

**GEORGIA BOARD OF PHARMACY**  
**Conference Call**  
**2 Peachtree Street, NW, 6<sup>th</sup> Floor**  
**Atlanta, GA 30303**  
**August 5, 2020**  
**9:00 a.m.**

**The following Board members were present:**

Lisa Harris, President  
Mike Faulk, Vice-President  
Carrie Ashbee  
Michael Azzolin  
Michael Brinson  
Bill Prather  
Dean Stone

**Staff present:**

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

**Visitors:**

Travis Clark  
Amanda Roberson  
Jason Neerman  
Becca Hallum, GHA  
Helen Sloat

**Open Session**

President Harris established that a quorum was present and called the meeting to order at 9:03 a.m.

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

**Approval of Minutes**

Vice-President Faulk made a motion to approve the Public and Executive Session minutes from the July 15, 2020 Conference Call and the July 29, 2020 Practical Exam Committee Conference Call. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

**Report of Licenses Issued**

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

**Petitions for Rule Waiver or Variance**

Mr. Brinson made a motion to grant the rule waiver petition from Augusta State Medical Prison, PHH006083. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

The Board recommended tabling the rule waiver petitions from Gregory E. Milanich and Halle H. Harrison for discussion later in the meeting.

**Correspondences**

President Harris stated that the correspondence from Mark Bolton, Greenwich Biosciences, Jason Neerman, Greenwich Biosciences, and Graham Thompson all concern Epidiolex. Director Troughton commented that each correspondence states that the DEA has descheduled Epidiolex. He stated that the

correspondence from Mr. Bolton references a letter from Dr. Terrence Boos, DEA. Director Troughton contacted Dr. Boos and stated that he could not find where the DEA had officially descheduled Epidiolex. Dr. Boos' response was that the DEA had not issued an official notice regarding such. Director Troughton stated that although the DEA has not descheduled it yet, the Board does have the ability to deschedule a drug by rule. Mr. Brinson made a motion to deschedule Epidiolex. Discussion was held. Director Troughton commented that the Board would just be descheduling Epidiolex from within the state of Georgia code. Mr. Prather commented that the Board has done this many times whether it be taking a scheduled drug to a non-scheduled drug or prescription drug to over-the-counter. Director Troughton stated that once the Board deschedules it under the rule, that will suffice until the legislature meets. He further stated that if legislature meets on time next year, it will go into the drug bill. With no further discussion, Mr. Prather seconded and the Board voted unanimously in favor of the motion.

#### **Correspondence from Bianca C. Johnson, Porzio Life Sciences, LLC.**

President Harris stated the Board recently considered a similar correspondence regarding the ability to ship drug samples directly to patients due to a recently released FDA guidance. Mr. Lacefield affirmed that was correct and stated that there is additional information with this correspondence and another under his Executive Director's Report that was not available to the Board last month. Director Troughton stated that the correspondence is requesting to know if samples can be sent directly to a patient's home as opposed to sending the samples to the doctor or hospital. The Board directed staff to respond by referring the individuals to O.C.G.A. § 16-13-72, which gives guidelines on how to provide samples.

#### **Georgia Drugs and Narcotics Agency – Dennis Troughton**

Director Troughton reported that GDNA has conducted 272 inspections and received 28 complaints for FY2021.

Director Troughton reported that he received a letter from the Director of Pharmacy at a hospital regarding a notice received from the Department of Public Health ("DPH") concerning COVID-19 patient overflow protocol for hospitals. Director Troughton stated it is concerning DPH's high level procedures on moving patients to the Georgia World Congress Center if they need to do that from area hospitals within the state. He further stated that part of that plan is for the originating hospital to provide a seven (7) day supply of all medications. Director Troughton stated that the Director of Pharmacy was asking some great questions as to how exactly that would work, how would those medications be labeled, and how would they be transported. Director Troughton stated that he has already emailed DPH on this matter and if the Board would allow him to do so, he will deal with them directly and report back to the Board in September. He stated that during this pandemic GDNA has assisted hospitals with getting permitted within two days, if needed. Director Troughton informed the Board members that in case he/she receives calls on this matter, GDNA is aware and will handle with DPH. President Harris responded by stating that if the Board needs to hold an emergency conference call at any point to deal with this matter, it can do so. Director Troughton commented that if there is anything that requires the Board's level of authority, he will report it right away. Mr. Azzolin requested Director Troughton forward the Board the notice from DPH so that the Board can peruse those documents. Director Troughton responded that he would post the documents to Sharepoint.

#### **Attorney General's Report – Max Changus**

No report.

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

**Continuing Education Report:** Report presented. Mr. Brinson made a motion to ratify the below continuing education program 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
07/09/2020	1	The Medical Center, Navicent Health	Therapeutic Equivalence, Herbal Products and OTC's	2020-0010

**Legal Services – Kimberly Emm**

No report.

