# **GEORGIA BOARD OF PHARMACY**

University of Georgia College of Pharmacy Pharmacy South Building 250 W Green St., Room 220 Athens, GA 30602 April 12, 2023 9:00 a.m.

The following Board members were present:

Michael Azzolin, President Chuck Page, Vice-President Jim Bracewell Michael Brinson Young Chang Cecil Cordle Michael Farmer Dean Stone **Staff present:** 

Eric Lacefield, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Nick Aderibigbe, Special Agent, GDNA
Max Changus, Senior Assistant Attorney General
Clint Joiner, Attorney
Brandi Howell, Business Support Analyst I

**Visitors:** 

Andrew Darley, UGA College of Pharmacy Brandon Brooks, Publix Diane Sanders, Kaiser Permanente Wilma Jones, Kaiser Permanente Melissa Reybold, GPhA Shea Ross-Smith, Kaiser Permanente

Ryann Miller, GHA

Mary Kate Snead, Guardian LTC

Susan Delmonico, Genoa
Jennifer Duckett, Walgreens
Kenneth Long, Amerita
Lauren Pollow, Amerita
Stephanie Kirkland, ElderCare
Melissa Robinson, Piedmont

Darren Chan, UGA Jordan Khail, UGA

### **Open Session**

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

Dean Kelly Smith welcomed the board members and visitors to the University of Georgia College of Pharmacy.

Representative Buddy Carter spoke to the Board. He stated that he appreciated the work the Board is doing. He further stated that it is an honor and privilege to represent the profession. He encouraged the members to assist him and to let him know what issues need addressing.

### **Approval of Minutes**

Mr. Stone made a motion to approve the Public Session minutes from the March 8, 2023, meeting as amended. Mr. Bracewell seconded, and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion to approve the Executive Session minutes from the March 8, 2023, meeting. Mr. Bracewell seconded, and the Board voted unanimously in favor of the motion.

#### **Report of Licenses Issued**

Mr. Stone made a motion to ratify the list of licenses issued. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

# **Correspondences**

Correspondence from Desmond M. Moronge, PHI-022800: The Board considered this request to receive hours earned by research be counted for intern hours. Mr. Stone inquired if there was any precedence for the Board to review anything outside of pharmacy. Mr. Lacefield responded by stating that requests have been made previously for those in research programs and in the past, if approved, the Board has granted one (1) hour of intern hours for every two (2) hours of research.

President Azzolin commented that this individual is studying for a PhD, but also has an intern license. President Azzolin inquired if the individual was in pharmacy school. Mr. Lacefield responded by stating that he could not speak to the specifics of this case, but generally when there is a foreign-trained pharmacist going through the intern process and has passed a Foreign Pharmacy Graduate Examination Committee (FPGEC) with NABP and is going through the experience requirements, as part of those experience requirements the Board's rule allows it to approve the pharmacy program.

President Azzolin commented that it would be helpful to know if the individual is going to attend pharmacy school upon completion of his PhD. He stated that if the individual has practiced as a pharmacist in another country even though it is another country's practice, that seems like a different scenario. President Azzolin continued by stating that it seems the individual would not have any experience as a pharmacist in that scenario as he would only have the experience of the PhD training. President Azzolin asked if it would it be inappropriate to ask if Mr. Moronge is a foreign license transfer. Mr. Lacefield responded by stating that the Board could not discuss if there was an application in Open Session as that is confidential information. He added that this is an intern trying to obtain experience hours and per the Board's rule, those hours can be granted. He stated that Rule 480-2-.03(a) states, "Any intern wishing to obtain internship credit for work in a research and /or industrial program must first submit a request for approval of the program to the Board along with an outline of the program from the individual who will supervise the intern in this program. If approved by the Board, the hours will be awarded in accordance with the standards set by the Board."

President Azzolin stated that logic would tell him that anything related to scientific studies would apply and courses such as scientific communications, investigations of problems, and scientific grant writing do not apply. He further stated that one thought would be to carve in the courses that seem to apply and carve out those that do not and then apply the formula 2:1 to what is left. After further discussion, Mr. Stone made a motion to have a board member review the courses and grant one (1) hour credit for every two (2) hours for the applicable courses. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

**Correspondence from Melissa Robinson, Piedmont:** President Azzolin summarized the request by stating that Piedmont want to perform DTM therapy modifications across multiple practices and they hope to have a protocol under a single medical director so they do not have to obtain a large number of signatures or protocols that have to be renewed annually for every pharmacist.

Mr. Stone commented that he understood the request, but thought it would be more related to the individual. He inquired as to why it has to be so specific in the rule because this will be broad having multiple physicians and pharmacists that the Board would not be able to track.

Ms. Robinson was present and answered questions from the Board regarding the request. President Azzolin asked Ms. Robinson if a protocol would be obtained from each pharmacist. Ms. Robinson responded by stating that each pharmacist would be under the same protocol. President Azzolin stated that all pharmacists and physicians would be listed on the protocol and the only one they would have to get a signature from is the Chief of Staff. He further stated that the rule is specific to a physician; however, the rule has the potential to be waived if one were requested. He continued by stating that the rule also references two (2) laws specific to provider prescription writing. He added that there are laws and rules pertaining to DTMs on the Medical Board side as well. President Azzolin inquired as to how those laws and rules would impact the facility's ability to do this if the Board were to allow such.

Mr. Changus commented that the law is designed to authorize pharmacists to engage in drug therapy modification. He stated that the protocol, which is mentioned in the rules, has been part of the focus for a long time and he does not think that is the Board's role here. He added that the pharmacist is authorized to engage in drug therapy modification and the protocol is subordinate to that concern. Mr. Changus stated that in terms of specifics and who signs it, he does not think that is much of an issue. He further stated that the question is the pharmacist authorized to do this or not. He continued by stating that given the expansion there are a number of physicians and pharmacists and the logical concerns of matching all of those up is an administrative concern, not a Board of Pharmacy concern. He explained that the Board's concern is whether or not this person is authorized to engage in this modification and then the supervising physician is certifying how this is supposed to be done.

President Azzolin stated that Rule 480-35-.01(5) defines supervision by a physician as "Supervision by a physician means the pharmacist has a means available to communicate with the physician for consultation, assistance, and direction in regards to drug therapy modification." He asked if the protocol piece that requires the physician who does the prescribing and is signing the protocol not necessary. Mr. Changus responded by stating that in looking at the statute first, the Board's obligation is to ensure the pharmacists engaging in this are authorized and able to do so and as far as how that is articulated in a protocol is less important.

President Azzolin stated that if the supervisory position is the Chief of Staff, who signs the protocol, and along with the submission of the protocol to the Board is a petition requesting a waiver of the need to have each physician sign the protocol, which the Board approves, and if the pharmacist needs to communicate with the physician, does it have to be the supervisory physician or can it be any physician. Mr. Changus responded by stating that the rule contemplates a one on one situation. He continued by stating that the Board is discussing a correspondence and how this could be accomplished may be through a rule waiver. He stated that there is no need to have an individual signature from each pharmacist and physician to establish a working relationship because they are all being grouped. A visitor with Piedmont commented that when orders are placed, it is under the individual physician not the Chief Medical Officer.

Mr. Stone inquired if a waiver request would be needed for each protocol. President Azzolin responded by stating that each application would need to have its own waiver request.

President Azzolin asked Ms. Robinson how many pharmacists would be involved. Ms. Robinson responded by stating that they are working towards getting pharmacists because without this in place they cannot have a pharmacist. She stated that they would have a standardized application for each pharmacist that would come into Piedmont.

Mr. Chang inquired if the Board was stating that a waiver would be required for each application. President Azzolin responded by stating that a waiver would be required for each application because the rule currently requires each physician doing the prescribing to sign the protocol. He added that Piedmont wants to do drug therapy management protocols across multiple clinics and as opposed to obtaining multiple signatures, the only way to accomplish that would be through a waiver.

Mr. Brinson asked Ms. Robinson what a "Physician Leader" was. Ms. Robinson responded by stating that the Physician Leader serves as the Medical Director. Mr. Brinson commented that when the Physician Leader leaves, this process would have to be done again.

