function as a secondary remote entry pharmacy. He stated 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."* He further stated he was informed the reason that is there is because the law or rule only requires the pharmacy to be licensed in Georgia. Mr. Azzolin stated that a pharmacist of a non-resident pharmacy is not required to be licensed in Georgia. He suggested the Board change that to require the pharmacist be licensed. He explained that there are times where you need to be at home and you need to process something at a pharmacy. Mr. Azzolin stated that by mandating the pharmacist be licensed you solve that problem.

Mr. Azzolin stated that Rule 480-36-.02(1) reads, *"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."* He explained that he feels the rule should be modified to allow the pharmacist to be anywhere he/she needs to be as long as that person is Georgia licensed.

Mr. Azzolin discussed Rule 480-36-.07(2), which states, *"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."* He explained that the problem with that is a workflow issue. Mr. Page stated that he agreed that the secondary pharmacist must be licensed in Georgia. Mr. Chang inquired if Mr. Azzolin was stating they would have to apply for a non-resident permit. Mr. Azzolin stated the pharmacist would need to reciprocate his/her license.

Mr. Prather commented that when these rules were written, he did not recall workflow ever being an issue. He stated that the consideration of the patient was what was important. He added that he thinks the Board needs to think long and hard before making any changes. Mr. Prather stated that the patient needs to be notified and asked if it is okay if his/her prescription are sent someplace else, and that place would be in a pharmacy in Georgia. Mr. Azzolin responded that he appreciated Mr. Prather's comments and agrees about patient safety. He stated that in doing stress tests, they check to see how much work the pharmacist is able to handle. Additionally, Mr. Azzolin stated that in reviewing the peer review literature pertaining to remote processing drug orders, what supports patient safety the most is a lack of distraction. Mr. Azzolin stated that if patient safety is the primary concern, then allowing a pharmacist to work in a more conducive environment should be important.

Mr. Cordle commented by stating that this is another situation where technology is advancing and is changing every day. He added that he believes it is important to have all pharmacy related practice in line with everything we are doing.

Mr. Chang stated that patient safety is the top priority. He inquired as to how the Board should better support this profession that is changing rapidly.

Mr. Page stated that during the first part of the pandemic, high risk pharmacists were not allowed to work in the pharmacy. He added that allowing them to work remotely worked very well, and they were accurate and thorough with what they did. Mr. Page continued by stating that most of their central fill locations are 99% accurate.

Mr. Page made a motion to accept Mr. Azzolin's recommended changes. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion. Mr. Azzolin stated he would provide Ms. Emm with the suggested amendments.

Rule 480-15-.02 Registration of Pharmacy Technicians: Mr. Azzolin discussed Rule 480-15-.02 and stated that the rule states that a pharmacy may only employ registered pharmacy technicians to perform pharmacy technician duties. He added that section (b)(1) requires the applicant to *"Submit an application to the Board on the form prescribed by the Board"*. He continued by stating that nowhere in the rule does it state the application has to be approved. Mr. Azzolin stated that 480-15-.02(c) states in part, *"The Board may deny registration or conditionally grant registration for any of the reasons…"* Mr. Azzolin stated that a number of pharmacies have contacted him stating that they can hire an individual, but he/she cannot work as a technician until the application has been approved. He stated that it is his understanding that technicians are required to be registered to further prevent drug diversion. He suggested allowing them to begin working and the Board retain the right to deny the registration if the background check were to come back with something that would prevent him/her from working as a technician, or add language to the application attesting to certain items that would not prevent them from beginning work.

Discussion was held by the Board. Mr. Page stated that it could take 4-5 weeks before a background check is received. He stated that some companies cannot pay the employee for that long and the employee will go somewhere else. Mr. Page explained that this is affecting many companies and the question is how we can get that person in the pharmacy quicker. Mr. Page mentioned hiring the person as a cashier until his/her application for registration is approved. Ms. Emm commented that there could be a situation where the technician went to work while waiting on the background check and the individual did not disclose an arrest on the application because he/she were told the record was expunged. She stated that the individual was allowed to handle drugs and explained that this type of situation would not look good in the eyes of the public. Mr. Page responded by stating that was his point of hiring the individual to be a cashier. Ms. Emm stated that when hiring the person as a cashier, the person has to be clearly identified as a cashier, but would not count against the technician ratio.