**Miscellaneous**

**Long-Term Care Facilities/Collection Receptacles:** President Harris stated that the Board discussed this topic at a previous meeting and determined the reverse distributor may not obtain drugs from long-term care facilities as they are required to be returned to the pharmacy. She continued by asking if Mr. Changus and Ms. Emm were looking at this matter further. Ms. Emm responded that she discussed this topic with Mr. Changus. She stated the Board does have rules regarding placing a collection receptacle in a long-term care facility, so there can be placement of the receptacle in the facility itself. She further stated that it is not owned by the facility, but rather it is owned by authorized collector. Ms. Emm stated the reverse distributor can pick up directly from the receptacle itself. Additionally, the receptacle itself has to be from an authorized collector. Ms. Emm asked if applications to place the receptacle in a long-term care facility have to go through GDNA. Director Troughton responded by stating that it is just a notification, not an application. He stated that the DEA is the only approving authority. He further stated that GDNA maintains a record of where they are located. Mr. Changus commented that Mr. Henderson led a lot of the discussion on this matter. Mr. Changus explained that the way this is designed through law and rules, the pharmacy will be in that sort of role, rather than the facility itself. He stated that the Board keeps bumping up against the same concern which is the ability of the long-term care facility to operate without some of the structures imposed by the Board’s law and rules. President Harris asked if there could be a work around. Director Troughton responded by stating that he does not think there is a way to say the facility is responsible for that box and they can handle themselves. He added that the pharmacy is responsible for the changing of the liners and does not think there is a way to take out the authorized collector from that process and have that receptacle at that facility.

**Emergency Rules:** Mr. Changus stated that the authority to pass emergency rules under the state of emergency has statutory limitations. He explained that when the Board was addressing these, it had concerns about them being totally open-ended. He stated that on some of the rules, the Board made determinations that they will only last for 120 days or for the duration of the state of emergency, whichever is shorter. Mr. Changus stated that back in March the Board could not have predicted Georgia would still be under the state of emergency, which as of last Friday was extended again to 09/10/2020. He stated the revisit of these rules is to see what needs to be refreshed, so that if these rules are still necessary as deemed by the Board, the Board could have them in place. Mr. Changus explained O.C.G.A. § 50-13-4 provides for a timeframe. He explained that the Board can adopt these rules again and eliminate the timeframe so they would last for the duration of the state of emergency and up to 120 days thereafter. Discussion was held regarding the language stating “*...and shall be effective for the duration of the emergency and for a period of not more than 120 days thereafter.*” Ms. Emm explained that this language is already drafted into Rule 480-2-0.41-.04 Examinations. She explained that Rules 480-10-0.38-.22 Medication Limitations, 480-15-0.40-.07 Temporary Pharmacy Technician Registration, 480-22-0.39-.16 Emergency Schedule II Prescription Drug Order, 480-36-0.36-.08 Remote Order Verification for Retail Pharmacy Permits, and Chapter 480-48-0.37-.04 Delivery by Mail need to be addressed.

Mr. Lacefield stated in regards to Rule 480-10-0.38-.22 Medication Limitations, the board office receives numerous inquiries requesting the Board change the content of the rule and not limit hydroxychloroquine. He stated that staff has been responding by referring the individual to the letters from DPH and the FDA that are posted on the Board’s website. Mr. Brinson commented that many people do not understand the

rule. He stated that section (d) of the rule states: *“This emergency rule will not apply to patients previously established on any of the above listed drugs prior to the effective date of this rule”*. President Harris commented that a diagnosis code just needs to be included. Mr. Brinson stated that if you have a person that is already diagnosed and took 120 of those drugs, they can continue to get those 120, but most pharmacists are only reading that first portion of the rule and are limiting patients to only 14 days. Ms. Emm commented that the board office is receiving inquiries from individuals who want hydroxychloroquine for COVID-19, not the patients who are on it for other medical conditions. She stated the question comes down to subsection (a) of the rule that says in part, *“consistent with the evidence for its use”*. She continued by stating that so far COVID-19 is not consistent with the evidence of the use of these drugs. After further discussion, Mr. Azzolin made a motion to repeal the rule. Ms. Emm commented that a motion does not need to be made in this case since it is an emergency rule. She explained that the Board can choose to not renew the rule. The Board agreed to not renew Rule 480-10-0.38-.22 Medication Limitations.

The Board discussed amending the language of Rule 480-15-0.40-.07 Temporary Pharmacy Technician Registration, Rule 480-22-0.39-.16 Emergency Schedule II Prescription Drug Order, Rule 480-36-0.36-.08 Remote Order Verification for Retail Pharmacy Permits, and Chapter 480-48-0.37-.04 Delivery by Mail to read, *“...and shall be effective for the duration of the public health state of emergency”*.

Director Troughton asked if the emergency rules being discussed have expired. Ms. Emm responded by affirming that the majority of them expired on June 30, 2020. Director Troughton stated that GDNA is encountering pharmacy technicians that have temporary licenses that are no longer effective. Ms. Emm responded by stating that the rule says, *“All temporary pharmacy technician registrations shall expire 60 days from the end of the declared state of emergency”*. She continued by stating that even though the rule has expired, the state of emergency has not. Mr. Changus stated there is a conflict, but the way the statute reads the idea is to last through the emergency and the Board has something counter to that.

