

GEORGIA BOARD OF PHARMACY
Conference Call
2 Peachtree Street, NW, 6th Floor
Atlanta, GA 30303
September 16, 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
Russ Moore, Special Agent, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst I

Visitors:

Angela Ammons
Shauna Markes-Wilson
Jimmy England
Travis Clark, Central Admixture Pharmacy Services
Lisa Rudolph-Watson
Stephanie Kirkland
Becca Hallum
Greg Reybold, GPhA
Jeenu Philip, Walgreens

Public Hearing

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

President Harris called the public hearing to order at 9:04 a.m.

Rule 480-6-.02 Nonresident Pharmacy Permit

No comments or written responses were received.

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

Public comments were received from Jeenu Philip, Walgreens: Mr. Philip thanked the Board for the opportunity to offer oral comments to the Board. Mr. Philip stated some pharmacies receive controlled substance orders via common courier. He commented that it seems the logic in having this rule makes sense to have the pharmacist sign and make sure the packages are received safely; however, there are some additional requirements and unnecessary risks that may not have been considered. Mr. Philip stated the packages being received through common courier are unmarked and the pharmacist would be required to sign for every package, which would be disruptive to the pharmacy and patients. He added that the pharmacist would have to step away every time a package is delivered. He stated that, in addition to having the pharmacist sign for these, he/she would be announcing to the courier there is a pharmacy item in the box, perhaps controlled substances. Mr. Philip commented that as we have seen in past

investigations, when couriers know there are controlled substances in the box, sometimes that temptation is too big to pass up. He stated that he agrees there should be a systematic process in place to ensure the pharmacy is receiving what they are supposed to and there be a check-in process, but he is asking the Board to not require the pharmacist to sign as part of that process. Mr. Philip stated that Walgreens has a recommendation which may be able to serve both purposes. He stated that the amendment currently reads: *“It shall be the responsibility of the pharmacist on duty to sign for all controlled substances upon receipt.”* He added that Walgreens’ recommendation is to change the wording to read: *“It shall be the responsibility of the pharmacist on duty to ensure all controlled substances ordered and scheduled to be received are properly accounted for”*. Mr. Philip stated that this change would allow for proper receipt of those deliveries which would not require the pharmacist’s signature and would not announce to the courier there are controlled substances in those packages. President Harris stated that she does like the suggestion. She added that when things arrive in her drug store they do not know if they are controls or non-controls. She stated that she does think the pharmacist should check them in to make sure they are received into the inventory.

Mr. Stone commented that the DEA requires the pharmacist to sign the invoice and was under the impression that was the Board’s intent as well. Mr. Azzolin agreed and stated the intent was for the pharmacist to sign the invoice inside the box once it is opened in the pharmacy. President Harris asked Ms. Emm if this could be clarified. Ms. Emm stated that it can, but since the Board is holding a public hearing, the process will start over again. She stated that she will make the suggested amendments and bring back at a future meeting.

Rule 480-10-.02 Prescription Department

Mr. Stone commented that in reviewing the written comments submitted by GPhA, House Bill 918 takes effect January of 2021 and the Board will have to revisit this rule to remove the exceptions for PBM retail pharmacies. Vice-President Faulk commented that he has no issue with a retail pharmacy located in the same place as the hospital pharmacy, but asked if the Board is making allowances for retail pharmacy hospitals to operate differently than other retail pharmacies. He inquired if a pharmacist is away from the pharmacy, if the retail part would be shut down. Mr. Azzolin responded by stating no and that it is the same as a retail pharmacist stepping out from the prescription department to do patient care in another area of the building. Vice-President Faulk asked if the pharmacist would be doing that for an hour and a half. Mr. Azzolin responded that one needs to keep in mind the unique nature of a hospital pharmacy space. He stated that this is not about a free standing retail pharmacy somewhere in the hospital. He added that it is a retail pharmacy space located in the same space as the hospital pharmacy space.