Mr. Changus commented that how this is done is under the Medical Practice Act versus the Pharmacy Practice Act. He stated that the question for the Board is are these people able to participate in this. He further stated that the provisions in O.C.G.A. § 43-34-24 have to be met. He added that this provision speaks to being under direct medical care and every physician must be able to be reached. Mr. Changus explained that what is being proposed blurs everything. He stated that the protocol itself when submitted to the Board is less important than making sure the requirements of the law are being followed to carry out what is trying to be accomplished. Mr. Changus stated that the Board does not have the ability to say how they plan to proceed is permissible because the requirements of the statute must be met and the relationship between the pharmacist that is engaging in the modification and the physician is clear.

President Azzolin stated that it sounds like there is a limit to what the Board can do. He further stated that the Board may be able to provide the authorization for Piedmont if they submit the application with the appropriate rule waiver, but that may not be enough for them to be able to accomplish this. He added that Piedmont would need to refer to the laws and rules to make their own determination.

Mr. Changus commented that the rule contemplates signature by each party. He added that in terms of whether or not the Board could grant a waiver to allow for the signature to be done by a physician, could be something the Board could accommodate, but the requirements of the statute must still be met.

President Azzolin informed Ms. Robinson that Piedmont will need to make sure it is complying with the requirements of the Medical Practice Act even if the Board of Pharmacy were to allow it.

### Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

Director Troughton introduced Special Agent Nick Aderibigbe to the Board. Director Troughton stated that at least one (1) agent will be attending the meetings going forward.

Director Troughton reported that GDNA conducted 2039 inspections and received 377 complaints for FY2023.

### Attorney General's Report - Mr. Max Changus

No report.

#### **Executive Director's Report – Mr. Eric Lacefield**

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

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
03/15/2023 &	3	Northside	Tobacco Treatment Specialist Certification	2023-0003
03/29/2023		Hospital	Program	

**NABP Delegate for Annual Meeting:** Mr. Lacefield reported that NABP has requested the Board designate a delegate to vote on the Board's behalf at the NABP Annual Meeting. Mr. Brinson made a motion to appoint Mr. Chang as the voting delegate. Mr. Cordle seconded and the Board voted unanimously in favor of the motion.

### <u>Legal Services – Mr. Clint Joiner</u>

Correspondence from Richard Iriye, Amerita, Inc.: Mr. Ken Long was present and spoke to the Board concerning Amerita's correspondence regarding electronically transmitted prescription orders. He explained that Amerita has a local pharmacy in Norcross that provides specialty infusion medications. He added that they are a retail pharmacy, but have specialty sterile compounding as part of license. Mr. Long stated that under typical circumstances, an infusion pharmacy like Amerita would receive a chart ordered prescription for a patient upon that patient's discharge from a hospital or other inpatient setting. He further stated that the prescription would be written by an attending physician, loaded into the facilities Electronic Medical Records (EMR) system and then transmitted to the patient's pharmacy provider as a chart order or discharge order that is intended for home infusion of the legend drugs required to provide therapy to treat a diagnosis. Mr. Long stated that under strict application of the rule, an infusion pharmacy provider cannot legally fill a legend prescription drug submitted through a hospital EMR system, as the system is regarded as an "intervening person or intermediary". The pharmacist in this scenario is required to contact the prescribing physician to gain verbal confirmation of the prescription before the legend prescription can be legally filled. He stated this requirement creates needless additional steps that cause delays administratively and for the patient. He requested the Board consider the transmission of electronically signed chart orders that are faxed to a pharmacy or extracted from an EMR system via portal access as a valid prescription for the dispensing of legend drugs when the discharging physician includes detailed instructions around the dispensing and administration of the legend drugs for IV therapy.

President Azzolin inquired as to what license type the pharmacy holds. Mr. Long responded by stating that it is a retail pharmacy and sterile compounding is a component of what they do. President Azzolin stated that in a hospital they do not have prescriptions on inpatients. He inquired if outpatient infusions that occur in a hospital are written on a chart order. Mr. Long answered affirmatively and stated they type the order into a chart, but the physician has to log in with an ID to get into that chart. He added that one of the physicians puts in the order, logs it, and it becomes part of the chart. President Azzolin asked if it then goes to an intermediary, such as a case manager, who reduces it to paper and faxes it. Mr. Long answered affirmatively. President Azzolin stated that nursing homes face the same issue. He further stated that currently, if they receive a hospital type order that does not meet the requirements of a prescription, they have to call and get a prescription. Mr. Long commented that is why Amerita sent the request to the Board as many physicians do not want to sign a second order.

President Azzolin commented that he understands many doctors do not like to do this, but a lot of the EMR systems have the ability to send e-prescriptions directly out of the system to a retail type pharmacy. He asked if they are not willing to do that. Mr. Long responded by stating that they have not done that, but Amerita can direct them to do it that way.

President Azzolin inquired if it was the law or rule that dictates how a prescription comes to a retail pharmacy. Director Troughton responded by stating that the rule lists the requirements that must be included in a retail pharmacy prescription drug order. He stated that in getting the prescription from an electronic medical record to a retail store, he does not see any issue if it is a discharged prescription and it contains the requirements of a retail prescription. He further stated that if it is sent by printing it out and faxing it, or sending it electronically, he does not see any issues from an enforcement standpoint as long as it is clearly a discharge prescription and it meets the requirements of the rule. Director Troughton stated that not taking the extra step from the hospital to send it properly does not make sense to him as most EMR systems have the ability to send e-prescriptions directly out of the system.

Discussion was held regarding the address being on the prescription. President Azzolin inquired if the prescription has to have the patient's address listed. Director Troughton responded by stating that the physician's address must be listed. President Azzolin stated that if the order, no matter how it looks, meets the requirements of a prescription drug order, then it would be sufficient. Mr. Long stated that most of the time the name and phone number are listed, but not an address. Director Troughton commented that if the hospital address is not listed that would be a system problem. He stated that the requirement is you have the origin, not just the name. Mr. Long commented that they will receive a cover sheet and then behind that comes the prescription. Director Troughton stated that GDNA would not consider a cover sheet to be considered part of the prescription. He further stated that if the hospital address is listed, that would be sufficient, but if the hospital cannot put the address on that discharged prescription, that is a problem and they need to figure out how to include it on there. Mr. Long responded by stating that they can request the hospital include that information in the template.

Mr. Changus commented that this seems like you have this produced and sent out. He stated that once you start adding things, that is what the rule is concerned about. He further stated that all that information seems like it can be generated electronically.

For clarification, Mr. Long inquired if the address should be on the physical order, and not on the secondary page. Director Troughton stated that if it is a two page prescription, the information has to be on those two pages. He added that a cover sheet may not be in the system. Director Troughton continued by stating that is a broad question and suggested Mr. Long review the rules and requirements concerning what has to be on the prescription.

### **Discussion Topics**

**Tech Immunization**: Mr. Stone discussed House Bill 416 and how the Board should modify its rules in preparation of the changes. President Azzolin inquired if it had been signed into law. A visitor present responded by stating that it had not been signed. President Azzolin stated that, from an enforcement perspective, even if the rule does not match the law you would adhere to what the law requires. Director Troughton commented that House Bill 416 almost looks like a rule the way it is written and that is what GDNA would be going by if it were conducting an investigation.

Mr. Changus stated that section (e) of House Bill 416 states, "The board shall promulgate rules and regulations necessary to implement the 58 provisions of this Code section." He stated that this seems to be self-implementing and he was unsure if there was any rule promulgation necessary. He added that the bill is authorizing this practice and a separate license would not be issued for a technician to be able to do this.

Vice-President Page commented by stating that this is a different scenario once a technician is administering a vaccine. He inquired as to what the Board could do as far as discipline if there was an issue with a technician administering a shot, such as an injury for example. He asked if the Board could suspend or revoke the technician's registration. Additionally, Vice-President Page inquired as to what could the Board do if something happened under the supervision of the pharmacist. Mr. Changus responded by stating that the Board may want to establish rules pertaining to required documentation and training that can be made available when GDNA goes into a pharmacy to ensure the technician has complied with those requirements.