Director Troughton stated that section 4(b) of the Board’s emergency policy pertaining to temporary pharmacist licensure reads in part, *“The temporary recognition of non-resident pharmacist licensure and pharmacy intern licensure shall cease at end of the month following the third board meeting conducted after the issuance of such license and shall not be renewed...”* He stated that the Board will have a case for discussion in Executive Session regarding this matter. Ms. Emm commented that the Board may run into an issue with that because that limitation is statutory. Mr. Azzolin added that this will cause a patient care issue. Director Troughton stated that if GDNA is doing an inspection and finds a pharmacist working with an expired temporary license, that will be a dilemma from the GDNA side. Mr. Azzolin asked how can this matter be corrected. Ms. Emm responded by stating that it may be something the Governor needs to address because that language is taken from O.C.G.A. § 26-4-43(a) which states: *“A temporary license may be issued by the executive director upon the approval of the president of the board if an applicant produces satisfactory evidence of fulfilling the requirements for licensure under this article, except the examination requirement, and evidence of an emergency situation justifying such temporary license. Except as provided in subsection (b) of this Code section, temporary licenses shall expire at the end of the month following the third board meeting conducted after the issuance of such license and may not be reissued or renewed.”* Mr. Azzolin asked if the Board could request the Governor address this law as soon as possible. Mr. Brinson stated that he does not understand why the Board cannot create a temporary emergency rule on this matter and send to the Governor to review. Mr. Changus responded that in talking about temporary licenses, the statute was not designed for a pandemic lasting this long. He stated the Board is not in the position of asking the Governor to accept an emergency rule that is in conflict with the law. Director Troughton commented that when GDNA comes across a pharmacist that has an expired temporary license it would normally tell that pharmacist he/she cannot be in the pharmacy. He stated that this is a law the Board would not have changed by the end of the meeting and until the Governor issues an Executive Order saying otherwise, the Board cannot change that law. He further stated that, unless he had

different direction, GDNA cannot allow them to continue practicing with an expired license. President Harris affirmed that was correct. With no further discussion, Mr. Brinson made a motion to amend Rules 480-15-0.40-.07 Temporary Pharmacy Technician Registration, Rule 480-22-0.39-.16 Emergency Schedule II Prescription Drug Order, Rule 480-36-0.36-.08 Remote Order Verification for Retail Pharmacy Permits, and Chapter 480-48-0.37-.04 Delivery by Mail as discussed and resubmit to the Governor's office for review. Ms. Ashbee seconded and the Board voted unanimously in favor of the motion.

**Practical Exam Committee Report:** President Harris reported the Committee recently met and a lengthy discussion was held. She stated that she learned a lot during that meeting. She further stated that she personally did not want to get rid of the practical exam. President Harris stated that different options were discussed. The first option is business as usual with a wet lab and request the schools' help with social distancing the candidates. The second option is to modify the in-person practical by having a dry lab, with no mixing of the compounds, students can still meet with board members for interviews, and practice social distancing. The third option would be to have a virtual practical examination.

President Harris stated that Mr. Lacefield provided information regarding pass/fail rates. She stated for new graduates, only 2.88% have to take the test more than once; however, for those reciprocating from another state, 12.5% have to take the practical more than once. President Harris stated that with these rates, it makes one ask what is the Board testing that NAPLEX is not testing. She further stated that many of the reciprocating pharmacists have practiced for years without any problem. She stated there must be a reason why they cannot pass the Board's practical examination, but can pass the MPJE and NAPLEX. President Harris stated that there are 47 states that do not have a practical. She asked for the Board's comments. Mr. Azzolin stated, to President Harris' point, one thing that the data shows relative to students is that whenever the candidate takes the NAPLEX only once, only 2.52% fail the practical. He added that 10.15%, however, have to take the practical more than once when the NAPLEX is taken more than once. Mr. Azzolin explained that the data clearly demonstrates the practical is redundant while making it hard for an individual to become licensed. He stated that it also takes the Board's time and money. He further stated that the data clearly supports the decision the Committee made to do away with the practical. President Harris commented that in her heart she does not want to do that, but times are changing and the Board is now in a situation with the pandemic.

Mr. Stone stated that when he became a member of the Board, he knew the practical exam had been around for a while. He stated that he does know the frequency of the exam does hinder people from being licensed. In regards to the validity of the test, Mr. Stone stated he spoke with some educators and competency statements were mentioned. He stated that as educators, you test students on what you teach them and if you see the majority are failing, you have to reevaluate your teaching style/methods. He asked if the Board could be challenged. President Harris stated that she has spoken to a member of the North Carolina Board who mentioned litigation. She asked Mr. Changus to shed some light on this for the Board. Mr. Changus stated with the exam sometimes they are challenged on the psychometrics. He asked is there validity in terms of measuring what the person should know, is there bias, etc. Mr. Changus stated that anyone can challenge anything, but he does not believe it holds a lot of water. He further stated that he does not think this is something the Board needs to be concerned about. He stated that he thinks an exam that is testing basic knowledge in a clinical setting would pass muster. He further stated whether or not someone could do an analysis saying what could be improved, is different. Mr. Azzolin commented that what he hears Mr. Stone saying is the Board is not professional testers. He stated that the Board's practical exam has not been accredited like NAPLEX. Mr. Azzolin stated his point is no one is coming behind the Board and accrediting what it is testing. Mr. Azzolin discussed compounding. He stated that some of the practical testing procedures do not meet the minimum requirements to even compound in an actual practicing pharmacy environment and the Board is testing on that subject. He further stated that the practical is not practical for licensing pharmacists.