President Brinson inquired as to how GDNA would police this. Mr. Azzolin stated that when technicians first started registering in 2011, the applicant kept a copy of the application, along with a receipt. He stated that the pharmacist should have that information readily available for GDNA. Mr. Lacefield commented that if the applicant mailed in an application, he/she would not receive a receipt for such. Additionally, Mr. Lacefield stated that until the application is entered in the system, that application would not exist. He continued by stating if the applicant applied online, he/she would receive a receipt. Director Troughton commented that GDNA would ask if individual had a receipt. He added that sometimes the applicant cannot provide a receipt of what they sent in for GDNA to verify. Director Troughton stated that at that point, GDNA would begin its investigation. Mr. Chang asked if an application goes into "Pending" status once it has been submitted and is that information on the website. Director Troughton responded by stating that until the Board or staff have approved that technician, there is nowhere for GDNA to verify information on that individual. Mr. Lacefield agreed. He added that applications are confidential by law. He stated that the application remains pending until approved, and once approved, a registration number is issued. He stated the registration number would be listed on the Board's website.

Application processing times were discussed. Mr. Prather inquired as to how long it takes an individual to get registered once the application is received. Mr. Lacefield responded by stating that it depends. He stated that when he was fully staffed, pre-pandemic, the average time was in the 2-3 week range. Mr. Lacefield explained that the process is driven by the applicant. He further explained that the applicant has to get fingerprints completed, along with additional information

he/she knows the Board requires with the application. Mr. Lacefield stated that if the board office has received all of the required information and the applicant has a clean background check, staff can issue the registration. He stated that the timeframe was previously two (2) weeks. Mr. Lacefield stated that just like pharmacies and other businesses, he is short staffed, so the process is longer now. Additionally, he stated that if the applicant has not provided all of the required information, the process is longer. He further stated that staff will reach out to the applicant to let him/her know what information is missing.

Mr. Prather stated that when the Board first required pharmacy technicians to become registered due to diversion, it also saw where organized crime was involved and technicians were being sent into stores to steal medications until he/she get caught because it was easier for the technician to get fired rather than go through the judicial system. Mr. Prather inquired as to how many narcotics could be stolen if someone who is not a registered technician were allowed in the pharmacy. He added that he does not see how it could be justified to put someone in the pharmacy who is not registered or has been vetted. Mr. Azzolin responded by stating that he understood Mr. Prather's point. He added that he does not intend to operate out of fear. He stated that pharmacists are overworked and that could cause errors. He further stated that he was open to suggestions. Mr. Azzolin suggested the Board mandate registration be done electronically. He inquired as to how long would it take an application to come before the Board if the applicant registered electronically. Mr. Lacefield explained that not all pharmacy technician applications come to the Board. He stated that the only applications that come before the Board are ones that have issues such as arrests, discipline, etc. Ms. Emm stated that the report of licenses issued reflects the applicants that were issued a license that did not come before the Board. Mr. Azzolin stated that this was good information to know. He further stated that from what he is hearing in the field, it is a problem. Mr. Azzolin stated that he understood Mr. Prather's point; however, he is asking for consideration for there to not to be a delay in processing. Mr. Page commented that there are still technicians that may have a clean background check that still divert. He suggested tabling this matter as there are also issues with staffing as Mr. Lacefield discussed. There being no further discussion, the Board suggested tabling this matter until its December meeting.

Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel: Consider language that allows multiple interns / externs if the number of techs is less than the max allowed only up to the total number of techs: President Brinson commented that he has spoken with GPhA about changing the law concerning the number of externs and interns.

Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed: Mr. Azzolin commented that if the responsibility is the same director, dictating the number of pharmacies they are in charge of is not necessary to him. He stated this is more of an issue in the retail setting and not a hospital setting. Mr. Azzolin stated that this subject was discussed by the Board at a previous meeting. Discussion was held regarding amending section (3) concerning language that states "not more than one pharmacy at one time". Mr. Cordle stated that he would want some sort of limit. Mr. Page agreed with Mr. Cordle. Vice-President Stone stated that he was more comfortable with the individual submitting a rule waiver petition and the Board considering it on a case by case basis. President Brinson agreed with Vice-President Stone.

Mr. Cordle discussed Rule 480-10-.02(4). Mr. Prather commented that this portion of the rule was aimed at pharmacies inside of stores, such as Walmart, that needed to be secured from the general public. Mr. Cordle stated that this portion of the rule states that a sign shall be displayed in the absence of the pharmacist from a pharmacy. He further stated that he understood why the pharmacy must be locked up and closed, but was not sure about the requirement of a sign. He suggested amending the rule to strike 480-10-.02(4)(a)(3) and (4)(b)(3). Vice-President Stone asked Director Troughton if GDNA had any issues regarding this matter. Director Troughton responded by stating

that he did not recall any cases saying there was not a "Closed" sign. Mr. Cordle stated that if this is required in the rule, it needed to be enforced. Director Troughton stated that GDNA enforces all of the Board's law and rules; however, he stated there were some violations that GDNA considered more imminent than others. He further stated that this would be a scenario where the agent would communicate with the pharmacist regarding the matter. Mr. Cordle responded by stating he understood. The Board agreed to take this matter under advisement.

Rule 480-2-.03 Experience Requirements: Mr. Cordle stated that this topic has come up a number of times. He stated that Rule 480-2-.03(1)(b) mirrors O.C.G.A. § 26-4-46(b), which reads as follows:
(b) *The following individuals shall be eligible to be licensed as a pharmacy intern:*
(1) *A student who is currently enrolled in an approved school or college of pharmacy;*
(2) *An individual who is a graduate of an approved school or college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or*
(3) *An individual who does not meet the requirements of paragraphs (1) and (2) of this subsection and is a graduate of a pharmacy school or college located in another country but who has completed all requirements of the Foreign Pharmacy Equivalency Certification Program administered by the National Association of Boards of Pharmacy. This shall include without being limited to successful completion of all required examinations, the issuance of the equivalency certificate, and an individual evaluation by the board of the applicant's proficiency in the English language.*

Mr. Cordle stated that he wanted to gain an understanding of the process of denying that license post-graduation, but prior to being licensed as a pharmacist. He stated that he did not see a need for the rule to change, but just wanted to bring this matter up for discussion. Vice-President Stone responded that, in his opinion, the PharmD programs changed the way hours were completed. He stated that it used to be 1500 hours with some of those hours being obtained in school and the remainder would be obtained by working somewhere else. Vice-President Stone stated that it seems the students that are coming out now have not really worked in any kind of setting. Mr. Cordle stated that he was mainly speaking about a student that attended pharmacy school out of state, may have been an intern in another state while in pharmacy school, and moves back to Georgia, as an example. He stated the Board is not granting them an intern license because they have graduated. He further stated the interpretation is they have met the minimum experience to sit for a license, so they do not need an intern license at this point and the Board denies it. President Brinson agreed with Mr. Cordle, but stated it is required by law. Mr. Changus stated this would be a matter of interpretation. He stated that the design under the statute was not to allow an unlimited intern license. He explained that it seems that at times when it has been presented to the Board it has been to address employment issues where the individual was trying to bridge the gap between graduation and obtaining a license, which does not seem to fit under the statute. Mr. Changus stated that, as Mr. Cordle said, the Board previously discussed a case from someone coming from another state, and the question was is there an advantage for someone who has met their threshold hours to continue to gain practical experience heading toward pharmacist licensure without potential abuse of that system. He added that he does not know if this was an issue, but if there was an impetus or incentive for the individual to just stay on with an intern license because that was easier for them or easier for the employer. Lastly, he stated that he does not think that was the intent of the law. Mr. Cordle thanked Mr. Changus for summarizing his thoughts.