Vice-President Page asked if there was something the Board could do to discipline the technician. Director Troughton responded by stating that from the majority of the cases received during the pandemic the majority of the technicians had completed the training and had the training documented, but just made a mistake. He stated that is what he believes the Board will see case wise. Director Troughton asked if the Board would be able to impose discipline on the technician if they were to administer the wrong shot. Mr. Changus responded by stating that if there is a violation of the law or rule, then discipline could be imposed.

Mr. Chang commented that there are cases where technicians give the wrong drug to the patient. Vice-President Page responded by stating that this is a different scenario as giving out the wrong drug is the pharmacist's responsibility. He added that a technician administering an injection is a different level of patient care.

President Azzolin inquired as to whether or not the Board should being promulgating a rule to address some of the issues. Mr. Changus discussed having documentation that the proper training has been given and reporting obligations if there was an adverse event. He stated that there is likely appropriate development of rules. He added that, to the extent there being something to build in to establish some sort of disciplinary framework if someone makes a mistake in administering these vaccines, may be something for the Board to think about.

Mr. Joiner commented that the bill has a provision that states "<u>Nothing in this Code section shall be construed to require any pharmacist to authorize a pharmacy technician to administer vaccines pursuant to this Code section or to require any pharmacy technician to administer vaccines pursuant to this Code section."</u>

Discussion was held regarding promulgating a rule. Mr. Changus stated that the Board does not need to duplicate the statute in a rule as the statute is always in control. He added that the Board can provide additional guidance as necessary such as how to document and how to report adverse events. President Azzolin stated that the Board should contemplate if the pharmacist should check each vaccine prior to the technician administrating it in order to hold the pharmacist accountable.

Mr. Chang commented that the bill states, "...under the direct supervision of the pharmacist". He added that the bill also requires the technician to complete a minimum of two (2) hours of training of immunization related continuing pharmacy education. He suggested this information be posted on the Board's website.

Vice-President Page commented that what he is proposing would be more appropriate for misfill guidance rather than a rule; however, he stated that he does understand putting something in the rule. Mr. Brinson agreed with Vice-President Page about including language in the misfill policy concerning technicians.

President Azzolin stated that he prefers to have less language than more language. He added that he does not see this as a restriction, but more as protection for the pharmacist and guidance on how to stay out of trouble. He continued by stating that if a technician administers something to a patient that does cause harm and if there is ambiguity in who will be held accountable, one board may say it is the pharmacist's or PIC's responsibility to check prior to the technician administering it whereas another board make up may say it is the technician's responsibility. President Azzolin stated that ambiguity is problematic.

Director Troughton stated that until the law has been signed and becomes effective, GDNA will gather all the facts and bring that information back to the Board. He stated that the Board will receive the same investigative information for each case. He added that GDNA already has a plan and knows how cases will be handled coming to the Board. President Azzolin responded by stating that he thinks the law is consistent in what GDNA will do in the investigative process. He added that he is concerned about the subjective nature of changing board members.

Mr. Farmer commented that technicians are a pharmacist's support and help with medication orders from beginning to end and the pharmacist is monitoring that process until the end point. He stated that the technician administering a vaccine is different. He added that discipline and accountability is different. Mr. Farmer stated that in regards to discipline, there is a place for the Board to be able to have accountability and to discipline when needed. Vice-President Page responded by stating that may be a part of misfill guidance or something to create a rule around.

President Azzolin stated that another reason to have something in a rule is because most pharmacists tend to to lean on the rules for their understanding of their regulatory responsibilities. Mr. Changus responded by stating that is why you see statutes repeated in the rules. He added that it is very true in pharmacy as Chapter 480 is exceedingly large and a lot of it is duplicative language from the statute.

After further discussion, Mr. Changus stated that the Board could require the maintenance of records for a specific time period, along with several other items. Mr. Lacefield stated that staff will work with Mr. Stone in creating a rule and will bring it back to the Board at a future date.

**Direct Supervision Definition:** Mr. Stone stated that the Board has discussed this topic several times. He further stated that during the pandemic, the Governor declared a State of Emergency which read as follows: "That the Georgia State Board of Pharmacy (the "Board") is authorized and directed to implement the suspension of O.C.G.A. § 26-4-82(c)(2) and Ga. Comp. R. & Regs r. 480-15-.03(d)(2), to the extent necessary to allow pharmacy technicians and pharmacists to complete computer-based processing of prescriptions at alternative locations, including from the residence of the pharmacy technician or pharmacist."

Mr. Stone stated that the pandemic changed a lot of things. He added that first and foremost, the Board is charged with protecting the public. He continued by stating that if the Board can improve pharmacy care and pharmacy practice, to the extent of helping the profession while maintaining patient safety, he thinks the Board can look at those things.

Mr. Stone stated that O.C.G.A. § 26-4-5(32) defines a pharmacy technician as "...those support persons utilized in pharmacies whose responsibilities are to provide nonjudgmental technical services concerned with the preparation for dispensing of drugs under the direct supervision and responsibility of a pharmacist."

Mr. Stone discussed being concerned about errors and drug diversion and how it goes back to the dispensing pharmacist or the verifying pharmacist in that process from the point of dispensing. He stated that when someone is putting information into the system that comes from an e-script or fax and then it goes to a pharmacist to review and verify the prescription before it goes to the patient, how is that considered clerical. He stated that when he thinks of direct supervision and the responsibility of the pharmacist, the pharmacist is directly supervising what that technician did and the pharmacist is responsible for that and is considered direct supervision. Mr. Stone stated that, until the pandemic occurred, he thought direct supervision meant the individual had to be there physically. He inquired if the law requires them to be physically present in the pharmacy.

President Azzolin commented that O.C.G.A. § 26-4-82(c) states that in the dispensing of all prescription drug orders:

- (1) The pharmacist shall be responsible for all activities of the pharmacy technician in the preparation of the drug for delivery to the patient;
- (2) The pharmacist shall be present and personally supervising the activities of the pharmacy technician at all times;

President Azzolin stated that nowhere in the statute does it state that the pharmacy technician has to be physically present.

Mr. Stone stated that when the pandemic occurred, his pharmacy was trying to figure out how to handle things when someone becomes ill. He further stated that technology has advanced and they use it to help and go through the process while ensuring patient safety and care. He added that he was only speaking to the part of data entry. He discussed Fla. Admin. Code R. 64B16-27.4001 section (2)(a) which states,

"Direct Supervision: means supervision by a pharmacist who is readily and immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed. "Readily and immediately available" means the pharmacist and technician(s) are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and technician(s)."

Mr. Stone stated that he contacted several long term care pharmacies. He stated that Guardian Pharmacy provided information on how they provided services remotely during the pandemic. He further stated that he wanted to discuss this because he knows the Governor is currently reviewing the amendments adopted regarding remote order entry, and as the Board moves forward in its discussions about direct supervision, could the Board discuss how technology is being used when the technician is not touching any drugs. Mr. Stone stated that he receives many calls related to workload issues. He added that the Board has discussed remote order entry as a way to possibly alleviate those workloads. He continued by stating that independent pharmacies have stated that remote order entry would be helpful. Mr. Stone stated that they found error rates went down because technicians were not distracted in a pharmacy.

Director Troughton stated that from an investigative standpoint, it seems like it would be better if the technology allowed direct supervision to expand to remote order entry. He further stated that if the Board were to decide that remote entry is a clerk function, it would be impossible for agents to walk into a pharmacy and easily determine who are technicians. He added that most stores have information on every person who touched the prescription. He continued by stating that if the Board makes data entry a clerk function, it is opening a door so wide that will never close.

President Azzolin inquired if there has ever been a time when the Board has issued any punitive action on a technician for a data entry error. Director Troughton responded by stating that he was not aware of such. He stated that until House Bill 416, it had never been mentioned that a technician was responsible for verification. President Azzolin stated that if a technician is not on site, they have no access to the physical inventory of drugs and the technician would only be doing data entry. He further stated that the Board has never issued any punitive action against a technician. He continued by stating that if the Board stated that it would be a clerk function, there would not be any obligation for the clerk to be accurate in their data entry as it would still fall on the pharmacist. President Azzolin added that he could see very good applicability of a data clerk transcribing info. He stated that he thinks Mr. Stone is asking if there is room for interpretation in O.C.G.A. § 26-4-82 and the rule to allow this to occur. Director Troughton stated that diversion is a small piece of what GDNA handles. He continued by stating that with many misfill cases, the pharmacist will say the technician entered the prescription wrong and the pharmacist missed it. He stated that if that is not considered a technician function, then GDNA will need assistance in determining what is.