Vice-President Faulk stated that each member of the Board has participated in the testing process. He stated that it is not rocket science. He continued by stating that it is an entry level competency exam. Vice-President Faulk stated that the Board has tested individuals who have no business practicing pharmacy. He stated that it is the Board's job to protect the citizens of Georgia. He continued by stating that he does not believe the Board should make a permanent decision based on a temporary crisis. Vice-President Faulk stated that at some point, the Board will be able to resume testing; however, if this Board determines it no longer needs the exam, maybe the Board should evaluate the exam and update it. President Harris responded by stating that for the individuals that have no business practicing are getting caught by the MPJE or NAPLEX. She stated that there are pharmacists from other states that have practiced 17 plus years and cannot pass the Board's practical exam. She stated that it is difficult for her to not give those pharmacists a license. Vice-President Faulk stated there are candidates from across state lines that want to reciprocate to Georgia. He continued by stating that the individual would go to another state and reciprocate to Georgia because he/she could not pass the Board's practical. He explained that the Board's intent was to stop individuals from circumventing the exam.

Mr. Brinson commented that the only issue he has is not being able to hire anyone after July 1st because the exam is not offered in October. He stated that he was placed on this Board not only to protect citizens of Georgia, but also to protect pharmacists and technicians. He stated many staff pharmacists and those in retail would like to keep the exam, but academia and hospitals would like to get rid of it. Mr. Brinson stated that the budget is also a concern. Mr. Prather disagreed with Mr. Brinson. He stated that this Board is charged with protecting the citizens of Georgia. He further stated this test has served this Board for over 100 years. It is a tool used to test the people the Board will give a license to. Mr. Prather stated the test is to ensure the candidate has basic knowledge. He stated that with each test, he is appalled at the number of students that ask him questions. He gave an example of a candidate asking about a label and what is for and where does it go. Mr. Prather stated that once the Board gives that person a license, he/she can do anything a pharmacist can do. He stated that he realizes times have changed. He continued by stating that all of the Board's rules have been vetted by pharmacists through the years that have a tremendous amount of experience. He stated that he thinks the Board is making a rush to judgement and thinks this is something that needs a tremendous amount of due diligence. He added that he does not feel the Board has done its due diligence yet. Mr. Prather stated that he is not saying the test does not need to be changed. He stated that he would like for the Board to speak to former members of this board who had a tremendous impact on this through the years. He further stated that if the Board decides today to do away with the practical, it would be making a mistake. Mr. Azzolin commented that this concept of protecting the citizens of Georgia by preventing somebody from doing something, in his opinion, can be the inverse of that. He stated if the Board is preventing someone reciprocating for instance, and a company needs that individual to work, the Board is causing more harm by not allowing licensure in his opinion. He further stated that he believes the Board is protecting the public by doing away with the practical because the Board is not professional testers, whereas the people that have created the NAPLEX and MPJE are. Mr. Azzolin stated that the committee made a decision on the data presented, which is hard evidence. He stated the Board created the committee to evaluate the practical and make a recommendation to the full Board, which the committee has done. He further stated that he thinks some of the considerations of protecting the public can go both ways.

Mr. Azzolin discussed labeling. He stated every computer system generates a Board of Pharmacy approved label. He added that when a practicing pharmacist from out of state comes into Georgia and there are 30 to 40 questions on the screen asking him/her to catch potential errors and omissions, those are not things in real life because the label will already have all those requirements on it. Mr. Azzolin stated that some of those things go too far in preventing a pharmacist from getting a license. Vice-President Faulk responded by stating he thought the purpose of the committee was to evaluate the exam and make recommendations on updating the exam as opposed to deciding whether or not the exam has relevance going forward. Mr. Azzolin commented that the purpose of committee meeting did include the consideration of whether the

practical needed to continue at all as that is documented in the minutes. He stated, in addition, the committee were challenged to not address the practical in a temporary sense, that has already been addressed. Mr. Azzolin stated the committee's challenge was to address the future of the practical as a whole. Mr. Prather stated he agreed with Vice-President Faulk. Mr. Prather stated his intent in asking President Harris to appoint a committee was not to decide not to do it or do it, but how to improve it. He stated that he cannot argue statistics, but expressed his concern at the last meeting when this committee was put in place and asked for someone who has already stated he was against this test, to be objective. President Harris commented that every board member had an opportunity to participate in that meeting. She stated that she is a traditionalist, but at the same time, sometimes it is time to move on. She is open-minded and asked each member to also be open-minded. She stated that this is the 20<sup>th</sup> century and many things have changed. She continued by stating whether one likes statistics or not, statistically it shows the exam is redundant. President Harris stated that it sounded like "this is the way it has always been done, so this is the way we do it". She stated that the budget is also a concern. Mr. Prather responded by stating that he recognizes there has to be a change. Vice-President Faulk stated that none of the members are going to expect an exam to be given if the funds are not there to do it; however, the Board does not need to end something without doing its due diligence. President Harris agreed. She stated that as the Board contemplates the practical, there are things that need to be taken care right of way. For instance, she stated that she does not think a reciprocity candidate needs to be denied a license if they have passed the MPJE and NAPLEX, and attended an accredited school. President Harris continued by stating that if the Board continues with giving the practical, it needs to allow calculators because she thinks it is ludicrous for the Board to prohibit them.