Mr. Stone commented that Rule 480-13-.04(1) states in part, *“When a licensed pharmacist is not physically present in the hospital and the pharmacy is closed, written policies and procedures shall be prepared in advance by the Director of Pharmacy for the provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and/or by access to the pharmacy.”* He stated that he understands what Vice-President Faulk is stating, but does not think it needs to be changed. Mr. Azzolin commented that there is no separate retail space as the retail pharm space exists in the same space as the hospital pharmacy space. He added that the door to the hospital pharmacy is always closed and locked. He explained that when the pharmacist has to step outside the pharmacy to handle patient care, Rule 480-13-.04 states that the pharmacist has to be in the hospital and not the hospital pharmacy, so it is appropriate for the pharmacist to be outside the pharmacy and the technicians can continue doing technician duties.

Mr. Stone commented that he is hearing conflicting statements. He asked if this removes the need for any kind of separate room for locked up drugs that belonged to the retail pharmacy. President Harris agreed and stated that is the conclusion the Board came to. Director Troughton commented that there will not be a separate retail space within that hospital pharmacy. He stated that the 1,000 square foot of the pharmacy is the retail space. Vice-President Faulk asked if there are separate inventories. Mr. Azzolin affirmed there

are separate inventories as the medications come from different contracts so they are separated and segregated, but they are in the same space.

Mr. Prather commented that it appears to him the Board is making a separate set of rules for a retail pharmacy and then a second set of rules for a hospital pharmacy. He asked if this was correct. Mr. Azzolin responded that was not correct as there are the same set of rules for both. He continued by stating that GDNA, according to the rules, started denying hospitals from obtaining a retail permit in the same space as the hospital pharmacy. Mr. Azzolin stated that the reason for that denial, is if there is a retail pharmacy in the same space as the hospital pharmacy, and nursing supervisors can go get medications from that hospital pharmacy when their patient needs it, and the nurse would be in violation of the retail rules because no one can enter a retail space, including a nurse. He explained that in a hospital space, a nurse can enter after hours. He stated that in order to fix the problem, the Board looked at this rule and stated when a retail pharmacy is located in the same space as the hospital pharmacy, the nursing supervisor can enter the pharmacy. Mr. Azzolin stated that hospital pharmacists have to walk out of the pharmacy and per Rule 480-13-.03(3), it can be anywhere in the hospital and functions of the hospital pharmacy can continue. Vice-President Faulk responded to Mr. Azzolin by stating this is asking the Board to allow a retail pharmacy in that space, but not requiring it to operate like a retail pharmacy. He commented that in his store, nurses are not allowed to conduct an inventory. President Harris stated when a nurse walks into a hospital pharmacy, all of those drugs are there. She stated, if she remembers correctly, there was a big discussion about the medications not being segregated and the Board came to the conclusion that there are drugs in a hospital pharmacy anyway and there is no difference with having the retail drugs there as well. Mr. Stone stated that the reason he kept asking is he had that same concern about the pharmacist leaving the pharmacy. He stated Rule 480-10-.02(4)(a)(2) states, *“In the absence of a pharmacist from the pharmacy, the area designated as the prescription department shall be closed and locked in such a manner as to prevent unauthorized entry”*. He continued by stating policy and procedures allow a supervising nurse to go access the pharmacy, per Rule 480-13-.04. Mr. Stone stated that he has a more strict view on the retail side, but now he is comfortable with this. He stated there was previous conversation about having a locked cabinet, but it is all in the same space. Mr. Brinson commented that on the hospital side, the medications are separated and are not intermingled with hospital medications. Mr. Azzolin agreed. President Harris responded by stating that is not necessary. She added that she thinks the discussion was that there was nothing going to be in the retail drug section that is not in the hospital drug section, so they will have access to drugs. President Harris stated that she did not feel like it mattered if the drugs were locked up or not. She added that this rule amendment came about to make the exception for retail, by adding language saying, *“Except for pharmacy benefit manager retail pharmacies and retail pharmacies located in the same space as hospital pharmacies...”* Mr. Azzolin commented that the wording clarifies what already has been allowed.