Mr. Stone stated that if they are doing any of those functions in the pharmacy, the individual has to be registered as a technician. He further stated that if it is done remotely, it would still have to be a technician doing the data entry and that would not count against the technician ratio. He continued by stating that the prescription still comes back to the dispensing pharmacy and a pharmacist has to be physically present in the pharmacy. He added that the Board did not see an increase in errors with process during the pandemic. Mr. Stone stated that he does not think there will be an increase in errors because pharmacies have already been doing this.

Director Troughton stated that this would require a new rule and requested the Board consider allowing the remote order entry with a registered technician that is being directly supervised. Additionally, he requested the Board exempt that technician from the in-store ratio. He continued by stating that he was concerned with the Board allowing the technician to work remotely from home without them being a registered technician.

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President Azzolin stated that he sees this as something to help the pharmacist by allowing the individual offsite to do data entry and does not negate the fact registration is needed for the onsite personnel. He further stated that if he was doing this, he would want the individual to be registered in case he needs them to come in. He continued by stating that, based on what Mr. Stone is saying, it seems clear that there is room for interpretation of physical presence by the pharmacist to mean only the pharmacist has to be physically present and that pharmacist personally supervises the activities of the technician when the technician is entering the drug order offsite. President Azzolin asked if there was room for interpretation of where the pharmacist can utilize technicians offsite for data entry as long as the technicians are registered.

Mr. Changus commented that when the term "direct supervision" was inserted into the statute and the rules, it contemplated a different universe than what we are operating from today. He stated that the way the statute and laws are written was designed to have pharmacy technicians under the watchful eye of the pharmacist. He further stated that the idea of expanding direct supervision is not really defined. He added that to define that as meaning the technician can be somewhere else and the pharmacist can still be directly supervising may make some sense, but in terms of enforcement, you are blurring what direct supervision was intended to be originally. Mr. Changus stated that statutes do not change quickly and getting authorization for technicians to administer vaccines is one thing that passed for pharmacy this year. He stated that when one contemplates the scenario of remote order entry in the context of the pharmacist being somewhere else, is adding a layer on top of that. He added that there are potential enforcement concerns.

President Azzolin inquired if the rules could be clarified to state that physical presence and personally supervising a technician can include supervising a technician who is offsite when they are only performing data entry functions. He stated that from an enforcement standpoint, as long as proof of the individual is registered is there, there is nothing that does not have to be reviewed by that pharmacist. He continued by stating that as long as they are not physically present, you remove a lot of the issues the technician could cause in an investigative process. President Azzolin stated that the data entry, review, and approval always has to go through the pharmacist and as long as that interpretation allows for personally supervising to be from an offsite location, it opens opportunity for the Board to add to the rule the ability to let data entry to occur offsite.

Mr. Stone stated that the Board previously discussed the pharmacist having a direct line of sight, but his mind has changed since the pandemic. He further stated that is something that could help the profession but still maintain public safety.

Director Troughton inquired if there would be any consideration for the Board to say the technician cannot sit down at a local restaurant and be entering information remotely. He stated that valuable information is on the screen such as the patient's personal information. He further stated that is something the Board should take into consideration. President Azzolin responded by stating that there are already laws in place from a federal perspective that protect against that. He stated that the Board could add language to a rule stating that data entry should be limited to being conducted in secure environments. He also suggested that language should be added to state what the Board is capable of enforcing.

Mr. Chang stated that there are multiple sections of the Board's rules that involve remote order entry that the Board needs to review. The Board recommended Mr. Chang work with Mr. Stone and Mr. Joiner regarding this matter.

Rule 480-35-.02 Pharmacist Certification: President Azzolin stated this topic was discussed in Executive Session at the Board's February meeting regarding the rule requiring the applicant to provide current practice setting and other information. He continued by stating that section (1)(a)(iii) requires "Current place of practice setting, including name, address, and telephone number and place where the protocol and patient records will be maintained."

President Azzolin stated that a pharmacist should not have to list a location in order to do a clinical service like a DTM. He further stated that if the pharmacist is doing DTM and is not dispensing, but is making a change of order under a protocol on behalf of a physician or another pharmacy, then he would argue that a pharmacist would not have to have a place on the protocol. He inquired if the pharmacist could allude to the physician's physical practice location and asked if a pharmacy had to be listed. He suggested just listing the physician's location of practice where they are performing services.

Mr. Stone inquired if an amendment to the rule would be required. President Azzolin responded by stating that it would be an interpretation that a physician's office was permissible. Mr. Changus commented that if it said pharmacy setting, then there would be an issue, but it just says place of practice.

Discussion was held regarding what address to list if partnering with multiple providers. The Board directed staff to modify the application to match the rule and add space for the applicant to list multiple provider addresses and bring it back to the Board for consideration.

**Pharmacy Permit** – **Non Transferable:** The Board discussed ownership changes triggering a new permit number. Mr. Stone stated that when ownership of a pharmacy changes and a new permit is issued, it triggers things behind the scenes that can delay patient safety and care. He further stated that when a permit number changes, it also triggers things with insurance companies and the DEA. Mr. Stone stated that the Governor wants to make it easier to do business in Georgia and when a permit number changes, that causes issues. He inquired if the same permit number could be kept as long as the Board is notified and it is approved.

President Azzolin stated that part of reason the statute states that the license is non-transferrable is because the license does not belong to the pharmacy permit holder, it belongs to the state. He further stated that the state can assign that permit to whomever as long as the statute allows the facility to submit an application for that permit and meet the requirements. He added that there should be authority for the state to use the same license number or reissue the same license number.

Vice-President Page commented 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." President Azzolin responded by stating that he is not talking about assigning, but rather talking about reissuing a license number to an entity.

Mr. Changus stated that the code section mentioned by Vice-President Page means the recipient cannot sell that license or transfer that license without the Board being involved in determining whether or not a license should be held by the person who the pharmacy is being sold to. He added that it means the Board gets to weigh in and say the facility meets the inspection requirements and personal requirements necessary for the person to have a pharmacy. He continued by stating that the possessor of the license does not have the ability to transfer the license to someone else. Mr. Changus stated that is what the statute requires and there are other requirements in the rules. He stated that if someone is looking to do business as a pharmacy they have to come to the Board for that authorization. He added that the permit number is reflective of the specific assignment of that authorization to that entity. Mr. Changus explained that there is an administrative component to it and there may be administrative concerns about reassigning that license, as well as enforcement concerns. He stated that as long as the entity matches up with the permit number and it has been approved by the Board, they are good to go.

President Azzolin stated that, based on Mr. Changus' comments, it sounds like there is potential to amend the rules where it states, "Permits shall not be transferable" and strike the language that states, "Permits become null and void upon the sale, or change of mode of operation of the business, or location of business." He further stated that clarification should be added about what an applicant must do in order to utilize the same license number and not have to apply for a new license.

Mr. Changus stated that what the statute requires is to make sure the Board can sign off on the receipt of a license regardless of what license number is used. President Azzolin suggested amending the application to add the option for the person to say they either want to keep the same license number or they want a new license number. Mr. Lacefield commented that it would be better administratively to do the same for everyone. He stated that an application is required for any of those changes such as location or ownership. He stated that the interpretation of the rules has changed over the years and staff need to know how to proceed.

President Azzolin stated that the Board cannot change anything at this moment, but it should decide if it is permissible to eliminate null and voiding of a permit number and change the interpretation to what the Board has discussed.

Mr. Farmer commented that on occasion a zip code can sometimes change an address. He inquired if that had happened before. Mr. Lacefield responded affirmatively and stated that staff would make the change administratively upon receipt of notification from the post office or whoever changed that address. He stated that in those cases, the license number does not change.