Mr. Lacefield stated that the Practical Exam Committee has shared its report. He asked the Board if it was ready to make a recommendation regarding the practical exam. President Harris stated that she is not ready to make a decision about doing away with the exam today. She stated that she would like for the committee to meet again to discuss more and anyone is welcome to join. Mr. Azzolin stated he did not know if the Board was following Robert's Rules of Order. He stated this was a committee appointed by the Board and he believes the next step is for the committee's recommendation to the Board be discussed and voted on either today or a future meeting by the Board. Vice-President Faulk inquired as to resolving the situation for those reciprocating. Mr. Changus responded by stating the Board would need to amend its rule. Discussion was held regarding reciprocity. Ms. Emm stated that reciprocity has its own rule, 480-2-.05. She stated the Board also needs an emergency rule addressing that specific code section because exams would apply essentially to new graduates looking to enter via exam. She continued by stating if the Board wants to allow new graduates in that have previously failed the practical, that would be adopting a new emergency exam rule without the language in there that says, "*any applicant who has previously taken and failed the Georgia practical exam will not be eligible for licensure under this emergency rule*". Ms. Emm stated that she would also need to create a separate rule for reciprocity candidates that would take out the practical exam requirements. Mr. Azzolin made a motion for the Board to direct Ms. Emm to draft an emergency rule for reciprocity candidates. Mr. Brinson seconded the motion. Discussion was held by Mr. Stone. He stated in terms of hardships, the pandemic has lasted so long that there are financial hardships for those that have student loans. He requested a change be made for new graduates that took the practical and previously failed. The Board agreed to not include language stating, "*any applicant who has previously taken and failed the Georgia practical exam will not be eligible for licensure under this emergency rule*" for both reciprocity and exam candidates. Ms. Emm stated that for the current exam emergency rule she will submit an amendment to the Governor's office to see if they will accept it without it being a new rule and for reciprocity, she will send a request to the Secretary of State's office for a new rule number. She continued by stating that she will try and draft the rules now for the Board consider at the end of the meeting. With no further discussion, the Board voted unanimously in favor of the motion.

The Board resumed its discussion on the practical exam. President Harris stated that the Board is not ready today to vote on what the committee proposed. Mr. Changus stated that there has been a recommendation

from the committee, which the Board considered. He added that the recommendation was discussed with the Board and there was indication of a difference of opinion on the matter. Mr. Changus stated the committee's charge has been fulfilled; however, the Board received the recommendation, but stated it needs more time for consideration. President Harris stated that she would like for the matter to be tabled for the time being and it can be picked up another time the Board deems appropriate.

### **Petitions for Rule Waiver or Variance**

The Board resumed its discussion on the two petitions that were tabled earlier in the meeting. Mr. Prather made a motion to deny the rule waiver petition from Gregory E. Milanich and Halle H. Harrison. Ms. Ashbee seconded and the Board voted unanimously in favor of the motion.

Mr. Brinson 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)(2) and § 43-1-2(k) 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 Carrie Ashbee, Michael Azzolin, Michael Brinson, Mike Faulk, Lisa Harris, Bill Prather, and Dean Stone.

## **Executive Session**

### **Appearances**

- M.L.M.
- C.S.

### **Georgia Drugs and Narcotics Agency – Dennis Troughton**

- J.L.P.

### **Cognizant's Report – Mike Faulk**

- GDNA Case # T33397
- GDNA Case # A33268
- GDNA Case # A33261
- GDNA Case # B33244
- GDNA Case # A33239
- GDNA Case # A33358
- GDNA Case # A33270
- GDNA Case # A33296
- GDNA Case # A33276
- GDNA Case # B33288
- GDNA Case # B33290
- GDNA Case # A33361
- GDNA Case # B33269
- GDNA Case # B33318
- GDNA Case # B33336
- GDNA Case # B33371
- GDNA Case # B33273
- GDNA Case # B33272
- GDNA Case # B33275
- GDNA Case #T33389
- GDNA Case #B33130



**Attorney General's Report – Max Changus**

Mr. Changus presented the following consent orders for acceptance:

- C.H.
- A.P.
- B.S.
- C.C.S.P.

**Executive Director's Report – Eric Lacefield**

No report.

**Legal Services – Kimberly Emm**

No report.

**Applications**

- M.J.L.
- V.A.G.
- L.F.W.
- H.E.A.
- E.A.
- L.N.I.
- P.F.I.
- R.S.N.
- R.S.N.

**Correspondences/Requests**

- D.P.S.
- D.P.S.
- H.C.
- H.C.
- H.C.
- T.H.C.
- T.H.C.
- H.
- R.C.
- E.P.
- O.P.
- S.P.
- C.D.
- E.P.
- W.P.N.
- C.P.S.
- W.P.N.
- W.P.N.
- D.S.I.G.
- M.S.P.
- A.J.G.
- A.M.G.

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

**Miscellaneous**

Ms. Emm stated that drafts of Rule 480-2-0.41-.04 Examinations, Rule 480-2-0.46-.05 Reciprocity, Rule 480-15-0.45-.07 Temporary Pharmacy Technician Registration, Rule 480-22-0.44-.16 Emergency Schedule II Prescription Drug Order, Rule 480-36-0.42-.08 Remote Order Verification for Retail Pharmacy Permits, and Chapter 480-48-0.43-.04 Delivery by Mail were available on Sharepoint for the Board to review.