Discussion was held regarding language stating the pharmacist cannot be absent from the pharmacy for more than three hours daily. Mr. Brinson stated that he does have an issue with the three hours daily. He stated that he was never gone out of the hospital more than an hour at a time to attend a meeting or code blue. Mr. Stone asked Mr. Brinson if he was speaking about being absent from the pharmacy and being somewhere in the hospital, or was he referring to being completely absent from the facility. Mr. Brinson responded by stating in the hospital. Mr. Stone stated that he interpreted the “three (3) hours daily” in Rule 480-10-.02(4)(a)(1) to mean outside the hospital; however, what he is hearing Mr. Brinson say is the pharmacist could be on the 5th floor or another area of the hospital. Vice-President Faulk commented that there are retail locations that close down for lunch and put a sign up saying the pharmacy is closed. He added that it means they are absent from the pharmacy and it is shutdown. He asked if they are now saying this does not apply to retail. Mr. Azzolin responded by stating that the language is there to allow the continuation of the operation of the hospital as this is not the same as a regular retail pharmacy. He added that the operations cannot be compared. Vice-President Faulk stated that what he is hearing is they do not want to abide by the same rules. He added that if one wants to be retail, the same set of rules should apply.

He continued by stating if you can do this in a hospital, why can it not be done for another location. President Harris stated that the language was added to allow for the pharmacist to leave to assist with a code blue, for instance, and allow the technician to continue to work. Mr. Brinson commented that nothing goes out of the hospital pharmacy until the pharmacist returns and checks the medications. President Harris stated that there are exceptions in a hospital because their situation is different. Vice-President Faulk responded by stating that he believes down the road this will cause confusion. President Harris disagreed and stated that the language provides clarification.

Mr. Prather commented that he believes the Board is making one set of rules for hospitals and one set for retail pharmacies. He stated that he agrees with Vice-President Faulk in that retail pharmacy rules should be retail pharmacy rules and hospital pharmacy rules should be hospital pharmacy rules. He stated that, given the contention, the Board should table this matter and revisit at a later time so that everyone is satisfied. President Harris responded by stating that there is retail and there is hospital; however, sometimes there are exceptions and this is an exception. She stated that it has been done successfully for a long time. She added that the time has come for the Board to recognize this exception exists in a hospital where there is a retail pharmacy. President Harris commented that she does not understand why it has to be so difficult for a situation like this to exist when it is beneficial to patients. Mr. Prather responded by stating when the Board starts making exceptions to the rule, he believes it needs to revisit the matter for further discussion. Mr. Prather asked Director Troughton if this has been going on for all these years, why has GDNA started enforcing something that needs an exception to the rule. Director Troughton responded by stating that he would first like to clarify for Mr. Azzolin that GDNA does not deny licenses or permits. He stated that GDNA gathers the information and conducts the inspections. He added that only the Board has the authority to approve or deny applications. He added that the change of this did not just occur. He stated that this goes back to years ago. Director Troughton stated since that time, the members of the board have changed and GDNA was given a different direction. He remembers it was the recommendation of the Attorney General's office saying this needs to change. He commented that GDNA will enforce whatever the rule is. He added that there is no rule stating the inventory has to be in a separate room. Director Troughton stated that is based on contracts in the hospital. He stated that Mr. Azzolin is right by stating the enforcement of this changed. He added that whatever direction GDNA receives from the Board is what they will enforce. President Harris commented that the members of this Board allowed this as recently as last year. Mr. Azzolin gave examples of when the Board issued permits in this situation. President Harris asked Vice-President Faulk why he had an issue with this. Vice-President Faulk commented that he does not have an issue with the same location. He stated that he thinks the "three (3) hours daily" needs to be cleaned up. President Harris responded by stating that the language states, "Except for..." and that is talking about regular retail. Vice-President Faulk commented that when you co-mingle a retail location in a hospital, it is still a retail location. Vice-President Faulk asked Mr. Brinson if he was happy with the rule. Mr. Brinson affirmed he was.