Discussion was held regarding a change in location not requiring a new license number. Mr. Lacefield stated that if the county or post office changes the zip code or street number of where that facility is located, a new application is not required. He explained that documentation that the entity has changed the address or zip code would be needed. He stated that if the facility changes its name, the facility will need to submit an application for such. He added that if there is a change of ownership, an application is required and the permit number will change.

President Azzolin stated that he and Mr. Farmer would work with Mr. Joiner since this applies to multiple rules.

Rule 480-35-.04 Requirements for a Protocol: President Azzolin stated that the Board's earlier discussion regarding Rule 480-35-.02 Pharmacist Certification should take care of this topic. Mr. Stone stated that the Board is not looking at the protocol, but rather wants to make sure there is a protocol signed by the physician. He further stated that the rule does not require a protocol be submitted, but the application requires one be provided. Mr. Lacefield commented that the rule does require a protocol and lays out the requirements of what the protocol should contain. He added that the Board is not approving the protocol. Mr. Stone stated he was good leaving the language on the application that requires a protocol be submitted. The Board determined no further action would be necessary regarding this topic.

Rule 480-2-.03 Experience Requirements: The Board discussed this rule which requires a list of preceptors be submitted to the Board for approval. Mr. Stone stated that he feels it is the pharmacy school's responsibility to review and approve the preceptors. President Azzolin inquired if the Board currently reviews preceptors. Mr. Lacefield responded by stating that the Board has received several submissions. Mr. Chang suggested amending the rule to remove the requirement of submitting the list to the Board, but require the school to maintain records on its approved preceptors for the last five (5) years and be readily retrievable upon request. The Board directed staff to make the appropriate amendments to the rule and bring back to the Board for review.

USP <800>: President Azzolin stated that this topic stems from discussion at the March 2023 meeting regarding correspondence received from a non-compounding pharmacy asking if the Board will require USP <800> compliance for non-compounding pharmacies. President Azzolin further stated that in that discussion the Board looked at some of the details of USP <800> that may apply to those types of pharmacies such as counting a hazardous drug on a counting tray that involves counting another drug on that same counting tray without following the proper procedures in cleaning that counting tray relative to

USP. He continued by stating that, at the time, the response was GDNA will ask pharmacies to be compliant with USP <800> including those aspects. Director Troughton added that there was a discussion based on the Board's current laws.

Mr. Stone commented that he thinks the Board should look at this in more depth. He discussed adding flavor to reconstituted products. Director Troughton responded by stating that is considered non-sterile. He further stated that GDNA has been enforcing that for years and is different than USP <800>. Director Troughton explained that USP <795> and <797> would be applicable come November. He stated that some things are changing, but GDNA has been enforcing USP <795> for years. He added that O.C.G.A. § 26-4-87 states, "The board shall promulgate rules and regulations governing the appropriate and proper storage and handling of controlled substances and dangerous drugs as defined in Chapter 13 of Title 16 which are consistent with those standards established by the United States Pharmacopeial Convention." Director Troughton stated that is the part that ties USP <800> to pharmacies in Georgia.

Mr. Stone stated that he understood it would become applicable in November, but suggested having a grace period to allow pharmacies time to adjust as there could be additional changes up until September. Director Troughton responded by stating that USP <800> has been in effect. He explained that <USP 800> is not the one that is becoming compendially applicable. He stated that USP points out that the reason November is important is because USP is mentioned in USP <795> to <797. Director Troughton explained that it will affect those that are sterile compounding cost wise. He stated that USP <795> and <797> will reference <800> and it is applicable when changes to USP <795> and <797> go into effect. He added that states can come up with their own decisions on how to enforce it outside of USP <795> and <797>.

President Azzolin inquired if GDNA was currently enforcing USP <800> in retail pharmacies. Director Troughton responded by stating they are not right now. President Azzolin asked if there was intention to enforce USP <800> in retail pharmacies? Director Troughton responded affirmatively and stated that GDNA would enforce it when changes to USP <795> and <797> become applicable. Director Troughton stated that this would be a big change for the pharmacy industry and GDNA will work with the pharmacies. He further stated that GDNA is in the mode of training now and as November gets closer GDNA will have to work with the Board as to how it wants GDNA enforcing.

Mr. Changus commented that there is the enforcement side which is determining whether or not there is a violation. He stated that on the discipline side is a list of things the Board can do. He further stated that in the learning phase just because it is a violation does not mean the pharmacy will get a public order. He added that the Board makes judgements all the time as to what is appropriate, and during this learning phase, if there is a violation, it may be appropriate as the first course of action to send a letter of concern stating you are in violation of this standard which you are required to meet. Mr. Changus stated that as it gets incorporated into practice, that may be time to impose discipline.

Director Troughton commented that GDNA will not know what it will see as far as non-compliance. He added that it will be a learning curve for everyone.

President Azzolin stated that Chapter 480-11 references USP <797> and USP-NF, and it discusses how the compounding of those drugs needs to be compliant with USP <797>. He further stated that since the rules speak to compliance with USP under various chapters of USP, the Board should think about adding USP <800> to the applicable locations such as under the retail rules. He added that the rules should probably allude to pharmacies being compliant with the aspects of USP <800> with things that are applicable to your area of practice.

Mr. Stone commented that the Board needs to be in agreement as to how these things will be handled.

Mr. Farmer commented that what started this discussion was the inquiry received last month about a non-compounding pharmacy. In looking at the list of hazardous drugs, Mr. Farmer stated that he meant to go through this and get a number of how many would be involved, along with how to store and properly handle those and what the impact will be in a non-compounding pharmacy. Mr. Brinson stated that the smaller hospitals will be under a lot of pressure and if they have not complied with all of the standards, they will be written up by the Joint Commission.

The Board determined no action would be necessary at this time regarding this topic.

At this time, the Board recessed for lunch at 11:29 a.m.

The Board meeting resumed at 12:04 p.m.

CE Monitoring/Audits: Mr. Chang discussed information he previously provided to the Board regarding NABP's CPE monitoring program. He explained that the current process is for the Board members to audit continuing education credits manually during renewal. He stated that there are several options available through NABP. Mr. Chang explained that option one involves board staff to query a specific date range. He stated that option two involves board staff providing a spreadsheet of licensees to be audited. He further stated that option three would be more of a proactive approach and involves board staff providing a spreadsheet of licensees to be audited prior to renewal. Mr. Chang stated that he does not think amending a rule would be required, but thinks it would be handled administratively if the Board wanted to work with NABP on any of the options mentioned.

Vice-President Page inquired as to cost. Mr. Chang responded by stating that there is no cost involved with options one and two. He added that there is a software fee involved for option three. Mr. Lacefield commented that typically, the Board is not charged for those NABP services as Georgia is a member and pays an annual fee.

Vice-President Page asked if licensees would have to have an NABP e-profile. Mr. Chang answered affirmatively. President Azzolin stated that the only CE's that would need to be uploaded manually are those that the Board has approved that are not approved by ACPE.

The Board recommended Mr. Chang reach out to NABP regarding conducting a presentation before the Board regarding this matter.

**Rule 480-10A-.05 Transmission and Labeling:** President Azzolin stated that this topic concerns discussion held by the Board at its February meeting regarding a request for a waiver of Rule 480-10A-.05(4)(a). President Azzolin explained that there were hardships presented in the request and the waiver was approved. He added that the Board requested to discuss the rule at the April meeting.

President Azzolin stated that Rule 480-10A-.05(4)(a) requires all transmission records to include "CENTRAL FILL" be written on the face of a prescription if it is a hard copy prescription. He discussed suggested language to the rule.

Vice-President Page inquired as to what the term "unique identifier" meant in subsection (6)(c). Deputy Director Karnbach responded by stating that in some central fill facilities they do not transfer the prescription, they transmit the data. He added that the central fill location is not receiving it as a prescription so they do not assign a prescription number, but will assign it a unique identifier or some other number that is utilized to track through the process.

Mr. Joiner stated he would create a proposed draft and submit it to President Azzolin to review.