Vice-President Faulk made a motion to adopt Rule 480-2-0.41-.04 Examinations, Rule 480-2-0.46-.05 Reciprocity, Rule 480-15-0.45-.07 Temporary Pharmacy Technician Registration, Rule 480-22-0.44-.16 Emergency Schedule II Prescription Drug Order, Rule 480-36-0.42-.08 Remote Order Verification for Retail Pharmacy Permits, and Chapter 480-48-0.43-.04 Delivery by Mail. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Rule 480-2-0.41-.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) Any applicant who has previously taken and failed the Georgia practical exam will not be eligible for licensure under this emergency rule.~~

(5) 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.

Rule 480-2-0.46-.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 480-15-0.45-.07 Temporary Pharmacy Technician Registration.

- (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 public health state of emergency. During the time this rule is effective, it shall replace Georgia State Board of Pharmacy Rule 480-15-.02.
- (2) In order to be issued a Temporary Pharmacy Technician Registration, a Georgia Resident applicant shall:
- (a) Submit an application to the Board on the form prescribed by the Board;
  - (b) Attest that applicant is at least 17 years old; and
  - (c) Attest that applicant is currently enrolled in high school, or has a high school diploma, or has a GED, or has a postsecondary education or college degree.
- (3) In order to be issued a Temporary Pharmacy Technician Registration, a Non-Resident applicant shall:
- (a) Submit an application to the Board on the form prescribed by the Board;
  - (b) Attest that applicant is at least 17 years old;
  - (c) Attest that applicant is currently enrolled in high school, or has a high school diploma, or has a GED, or has a postsecondary education or college degree; and

- (d) Submit proof of valid pharmacy technician license/registration in another state which is current and in good standing.
- (4) All temporary pharmacy technician registrations shall expire 60 days from the end of the declared state of emergency.
- (5) A temporary registrant must complete the standard technician application process as outlined in rule 480-15-.02 within those 60 days if he or she intends to continue working as pharmacy technician.

Rule 480-22-0.44-.16 Emergency Schedule II Prescription Drug Order.

- (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 public health state of emergency. During the time this rule is effective, it shall replace Georgia State Board of Pharmacy Rule 480-22-.04(3) only, the remainder of 480-22-.04 shall remain unaltered and in full effect.
- (2) In the case of an emergency situation, a pharmacist may dispense a schedule II (C-II) controlled substance only upon receiving oral authorization of the prescribing practitioner. For purposes of this paragraph, an emergency situation means a situation in which the prescribing practitioner determines that immediate administration of a schedule II (C-II) controlled drug is necessary, there is no appropriate alternative treatment or drug in a schedule less than CII, and it is not reasonably possible for the practitioner to provide a written prescription drug order for the pharmacist dispensing the drug prior to issuance. Such emergency prescription drug order is permissible provided that:
  - (a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period must be pursuant to an additional written prescription drug order signed by the prescribing practitioner;
  - (b) The prescription drug order shall be immediately reduced to writing by the pharmacist or pharmacy intern/extern working under the direct supervision of a licensed pharmacist and shall contain all information required in Rule 480-22-.03, except for the signature of the prescribing practitioner;
  - (c) If the prescribing practitioner is not known to the pharmacist, the pharmacist must make reasonable effort to determine that the oral authorization came from a licensed practitioner, such effort may include a callback to the prescribing individual using his or her telephone number and/or other good faith efforts to insure the practitioner's identity; and
  - (d) Within 15 days after authorizing an emergency oral prescription drug order, the prescribing practitioner shall cause a written prescription drug order to be delivered to the dispensing pharmacist for the emergency quantity prescribed via one of the permissible means listed below. In addition to conforming to the requirements of Rule 480-22-.03, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral emergency order.
    - 1. The permissible delivery methods include:
      - i. Delivery by mail - must be postmarked within the 15 day period;
      - ii. Facsimile; or
      - iii. Photograph or digital scan of the written follow-up prescription drug order sent to pharmacy in place of paper prescription.
    - 2. Upon receipt, the dispensing pharmacist shall attach this prescription drug order to the emergency oral prescription drug order, which had earlier been reduced to writing. The pharmacist shall notify the Georgia Drugs and Narcotics Agency, if the

prescribing practitioner fails to provide a written emergency prescription drug order to the dispensing pharmacist.