Mr. Changus commented that this is an issue of trying to merge two situations where, in a normal course, would operate differently. He stated the Board is dealing with the fact that it has allowed retail and hospital pharmacies to exist in the same space. He further stated that the question is how will the Board treat each if the entities reside in the same space. Mr. Changus questioned whether the Board was comfortable with allowing a retail pharmacy, because it is in a hospital space, to operate differently.

Public comments were received from Angela Ammons, Clinch Memorial Hospital: Ms. Ammons stated that she would like to stress that the hospital setting is different from a retail space. She stated that, given the pandemic and the hospital being located in a rural area, the reason they wanted to have retail space in the hospital is so they could provide better care. Ms. Ammons stated to the point of someone wanting to enter with negative intent, he/she already has access whether it is a retail space or not. She stated that there is a separate set of policies. She further stated that the pharmacist may step out, but rules and regulations do not allow any dispensing unless the pharmacist signs off. Ms. Ammons explained that it is imperative

for the success of the hospital that they are able to implement a retail space since two hospitals in Georgia have announced closure. She stated if the hospital were to close, it would be devastating to the county. Ms. Ammons requested the Board to move forward and adopt the rule versus tabling it. President Harris agreed and thanked Ms. Ammons for her comments. After further discussion, President Harris stated she did not want to table the rule for further discussion and suggested the Board proceed with adopting it.

Written responses were received from Greg Reybold, GPhA, and Becca Hallum, GHA.

Rule 480-10-.12 Minimum Equipment for Prescription Departments

No comments were received.

A written response was received from Becca Hallum, GHA.

Rule 480-10-.18 Pharmacy Anti-Steering and Transparency Act and Affiliates

No comments or written responses were received.

Rule 480-11-.04 Facilities and Equipment

No comments were received.

A written response was received from Becca Hallum, GHA.

Rule 480-13-.06 Drug Distribution Control

The Board recommended tabling this rule.

Rule 480-18-.05 Physical Requirements and Equipment

No comments were received.

A written response was received from Becca Hallum, GHA.

Rule 480-31-.01 Patient Counseling

Public comments were received from Greg Reybold, GPhA: Mr. Reybold stated that he appreciated the opportunity to comment. He stated GPhA feels that offers to personally counsel should remain verbal when patients are in the pharmacy. Ms. Emm stated that Mr. Reybold is correct. She added that the discussion came in regards to the delivery of drugs to patients, not necessarily with patients in pharmacy. The Board recommended tabling this matter for additional clarification.

A written response was received from Greg Reybold, GPhA.

Rule 480-33-.05 Physical Requirements

No comments were received.

A written response was received from Becca Hallum, GHA.

Rule 480-36-.03 Personnel and Supervision

No comments or written responses were received.

Mr. Azzolin made a motion to adopt Rule 480-6-.02 Nonresident Pharmacy Permit. Ms. Ashbee seconded and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion to table Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security. Vice-President Faulk seconded and the Board voted unanimously in favor of the motion.

Mr. Brinson made a motion to adopt Rule 480-10-.02 Prescription Department. Mr. Stone seconded and the Board voted in favor of the motion, with the exception of Mr. Prather and Vice-President Faulk who opposed.

Mr. Stone made a motion to adopt Rule 480-10-.12 Minimum Equipment for Prescription Departments. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion to adopt Rule 480-10-.18 Pharmacy Anti-Steering and Transparency Act and Affiliates. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion to adopt Rule 480-11-.04 Facilities and Equipment. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

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

Mr. Stone made a motion to adopt Rule 480-18-.05 Physical Requirements and Equipment. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion to table Rule 480-31-.01 Patient Counseling. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion to adopt Rule 480-33-.05 Physical Requirements. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion to adopt Rule 480-36-.03 Personnel and Supervision. Ms. Ashbee seconded and the Board voted unanimously in favor of the motion.

The public hearing was concluded at 10:10 a.m.

Open Session

President Harris spoke of the late Hal Henderson, who passed away on August 20th. President Harris stated that Mr. Henderson was a valued member of the Georgia Board of Pharmacy.