Rule 480-10-.16 Security System Approval: President Azzolin stated that the rule speaks to a corporation or entity that operates multiple pharmacies to provide details of any lockbox to be utilized be submitted to the Board for approval. He further stated that the rule does not address whether or not a single pharmacy might have a lockbox. He added that there are concerns regarding a single pharmacy not knowing they have to submit a request for approval of a lockbox as well. President Azzolin stated that there are so many versions of lockboxes that it seems subjective and ambiguous for the Board to deem what is an appropriate lockbox. He further stated that he knows there are electronic locks which also have a key code on them that can be issued electronically through a cell phone. He added that one of the considerations was that it is the responsibility on the submission of security system approval of the Director of Pharmacy or the Pharmacist in Charge to restrict utilization of those types of locks to only approved personnel and not technicians. He stated that he knows the lockbox has presented a problem for several pharmacies.

Mr. Chang commented that his initial thought on the lockbox is that it puts you in a specific mode of a security system versus a security system that needs to be reviewed and approved. He continued by stating that a lockbox does not solve the issue if it is in a box on the wall or the floor. He stated that the Board talked about different methods of security pharmacies have such as video surveillance. He added that he is not aware of where the term "lockbox" came from. Mr. Chang stated that it is not the only mode of security pharmacies use as most have more than just a lockbox.

Mr. Chang inquired if there was some language that needed to be changed that would focus on security. President Azzolin inquired if the Board should change the term "lockbox" to mean that if it is tampered with there is evidence of tampering as opposed to a lockbox glued on the side of a brick wall or one that is bolted into a brick wall.

Vice-President Page commented that the lockbox contains an access code and key, but it is the security of that system that needs to be made more secure. President Azzolin stated that there was a request from a pharmacy concerning a lockbox and the Board asked the facility to change it because the pharmacy had a box that was screwed into the wall. He further stated that the Board's issue with that was it could be knocked off the wall. He added that the pharmacy thought it was appropriate, but that was not sufficient for the Board. President Azzolin stated that in the event of there being more than one pharmacy the rule does specify the pharmacy has to receive approval from the Board before it can be utilized. He suggested keeping that language in the rule, but add language requiring a single pharmacy to obtain approval as well.

Mr. Chang asked Director Troughton if security is checked as part of the inspection of new pharmacies. Director Troughton affirmed that was checked as part of an initial opening inspection. President Azzolin inquired if it was clear in the rule as to when a security system is required to be approved. Director Troughton responded that it is not. He added that there are thousands of security systems. He stated that GDNA checks the overall security of the space at every inspection. He continued by stating that the Board has not stated what type of security system is required.

President Azzolin stated that Rule 480-10-.16(1) states, "Any retail pharmacy located in a general merchandising establishment which does not have a prescription department set aside and permanently enclosed with a partition from floor to ceiling as set forth in O.C.G.A. 26-4-110, must submit to the Board in writing a request to approve its particular security system accompanied by a detailed description of that security system. This request must be made prior to a pharmacy receiving its retail pharmacy permit;"

Discussion was held regarding requiring a single retail pharmacy to obtain approval in order to utilize a lockbox. The Board directed Mr. Joiner to make the appropriate changes and bring them back to the Board for consideration.

**Rule 480-24-.04 Drug Distribution:** President Azzolin stated that the Board previously discussed chart orders not serving as an appropriate prescription order for pharmacies filling prescriptions for nursing homes.

Mr. Brinson stated that this topic and the topic of Chapter 480-24 Nursing Homes, Long Term Care Facilities and Hospice Emergency Drug Kits could be discussed together. He stated that Ms. Stephanie Kirkland provided a draft of suggested changes to Chapter 480-24. The Board recommended tabling this topic until the Board's May meeting to allow additional time to review the suggested changes provided by Ms. Kirkland.

# Rule 480-27-.04 Use of Facsimile Machine to Transmit or Receive Prescription Drug Order:

President Azzolin stated this came from discussion about what was considered a fax. He added that there was some confusion around that relative to it being digitally received versus on paper. He stated the rule references O.C.G.A. § 26-4-80. He continued by stating that section (4) of Rule 480-27-.04 states, "A prescription drug order may be accepted by a pharmacist or pharmacy intern or extern in written form, orally, via an electronic visual image prescription drug order, or via an electronic data prescription drug order as set forth in this chapter or as set forth in regulations promulgated by the board."

President Azzolin stated there are two different versions of electronic. He stated that one is an electronic visual image of the prescription and the other is an electronic data prescription. He explained that an electronic visual image is when an image of an order comes through digitally on the computer. He stated that it seems logical to infer a fax received digitally rather than on paper would count as an electronic visual image prescription. President Azzolin stated that if that is the case, it seems the Board should add language to the rule stating that if a fax is received as an electronic visual image and not on paper, then it constitutes a visual image and does not need to be reduced to paper. The Board agreed.

Director Troughton commented that GDNA does not require pharmacies to print them out now. Mr. Changus stated that the requirement to print it out is in the rule currently. Director Troughton stated that GDNA does require the pharmacies to print an emailed prescription. He explained that as far as visual faxes as an image, GDNA does not require them to be printed. He stated that those are saved and GDNA has immediate access to those.

President Azzolin inquired if a prescription has to be printed if it is emailed because that is an image. Director Troughton responded by stating that the rule specifically requires emailed prescriptions be printed out. President Azzolin stated that, as the Board discussed last month, he can go to a fax machine and fax to a number that is a VOIP (Voice Over Internet Protocol) number and when that happens it is emailed to an email address of a pharmacist. He stated that Deputy Director Karnbach commented that GDNA does not look at how the prescription was sent, it looks at how it was received. President Azzolin explained that it is a new version of a fax, not an email. He added that if one refers to a visual image versus a paper order, then it would not have to be printed. He stated that a visual image, whether sent through an email or transmitted from a physician's office directly to the pharmacy, is still considered a visual image.

Director Troughton commented that GDNA does not know the difference when it is looking at the prescription. He continued by stating that agents do not ask how it was sent. He added that GDNA goes by what the rule requires. He stated that if the Board tells GDNA not to worry about that, GDNA is fine if it is a visual image, and if that is what the Board decides that is one less thing GDNA has to do.

Mr. Changus commented that the question is can the information be retrieved and printed out as a result of the rule. He further stated that if the Board wants to eliminate that requirement, it can.

Director Troughton commented that the pharmacy industry and technology has changed through the years. He stated that GDNA just needs the prescription to be immediately retrievable. After further discussion, President Azzolin stated he would send suggested language to Mr. Joiner to review and bring back to the Board for consideration.

**Public Consent Orders versus Private Consent Orders:** President Azzolin stated this topic was tabled at the Board's November meeting since Mr. Stone could not attend that day. President Azzolin stated that the November minutes reflect the following:

"Vice-President Azzolin asked if there were any comments relative to how the Board determines if a consent order should be public versus private. Mr. Brinson responded by stating that he felt Vice-President Azzolin was doing a great job in trying to keep things consistent. Mr. Prather commented that it may be a good idea for the President to appoint a two (2) man committee to study this with the idea of coming up with something similar to the Board's Misfill Policy concerning determining when a consent order should be public or private. Vice-President Azzolin stated he would defer this matter to the President for consideration."

Mr. Brinson commented that the Board has made great strides with this. He stated that thanks to Vice-President Page as Cognizant, the Board is becoming more consistent with the orders. Vice-President Page commented that the Board has flexibility as to whether or not an order should be public or private depending on the circumstance.

The Board determined no further action would be necessary regarding this topic.

**Physical Area Requirement:** President Azzolin stated that there is currently a requirement of 150 square feet in most pharmacies. He explained that Mr. Prather previously requested the Board amend the rules regarding the minimum 150 square feet requirement be at the discretion of the Georgia Drugs and Narcotics Agency. President Azzolin continued by stating that the requests for waivers are consistent. He inquired if the Board wanted to have GDNA to determine if the square footage was appropriate or not. Director Troughton responded by stating that GDNA prefers to go by what is required in the rules. He explained that he felt it was not a good idea to have GDNA make discretionary decisions.

Mr. Brinson commented that the Board receives waivers from opioid treatment facilities because those types of facilities do not need a large area to operate. Mr. Cordle inquired if the Board could amend the language to state that 150 square feet is required unless it is an opioid treatment facility and carry less than "x" amount of drugs. Mr. Brinson responded by stating that he did not think that would be a good idea because some facilities may start off with a certain number of drugs, but could increase that number throughout the year.