Rule 480-36-0.42-.08 Remote Order Verification for Retail Pharmacy Permits

- (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 public health state of emergency. During the time this rule is effective, it shall replace Georgia State Board of Pharmacy Rule 480-36.
- (2) Definitions. As used in this chapter, the following terms:
- (a) "Board" shall mean the Georgia Board of Pharmacy.
- (b) "Remote prescription drug order processing" shall mean the processing of prescription or patient information from a location other than the location from which the prescription medication is received and dispensed. It shall not include the dispensing of a drug, but may include:
1. Receiving the prescription order from the primary dispensing pharmacy
  2. Interpreting, analyzing, or clarifying prescriptions;
  3. Entering prescription or patient data into a data processing system;
  4. Transferring prescription information;
  5. Performing a drug regimen review;
  6. Performing a drug allergy review;
  7. Performing therapeutic interventions; or
  8. Any combination of these order processing functions.
- (c) Primary dispensing pharmacy. A primary dispensing pharmacy shall be defined as the retail pharmacy located in this State from which a prescription is physically received and dispensed to the patient or the patient's caregiver.
- (d) Secondary remote entry pharmacist. A secondary remote entry pharmacist shall be defined as pharmacist who performs remote prescription drug order processing but does not dispense the medication to the patient or the patient's caregiver. There shall only be one secondary pharmacist to assist the primary dispensing pharmacy with remote prescription drug order processing per prescription.
- (3) Policy and Procedures. The primary dispensing pharmacy shall have written policies and procedures regarding remote prescription drug order processing that are available for inspection by the Board or its representative. The policy shall at a minimum include the following:
- (a) The responsibilities of the primary dispensing pharmacy and the secondary remote entry pharmacist;
  - (b) Procedures for protecting the confidentiality and integrity of patient information;
  - (c) Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
  - (d) Procedures for maintaining required records;
  - (e) Procedures for complying with all applicable laws and regulations to include counseling.
- (4) Record Keeping.
- (a) The primary dispensing pharmacy and the secondary remote entry pharmacist shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.
  - (b) In addition to any other required records, the primary dispensing pharmacy and the secondary remote entry pharmacist shall maintain retrievable records which show, for each prescription remotely processed, each individual processing function and identity of the

person who performs a processing function and the pharmacist who checked the processing function.

(c) The record keeping required by this rule is in addition to the record keeping required under Rule Chapter 480-10 and any other Board rules and state and federal laws.

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

#### Chapter 480-48-0.43-.04 Delivery by Mail

(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 public health state of emergency. During the time this rule is effective, it shall replace Georgia State Board of Pharmacy Rule 480-48.

(2) Definitions. For purposes of this chapter of the Rules and Regulations, the following definitions apply:

(a) "Board" shall mean the Georgia Board of Pharmacy.

(b) "Delivery by Mail" or "delivered by mail" or "delivery by mail" shall mean delivery to a patient or the patient's designee by the United States Postal Service or by a commercial common carrier from the pharmacy which fills the prescription.

(c) "Delivery by Pharmacy" shall mean delivery directly to a patient or patient's designee from the pharmacy by contract or private carrier or by an employee of the pharmacy.

(d) "Mail order pharmacy" shall mean a pharmacy that uses delivery by mail as a means of delivery of a prescription drug to a patient or the patient's designee.

(e) "Pharmacy" means a pharmacy holding a current Board issued license to operate a pharmacy in Georgia, including pharmacy benefit managers required to be licensed pursuant under O.C.G.A. § 26-4-110.1, and nonresident pharmacy permit holders.

(3) Conditions for Use of Delivery by Mail.

(a) Any pharmacy can regularly employ the U.S. Postal Service or a common commercial carrier to deliver a drug which requires a prescription to a patient only after the patient has requested that a pharmacy deliver by mail his/her filled prescription drugs. Any pharmacy providing delivery by mail to its patients is required to follow applicable Georgia laws and rules.

(b) A mail order pharmacy located outside this state is required to follow all applicable pharmacy and drug rules and laws of the state in which the pharmacy is physically located.

(c) A mail order pharmacy shall ensure that all prescription medications are delivered to the patient in accordance with standards of the manufacturer, United States Pharmacopeia, Federal Food and Drug Administration and other recognized standards. A pharmacy shall ensure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by mail order and provide a notification to the patient of the timeliness in addressing the proper storage of the medication.

1. The shipping method may include the use of temperature tags, time temperature strips, insulated packaging, or a combination of these.

2. The notification method may be by verbal, written, electronic, or other technological means. If verbal, then the pharmacy must document the notification and maintain such documentation.

(d) Any pharmacy using delivery by mail to deliver dispensed prescription drugs shall comply with the following conditions:

1. Any pharmacy that uses delivery by mail is accountable to the Board to arrange for the appropriate mailing/shipping process.
  2. A mail order pharmacy shall provide a method by which a patient or patient's caregiver can notify the mail order pharmacy as to any irregularity in the delivery of their medication to include but not be limited to:
    - (i) Timeliness of delivery;
    - (ii) Condition on the prescription drug upon delivery; and
    - (iii) Failure to receive the proper prescription drug.
  - (e) A mail order pharmacy shall provide a process by which, if the delivery of a prescription medication is in any way compromised, the pharmacy will replace the patient's medication, to be delivered by next-day delivery or the mail order pharmacy will immediately contact the patient's prescriber to arrange for a prescription for a minimum seven (7) day supply of the medication to be dispensed to the patient by a licensed pharmacy of the patient's choice.
  - (f) A pharmacy that employs delivery by mail must provide written information, set forth in Board Rule 480-31-.01, for each drug that is delivered, and a method of electronic or telephonic communications for a pharmacist or a Georgia-licensed pharmacy intern under direct supervision of the pharmacist to provide consultation or counseling in accordance with the obligations of O.C.G.A. § 26-4-85. All such counseling will be documented in the pharmacy's patient records. It is sufficient proof to show counseling was refused if a patient or patient's caregiver does not contact the pharmacy.
  - (g) The pharmacy shall provide information to the patient on the procedure that the patient should follow if any prescription drug does not arrive in a timely manner, or if the integrity of the packaging or medication has been compromised during shipment and delivery by mail.
  - (h) A pharmacy using delivery by mail shall document in its records when the prescription drug was sent to the patient.
  - (i) A pharmacy using delivery by mail shall document the instances when prescription drugs have been compromised during shipment and delivery by mail or when drugs do not arrive in a timely manner, and shall maintain such documentation for two (2) years. In addition, the mail order pharmacy shall maintain reports of patient complaints and internal/external audits about timeliness of deliveries, condition of the medication when received by patient including medication that was compromised in delivery, misfills of prescriptions, and the failure of a patient to receive medication. Such records shall be provided to the Board, upon request.
  - (j) A pharmacy or a pharmacist shall refuse to deliver by mail a prescription drug which, in the professional opinion of the pharmacy or pharmacist may be clinically compromised by delivery by mail.
  - (k) A mail order pharmacy shall make available to the patient or the patient's caregiver contact information of the Board of Pharmacy.
- (4) Delivery by Pharmacy. Any pharmacy may provide for delivery by pharmacy upon the request of the patient or the patient's designee. The Board will hold the pharmacy responsible for any problems in the service of delivery by pharmacy. In order for a delivery to be considered delivery by pharmacy, the delivery must be on a continuous route from the pharmacy to the patient or the patient's designee. All medications shall be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed.