Approval of Minutes

Mr. Prather made a motion to approve the August 5, 2020 Public and Executive Session Conference Call minutes with the changes noted. Mr. Brinson 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. Brinson seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

The Board discussed the rule waiver petition from AU Medical Center Inpatient Pharmacy, PHH003623. President Harris commented that the petition requested a waiver of Rule 480-15-.05(a)(6). She asked

Director Troughton if this was allowed by law. Director Troughton responded by stating that GDNA visited the facility twice and 10% are patient-specific labeled prescriptions. He continued by stating that products going out of the pyxis are not being dispensed by the pharmacy. Director Troughton stated that O.C.G.A. § 26-4-60(j) states in part, “...no prescription shall be given to the person requesting the same unless the contents and the label thereof shall have been verified by a licensed pharmacist or practitioner.” Director Troughton commented that the facility could not verify 10% of what comes out of the pyxis. He stated that the law requires every patient-specific prescription to be verified by the pharmacist. He continued by stating that they are only verifying a portion of patient-specific labeled prescriptions. President Harris responded by stating if the law prohibits it, that ends the discussion. Ms. Emm stated that O.C.G.A. § 26-4-88(d)(2) states that a pharmacy technician cannot fill the prescription without certification of the pharmacist. Director Troughton added that Rule 480-15-.05(6) states this information as well.

Discussion was held by Mr. Azzolin who commented that a RAMS dispenses medications in a package with a label where no pharmacist checks it in a setting just like the one the Board is discussing. He further stated that he agrees the Board cannot deviate from the law, but did want to mention that there is another setting where this does occur that he knows is safe and would make their work load more efficient.

With no further discussion, Vice-President Faulk made a motion to deny the rule waiver petition. Discussion was held. Mr. Changus stated that this facility is requesting an exception to a rule that is backed by law. He further stated that their reasoning for such is not a substantial hardship. Mr. Stone stated that O.C.G.A. § 26-4-60(j) reads in part, “...no prescription shall be given to the person requesting the same unless the contents and the label thereof shall have been verified by a licensed pharmacist or practitioner.” He inquired as to who the “practitioner” is. Ms. Emm responded that O.C.G.A. § 26-4-5(33), defines a practitioner as “a physician, dentist, podiatrist, optometrist, or veterinarian and shall include any other person licensed under the laws of this state to use, mix, prepare, dispense, prescribe, and administer drugs in connection with medical treatment to the extent provided by the laws of this state.” There being no further discussion, Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Mr. Brinson made a motion to grant the rule waiver petition from Memorial Satilla Health-Rehabilitation. Ms. Ashbee seconded and the Board voted unanimously in favor of the motion.

Mr. Prather made a motion to deny the rule waiver petition from Rachel M. Peters. Ms. Ashbee seconded and the Board voted unanimously in favor of the motion.

The Board discussed the rule waiver petition from The Hemp Farmacy. Director Troughton stated that O.C.G.A. § 26-4-110(g) states, “It shall be unlawful for any person in connection with any place of business or in any manner to take, use, or exhibit the title “drug store,” “pharmacy,” “apothecary,” or any combination of such titles or any title or designation of like import or other term to take the place of such title, unless such place of business is licensed as a pharmacy under the provisions of this chapter, has submitted a written request to the board and received a waiver from this subsection, or meets the provisions of any rule or regulation regarding use of such titles and promulgated by the board.” Mr. Azzolin stated that he reviewed their website and there are six locations in North Carolina and one in Georgia. He further stated that in looking at the pictures, the spirit of the law is not to confuse the patient. Mr. Changus commented that this request has been submitted in the form of a rule waiver; however, this is a statute. He explained that the Board considered a request about a year ago that was designed to be a restaurant and the Board granted the request. Mr. Changus stated that in this case, as Mr. Azzolin pointed out, this does not look distinct from a pharmacy, an attempt has been made to liken it to a pharmacy and it does look like a pharmacy, but it is a very different kind of business. He stated that the Board has the

power to grant or deny a waiver in the law. Vice-President Faulk made a motion to deny the request. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jada L. Evans