Vice-President Page inquired if a minimum amount of square footage was needed at all. Director Troughton responded affirmatively and stated that GDNA has been in places where the pharmacy did not have the required square footage and told the pharmacy to request a waiver. He added that he thinks there should be a minimum requirement in the rules. Director Troughton stated that if a pharmacy requests a waiver, GDNA will go inspect the facility and take pictures so the Board can make a determination. President Azzolin stated that the Board has considered waivers in the past, but does not feel it is an overwhelming amount.

The Board determined no further action would be necessary regarding this topic.

**Naloxone:** Vice-President Page explained that this topic came up because Naloxone was approved by the FDA for OTC status. He stated that he had asked Director Troughton what the process was to remove it from the dangerous drugs list.

Director Troughton commented that the Board has the ability to alter the dangerous drugs and controlled substances list during the year. He explained that the normal process that occurs when a drug is removed from prescription status by the FDA is to remove the drug from the dangerous drug list during the next legislative session via the Drug Update Bill which he prepares for the legislators. Additionally, he stated that the Board has also be able to use Chapter 480-34 to delete drugs from the dangerous drugs list.

Mr. Changus stated that O.C.G.A. § 16-13-71(e) states, "The State Board of Pharmacy may delete drugs from the dangerous drug list set forth in this Code section. In making such deletions the board shall consider, with respect to each drug, the following factors:

- (1) The actual or relative potential for abuse;
- (2) The scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the drug;
- (4) The history and current pattern of abuse, if any;
- (5) The scope, duration, and significance of abuse;
- (6) Reserved:
- (7) The potential of the drug to produce psychic or physiological dependence liability; and
- (8) Whether such drug is included under the federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C. Section 301, et seq., as amended."

The Board determined no further action would be necessary regarding this topic.

**Rule 480-5-.03 Code of Professional Conduct:** President Azzolin explained that an amendment to this rule was discussed by the Board at its December conference call and the Board voted to table further discussion until its next work session to allow additional time for research.

Vice-President Page stated that when this came up it was emotional for the Board to deal with regarding sexual harassment and unprofessional conduct. He explained that the discussion at the time was concerning what could the Board do about it. He stated that after consideration, he feels it would be difficult to enforce. He stated that he was not sure the Board needed to do anything differently at this point.

The Board determined no further action would be necessary regarding this topic.

White Bagging/Brown Bagging: Mr. Stone requested to withdraw his request to discuss this topic.

**Point of Care Testing:** Mr. Stone discussed O.C.G.A. § 26-4-5(31). He stated that he does feel there needs to be a change in the law so that pharmacists can expand their ability to help, monitor, and screen patients for diseases and help physicians improve patient care.

**NABP Verify:** President Azzolin stated there was a question regarding reciprocity and could a pharmacist choose to obtain reciprocity other than taking the MPJE. He further stated that the proposal was to consider NABP Verify as a replacement or alternative option for the current reciprocity process. President Azzolin suggested it be an alternative, not a replacement. He inquired if the Board wanted to consider looking into NABP Verify and if it does, did the Board want to request NABP Verify provide a presentation to educate the Board on what NABP Verify can do. The Board stated it would be in favor of having NABP Verify make a presentation before the Board.

Mr. Farmer inquired as to what the driving mechanism for this was. President Azzolin stated this concerns a pharmacist that wants to do any remote data processing from one state to another state. He used Alabama as an example, which has its own rules and requirements. He explained the pharmacist has to be licensed and inside an Alabama licensed non-resident pharmacy. President Azzolin continued by stating that North Carolina has adopted what NABP has put together. He stated that they are trying to standardize a simple

way so that as long as the pharmacist is not physically in the state and not physically dispensing, then he/she can get a license in a state that accepts that process by applying one time.

Mr. Farmer inquired if the Board was envisioning two (2) different levels of reciprocity. President Azzolin responded by stating two different versions. Discussion was held regarding NABP Verify not limiting the pharmacist to data processing. He stated that if the Board approved it, NABP Verify would allow the pharmacist to reciprocate. Mr. Farmer stated that if someone had a desire to do remote entry in Georgia, and if it would be an easier way to reciprocate, he thinks the Board would want to make that available to anyone. President Azzolin responded by stating that is the reason why the Board would like for NABP to conduct a presentation. He stated that it may be that their intention is for just data processing. Mr. Farmer stated that his only concern is to making it easier for someone who is just doing remote data entry in another state versus someone who wants to practice in the state.

Mr. Lacefield commented that he does not think there is anything wrong with listening to what NABP has to say; however, it may require a legislative change. He added that in order to reciprocate to Georgia, the pharmacist has to take the MPJE.

Mr. Chang stated that his understanding of NABP Verify is that it does not meet the requirements of reciprocating a license. He added that it is a way of connecting the Board so the pharmacist is able to process remotely without actually holding a license. Mr. Chang stated that it does not give the pharmacist the right to practice, but will give them the option to do remote order processing. Mr. Chang stated that it would be a type of credentialing that would be used as an option for remote order entry.

President Azzolin inquired if there was a vehicle through legislation that would allow that to turn into someone being able to process a prescription in Georgia from a remote location without obtaining a license by reciprocity. Mr. Changus responded by stating that data processing of an order constitutes the practice of pharmacy. He stated that unless there was a legislative change, he does not see how it would be permissible.

Mr. Lacefield stated that there is a lot of emphasis now across all boards and states concerning portability with licensure. He asked Mr. Joiner to inform the Board of Senate Resolution 85.

Mr. Joiner stated that Senate Resolution 85 was adopted this year which formed a Senate Occupational Study Committee which will look at all of the portability of professional licensing. He added that it has no binding right now; however, the licensing laws may change soon.

President Azzolin commented that it seems there is no pathway to use at this time. He added that NABP Verify would not allow a person to work in Georgia unless he/she reciprocated. He continued by stating that the Board should hold off on requesting a presentation from NABP Verify until there is a change in the law. Mr. Changus stated that in terms of talking about what NABP Verify does, it may be helpful to request they provide a PowerPoint versus them coming in person since the requirements for licensure are set out in statute. The Board agreed to request any written information from NABP Verify that could be provided to the Board for review.

**Database:** President Azzolin stated that this topic is relative to management of decisions made by the Board. He further stated that it was discussed about there being an easier way to search for a pharmacist to find items/topics. President Azzolin continued by stating that Mr. Joiner mentioned that information is very broadly available by searching terms or rule numbers on the Board's website. He stated that he has been able to find some things, but it does not have as many fields as he would like for it to have, but feels it is not worth the time to develop a database or invest in one at this point.

Name Change Application for DMEs: Deputy Director Karnbach explained that this topic was mentioned due to a facility inspection at a DME that changed names. He added that the law and rules do not address name changes as a requirement for DME; however, it is addressed for other license types. President Azzolin stated that if the Board is responsible for oversight, there should be some consistency regarding name change requests. The Board directed staff to make the appropriate amendments and bring them back to the Board for consideration.

**Rule 480-33-.01 Definitions:** Mr. Joiner commented that section (1) of this rule currently states in part, "...providing outpatient treatment or case.." Mr. Joiner stated that the word "case" should be changed to "care". Additionally, the rule starts with (1)(b) instead of (1)(a). Mr. Joiner will make the necessary changes and bring back them to the Board for consideration.

**Rule 480-7-.05 Reverse Distributors:** Mr. Joiner commented that section (2) of this rule currently states in part "In order or any Reverse Distributor.." Mr. Joiner stated that the word "or" should be changed to "for". Mr. Joiner will make the necessary change and bring back to the Board for consideration.

**Rule 480-7A-.03 Restriction on the Distribution of Listed Chemicals:** Mr. Joiner commented that the rule references 480-71-.02; however, there is no rule with this particular number. He stated that "480-71-.02" should be changed to "480-7A-.02". Mr. Joiner will make the necessary change and bring back to the Board for consideration.