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

**Appearances**

- M.L.M.                                      Denied Pharmacy Technician                                      Table pending receipt of

- C.S. Denied Durable Medical Equipment

additional information  
Overturn denial and approve application

**Georgia Drugs and Narcotics Agency – Dennis Troughton**

- J.L.P. Pending Pharmacist Examination

Board directed staff to notify the individual that her temporary license has expired. Table pending receipt of additional information and once that information is received, schedule to meet with the Board.

**Cognizant’s Report – Mike Faulk**

- GDNA Case # T33397 Accept Signed Voluntary Surrender
- GDNA Case # A33268 Refer to the Department of Law
- GDNA Case # A33261 Table pending receipt of additional information
- GDNA Case # B33244 Misfill Policy #1
- GDNA Case # A33239 Investigative Interview
- GDNA Case # A33358 Refer to the Department of Law
- GDNA Case # A33270 Refer to the Department of Law
- GDNA Case # A33296 Table to allow time for further review
- GDNA Case # A33276 Refer to the Department of Law
- GDNA Case # B33288 Misfill Policy #1
- GDNA Case # B33290 Close case with no action
- GDNA Case # A33361 Table to allow time for further review
- GDNA Case # B33269 Close case with no action
- GDNA Case # B33318 Close case with no action
- GDNA Case # B33336 Close case with no action
- GDNA Case # B33371 Close case with no action
- GDNA Case # B33273 Close case with no action
- GDNA Case # B33272 Close case with no action
- GDNA Case # B33275 Close case with no action
- GDNA Case #T33389 Accept Signed Voluntary Surrender
- GDNA Case #B33130 Close case with no action

**Attorney General’s Report – Max Changus**

Mr. Changus presented the following orders for acceptance:

- C.H. Voluntary Surrender accepted
- Amex Pharmacy Public Consent Order accepted
- Barbara Smith Public Consent Order accepted
- C.C.S.P. Private Consent Order accepted

**Executive Director’s Report – Eric Lacefield**

No report.

**Legal Services – Kimberly Emm**

No report.



## Applications

• Maranda J. Lewis	Pharmacy Technician	Approved for registration
• Victoria A. Gibson	Pharmacy Technician	Approved for registration
• Latisha F. Warren	Pharmacy Technician	Approved for registration
• H.E.A.	Pharmacist Intern	Approved request for extension
• E.A.	Pharmacist Reinstatement	Policy 3A
• L.N.I.	Pharmacist Reciprocity	Approved to sit for the exam
• P.F.I.	Wholesaler Pharmacy	Refer to the Department of Law
• R.S.N.	Wholesaler Pharmacy	Refer to the Department of Law
• R.S.N.	Wholesaler Pharmacy	Refer to the Department of Law

## Correspondences/Requests

• D.P.S.	Notice of Discipline	No action
• D.P.S.	Notice of Discipline	No action
• H.C.	Notice of Discipline	No action
• H.C.	Notice of Discipline	No action
• H.C.	Notice of Discipline	No action
• T.H.C.	Notice of Discipline	No action
• T.H.C.	Notice of Discipline	No action
• H.	Notice of Discipline	No action
• R.C.	Notice of Discipline	No action
• E.P.	Notice of Discipline	No action
• O.P.	Notice of Discipline	No action
• S.P.	Notice of Discipline	No action
• C.D.	Notice of Discipline	No action
• E.P.	Notice of Discipline	No action
• W.P.N.	Notice of Discipline	No action
• C.P.S.	Notice of Discipline	No action
• W.P.N.	Notice of Discipline	No action
• W.P.N.	Notice of Discipline	No action
• D.S.I.G.	Notice of Discipline	No action
• M.S.P.	Notice of Discipline	No action
• A.J.G.	Request for 5 <sup>th</sup> attempt at MPJE	Approved request
• A.M.G.	Appearance request	Approved request

Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 2:23 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, September 16, 2020 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6<sup>th</sup> floor, Atlanta, GA 30303.

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