Federal Memorandum of Understanding: President Brinson stated that Mr. Changus reported on this matter earlier in the meeting. This matter will be tabled for the time being.

White bagging vs. brown bagging/anti-steering: Mr. Changus stated that the Board had discussed this matter several times. Mr. Changus directed the Board to correspondence received from Ms. Becca Hallum, GHA. He explained that the difficulty concerns how far does the Board's ability to dictate corporate practice go. He stated that if the Board could identify a legitimate a health concern, it may be able to pass a rule stating this sort of practice is inappropriate, but it would be met with resistance.

Vice-President Stone commented that he did not think the Board could promulgate a rule regarding this matter, but felt the Board should do something. Mr. Azzolin commented that there are laws in place that he believed the Board should look into those. He stated that maybe a complaint needed to be filed before anything could happen. He further stated that there was evidence that had been submitted by pharmacists to GPhA showing the labels on the prescription were not complete. President Brinson responded that he had not seen anything pertaining to mislabeling. President Brinson stated if complaints had been made, they have not been submitted. Mr. Azzolin stated that the complaints were submitted to him and he will send them over to GDNA and the board office. Mr. Changus commented that if there was a violation of the labeling requirements, the Board could act. In regard to anti-steering, the Board may have the ability to act on that; however, he has found that once you get into the world of insurance, it gets complicated in terms of what can be regulated. Mr. Changus stated that creating a separate rule for the chain of custody of drugs may be outside of the law, and may be a patient safety aspect which the Board may want to develop further.

Mr. Reybold commented that, with regard to white bagging, he does not know if it fell squarely within O.C.G.A. § 26-4-119 or not, but to the extent it is mandating the prescription be filled at a certain location, it sounds like it is worthy of scrutiny. He stated that it is against public policy of the state. He noted that the United States Court of Appeal for the Eleventh Circuit has looked at this issue. Mr. Reybold stated that this law is regulating health care providers, not plans. He continued by stating that even if you are on the provider side, U.S. Supreme Court case on pre-emption, came out in favor of regulating pharmacy benefit managers. He further stated that this law regulates pharmacy and says you cannot bill for a prescription that has been illegally referred. In regard to central fill, for example, you have to enter into an agreement. Mr. Reybold continued by stating that, to the extent a company decides to vertically integrate, that does not change the regulation of pharmacy. Mr. Reybold urged the Board to not to be intimidated by giant companies. President Brinson agreed with Mr. Reybold and stated that many hospitals have already signed these agreements. Mr. Azzolin commented that the agreement is for them to accept a reduced rate, and if they do not sign it, they will be forced to accept it. President Brinson asked Mr. Reybold for his thoughts on what the Board could do. Mr. Reybold responded by stating that he thought it was worth looking at O.C.G.A. § 26-4-119, but to the extent it falls within the four (4) corners of steering, the Board does not need to be concerned with plans. He added that pharmacies do not get to pick and choose based on plans. He stated that they have to abide by all Board of Pharmacy regulations. With regards to white bagging, Mr. Reybold stated that if there are concerns, it would be worth looking at Central Fill and Central Processing. President Brinson thanked Mr. Reybold for his comments. The Board recommended tabling this matter until additional information has been received.

At this point in the meeting, the Board went back to the rules it voted to post earlier in the meeting, which were Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security, Rule 480-13-.06 Drug Distribution Control, Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Prescription Drug Orders, Rule 480-31-.01 Patient Counseling, Emergency Rules 480-2-0.49-.05. Reciprocity and 480-2-0.48-.04 Examinations.

A motion was made by Vice-President Stone, seconded by Mr. Azzolin, and the Board voted 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 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 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.

There being no further business to discuss, the meeting was adjourned at 3:47 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Thursday, October 14, 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