The Board considered this correspondence regarding whether or not assisted living facilities are considered as long term care facilities for purposes of receiving faxed C2 prescriptions as an original script. Mr. Prather made a motion to direct staff to respond to Ms. Evans by referring her to O.C.G.A. 26-4-80(c)(1) which states, *“Electronically transmitted prescription drug orders shall be transmitted by the practitioner or, in the case of a prescription drug order to be transmitted via facsimile, by the practitioner or the practitioner's agent under supervision of the practitioner, to the pharmacy of the patient's choice with no intervening person or intermediary having access to the prescription drug order. For purposes of this paragraph, “intervening person or intermediary” shall not include a person who electronically formats or reconfigures data or information for purposes of integrating into and between computer or facsimile systems of practitioners and pharmacists;”* Based on the information provided in her correspondence, accepting a prescription from an assisted living facility would be considered an intermediary, and by law is not permitted. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Correspondence from Dr. Lisa Rudolph-Watson

The Board discussed this correspondence regarding a 30-bed Crisis Stabilization Unit (CSU), which utilizes an automated dispensing unit as an emergency drug kit. In her inquiry, Dr. Watson requested to change its use from an emergency kit to the primary source of medications during all hours of operation of the CSU and pharmacy. Ms. Emm commented that they are wanting to use it as more than an e-kit. She explained they are wanting to use it as daily dispensing. President Harris asked if that was allowed by law. Director Troughton responded by stating that it is not. He added that they want to use the e-kit for all doses as opposed to using for only emergency reasons. Vice-President Faulk made a motion to deny the request. Ms. Ashbee seconded. Discussion was held regarding how this was different from a RAMS or pyxis. Director Troughton stated what they are using is similar to a pyxis or omni-cell. He stated it is a sophisticated storage cabinet being used as floor stock, which is not allowed by law or rule.

Mr. Jeff Woodside spoke to the Board regarding this matter. He stated that there is a hospital pharmacy permit and hospital pharmacy space in this CSU. He explained that the request is to use the device as a pyxis. Mr. Woodside stated that the clinic, like other CSUs, does maintain stock bottles of prescription drugs. He added that they are looking to formalize it and provide more accountability around it by providing passcodes. He stated there is a retail pharmacy associated with this clinic that is located across town, but there is a hospital pharmacy permit located in same building as the CSU. Director Troughton responded that knowing they have a hospital permit in the building certainly makes a difference and to the question of whether they can use a cubex instead of pyxis, he does not see any issue with that. Mr. Brinson agreed with Director Troughton. Mr. Brinson asked if the orders are verified by a pharmacist before they are removed from the device. Mr. Woodside responded that since they are just using it as an e-kit, they are looking for guidance suggesting the pharmacist is engaged in the dispensing practice. Mr. Brinson stated during pharmacy hours, the order would be sent to the pharmacist first and for after-hours the policy would have to state that the nurse can remove whatever is needed after the pharmacist has verified it.

Director Troughton stated that prior to the rule that is in place under nursing homes, there were numerous discussions on how to help these CSUs do what Mr. Woodside has described. He continued by stating that former GDNA Director Rick Allen worked with the Board and the alternative was to allow a CSU to get a hospital permit and use the hospital space, but they still had to comply with the applicable rules. Director Troughton stated that the Board came up with Rule 480-24-.08 for that reason. He stated there was a need and that was part of what the solution was to help the need. He further stated that the provider pharmacy had the hospital permit. President Harris responded by asking if Genoa is the providing pharmacy and is in the same building as the CSU, would this be permitted. Director Troughton responded in the affirmative.

Dr. Lisa Rudolph Watson spoke to the Board. She stated that the CSU is the holder of the pharmacy permit in order to render the medications. She further stated that they have a dedicated space on site that is licensed and inspected yearly through Genoa. President Harris asked if the CSU has a pharmacy and is licensed as hospital pharmacy. Dr. Watson affirmed that was correct. The previous motion to deny the request was withdrawn. Mr. Brinson made a motion to direct staff to respond by stating that, based on the information provided, this would be permissible as long as all rules and regulations were followed. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Megan R. Scott

The Board recommended tabling this correspondence until after the vaccination discussion under the Executive Director’s Report.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA has conducted 598 inspections and received 77 complaints for FY2021.