Rule 480-10-.06 Licensure, Applications, and Display of License and Renewal Certificate: Mr. Joiner commented that the lettering in the rule is incorrect as it references (1)(c) twice. Mr. Joiner will make the necessary change and bring back to the Board for consideration.

Rule 480-5-.04 Imparied Pharmacists, Interns and Externs: Mr. Joiner commented that the rule title reflects "Imparied" and should be corrected to "Impaired". Additionally, the rule states in part, "...to place appropriate conditions or limitations on that person's license, including conditions or limitations on that person's license..." which is duplicative. Mr. Joiner will make the necessary changes and bring them back to the Board for consideration.

Rule 480-3-.03 Continuing Pharmacy Education: Mr. Joiner stated the Board office has received several inquiries requesting clarification regarding dates. He explained that the term "to July" seems to conflict with the "last six (6) months" language. He stated that section (5) of the rule states, "A pharmacist licensed before or during the first six (6) months of the biennium (January to June), shall be required to obtain 30 hours of C.E. A pharmacist licensed during the following twelve (12) months (June to July) shall be required to obtain 15 hours of C.E. A pharmacist licensed during the last six (6) months of the biennium shall be exempt from continuing education for that biennium only." Discussion was held regarding clarifying the language to be clearer. Mr. Joiner will make the necessary changes and bring them back to the Board for consideration.

#### Miscellaneous

Mr. Lacefield commented that there are an additional seven (7) rules that need to be updated to reflect the Board's and GDNA's new address. He stated that staff will make the necessary revisions and bring them back to the Board for consideration.

Mr. Stone requested a status on Rule 480-22-.02. Mr. Lacefield responded by stating that the Board voted to adopt amendments in October and those are currently being reviewed by the Governor's office. He stated that there were additional changes voted on by the Board at its November meeting. He further stated that staff would make the appropriate changes and bring back to the Board.

Mr. Farmer made a motion and Mr. Stone seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h) and § 43-1-2(h) to deliberate and to receive information on applications, investigative reports, and the Assistant Attorney General's report. Voting in favor of the motion were those present who included Michael Azzolin, Jim Bracewell, Michael Brinson, Young Chang, Cecil Cordle, Michael Farmer, Chuck Page, and Dean Stone.

### **Executive Session**

### Georgia Drugs and Narcotics Agency - Mr. Dennis Troughton

No report.

# Cognizant's Report - Mr. Chuck Page

- GDNA Case # A34698
- GDNA Case # A34664
- GDNA Case # B34646
- GDNA Case # B34633
- GDNA Case # B34579
- GDNA Case # B34663
- GDNA Case # B34632
- GDNA Case # B34640
- GDNA Case # B34592
- GDNA Case # T34709

# Attorney General's Report - Mr. Max Changus

Mr. Changus presented the following consent orders for acceptance:

- B.P.S.
- P.P.G.I.
- C.P.
- L.C.D.
- T.M.S.C.
- M.O.M.
- L.A.S.
- A.H.

Ms. Simpson discussed the following cases:

- L.A.E.C.
- Y.B.

# Executive Director's Report - Mr. Eric Lacefield

No report.

### **Legal Services – Mr. Clint Joiner**

No report.

#### **Applications**

- F.S.
- D.Z.B.
- D.S.S.
- C.A.M.

- A.K.G.
- K.M.M.
- S.S.F.
- J.M.R.
- L.L.K.
- A.M.P.
- M.T.D.
- P.K.
- S.A.S.
- S.T.R.
- T.M.S.

### **Correspondences/Requests**

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

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

# **Open Session**

Mr. Cordle asked Mr. Joiner for an update regarding the low THC rules voted on by the Board at its March meeting. Mr. Joiner responded by stating that there currently is no update to provide as the Governor's office has been busy due to the legislative session. Mr. Lacefield commented that even though the Governor has 90 business days to review the rules, the Board must receive the Certificate of Active Supervision.

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

# Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

No report.

### Cognizant's Report - Mr. Chuck Page

GDNA Case # A34698 Refer to the Department of Law
 GDNA Case # A34664 Refer to the Department of Law

• GDNA Case # B34646 Misfill Policy #1A

• GDNA Case # B34633 Pharmacist #1 - Refer to the Department of Law

Pharmacist #2 and #3 – Misfill Policy #1A

• GDNA Case # B34579 Misfill Policy #1A

GDNA Case # B34663 Close with letter of concern
 GDNA Case # B34632 Close with letter of concern

GDNA Case # B34640 Close with no action
 GDNA Case # B34592 Close with no action

• GDNA Case # T34709 Revoke Technician Registration

# Attorney General's Report - Mr. Max Changus

Mr. Changus presented the following consent orders for acceptance:

B.P.S. Private Consent Order accepted P.P.G.I. Public Consent Order accepted • C.P. Public Consent Order accepted L.C.D. Public Consent Order accepted T.M.S.C. Public Consent Order accepted M.O.M. Public Consent Order accepted L.A.S. Public Consent Order accepted Private Consent Order accepted A.H.

Ms. Simpson discussed the following cases:

L.A.E.C. Close case with no actionY.B. Offer counterproposal

# Executive Director's Report - Mr. Eric Lacefield

No report.

# <u>Legal Services – Mr. Clint Joiner</u>

No report.

### **Applications**

• F.S. Pharmacy Technician Appro	ved for registration
• D.Z.B. Pharmacy Technician Appro	ved for registration
• D.S.S. Pharmacy Technician Appro	ved for registration
• C.A.M. Pharmacy Technician Appro	ved for registration
• A.K.G. Pharmacy Technician Appro	ved for registration
• K.M.M. Pharmacy Technician Appro	ved for registration
• S.S.F. Pharmacy Technician Appro	ved for registration
• J.M.R. Pharmacist Reinstatement Appro	ved application
• L.L.K. Pharmacist Reinstatement Appro	ved application
• A.M.P. Pharmacist Certification of DTM Appro	ved application
• M.T.D. Pharmacist Certification of DTM Appro	ved application

• P.K.	Pharmacist Certification of DTM	Approved application
• S.A.S.	Pharmacist Certification of DTM	Approved application
• S.T.R.	Pharmacist Certification of DTM	Approved application
• T.M.S.	Pharmacist Certification of DTM	Approved application

# **Correspondences/Requests**

• A	A.R.W.P.	Notice of Discipline	No action
• N	<b>Л.С.Р.</b>	Notice of Discipline	No action
• P	P.I.	Notice of Discipline	No action
• A	A.R.P.	Notice of Discipline	No action
• C	C.H.P.S.	Notice of Discipline	No action
• H	I.V.	Notice of Discipline	No action
• Z	Z.H.	Notice of Discipline	No action
• A	A.P.I.	Notice of Discipline	No action
• P	P.L.	Notice of Discipline	No action
• P	P.L.	Notice of Discipline	No action
• T	C.M.R.	Notice of Discipline	No action
• N	Л.F.V.	Notice of Discipline	No action
• E	E.P.I.	Notice of Discipline	No action
• C	C.P.	Notice of Discipline	No action
• C	C.K.	Notice of Discipline	No action
• R	R.A.F.	Appearance Request	Approved request
• N	Л.L.A.	Correspondence	The Board viewed this
			correspondence for informational
		a.	purposes only.
	A.L.E.	Request for 4 <sup>th</sup> attempt to retake MPJE	Approved request
	3.R.	Request for 4 <sup>th</sup> attempt to retake MPJE	Approved request
	A.L.B.	Request for 5 <sup>th</sup> attempt to retake NAPLEX	Approved request
• D	D.Y.C.	Request for extension of intern license	Approved extension through 12/31/2026
• E	E.A.S.	Request to Terminate Probation	Approved request effective 05/23/2023
• W	V.	Request to Terminate Probation	Approved request
• L	C.C.	Request for extension to complete assessment	Refer to the Department of Law

Mr. Stone seconded, and the Board voted unanimously in favor of the motion. In the same motion, the Board voted to approve its Misfill Policy Guidelines as amended.

There being no further business to discuss, the meeting was adjourned at 3:36 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, May 24, 2023, at 9:00 a.m. at 2 MLK Jr. Drive, SE, 11<sup>th</sup> Floor, East Tower, Atlanta, GA 30334.

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