Director Troughton reported that the U.S. Department of Health and Human Services (HHS) recently distributed a letter regarding the distribution of COVID-19 vaccines in the fall of 2020. He stated that the CDC has contracted with McKesson Corporation to distribute the vaccines. As such, he is under the assumption that McKesson will submit an application to obtain the proper permits/licenses. Director Troughton stated that once the applications are received, GDNA will inspect those facilities as quickly as possible.

Attorney General’s Report – Max Changus

No report.

Executive Director’s Report – Eric Lacefield

Continuing Education Report: Report presented. Mr. Stone made a motion to ratify the below listed 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 |
|-----------------|-------|---------------------------|--|-----------|
| 08/05/2020 | .5 | Kaiser Permanente Georgia | The ABCDs of BPSD: A Refresher on Dementia Behaviors | 2020-0011 |

Vaccine Distribution: Mr. Lacefield reported that Director Troughton discussed the memo distributed by HHS. Mr. Lacefield stated that the memo from HHS is available on Sharepoint for the board members to review.

Correspondence from Megan R. Scott: The Board discussed this correspondence requesting guidance for pharmacies that want to engage in administering the COVID-19 vaccine and vaccines for children. Mr. Azzolin asked if the Board could require them to update their protocols. Director Troughton responded that protocols are under the Georgia Composite Medical Board law and that law limits the type of vaccines; however, the memo from HHS overrides state law. He stated his understanding is that many states use similar language in their protocols and rules as those required by the guidelines for COVID-19 and pediatric vaccines. He added that GDNA looks for those things when conducting inspections. He stated that he does not think that this is anything different from what is already required, so no protocol would be needed. Director Troughton stated the question is if there are any violations, can the Board do anything about that and to whom would the violations be reported to. Ms. Emm commented that this

exception is only during the COVID-19 pandemic. She added that once the pandemic is declared over, allowing childhood vaccines to be administered by a pharmacist goes away.

Mr. Changus asked what the Boards' advice is for pharmacists in the field. He stated the federal government has attempted to give pharmacists the authority to order and administer these vaccines. He further stated that to the extent the practicalities have not been addressed in the federal directive, there is only so much that will be solved. Mr. Changus stated this eliminates the ability of the Board to discipline someone who is working in good faith under the federal guidelines. He stated the difficulty of having regulation at the state and federal levels do not always align. He further stated that he believes there is only so much direction the Board can provide as this is very different territory.

President Harris commented that if this is coming from HHS whether Georgia law be disregarded. Mr. Changus responded that one would not be disregarding Georgia law, rather there is a conflict between federal law and state law. Discussion was held by Mr. Reybold. He stated that under the Emergency Preparedness Act, there is pre-emption. He added that because this authorization from HHS gives the pharmacist the ability to order and administer, it negates the purpose of Georgia's protocol. Mr. Reybold commented that HHS may clarify its position, but for now there is no authority under Georgia law for a physician to enter into a protocol for childhood vaccines. He added that on a national level, they are looking for some clarification from HHS. Mr. Reybold stated there will be some growing pains with a pharmacist's ability to bill and get reimbursed. Mr. Azzolin commented that if the Board is giving guidance it should be to say that the law allows it but the pharmacist may have issues not getting reimbursed. The Board recommended directing staff to respond to Ms. Scott's correspondence by stating that per the guidance of the U.S. Health and Human Services (HHS), state licensed pharmacists are authorized to order and administer vaccines under the HHS access expansion. The Board suggests state licensed pharmacists should follow the guidelines issued by HHS.

In regards to vaccine distribution, Mr. Lacefield stated that board staff will process the applications expeditiously and send them to GDNA as quickly as possible.

Legal Services – Kimberly Emm

Correspondence from Jeanie Kim, Innovation Compounding, Inc.: Ms. Emm discussed this inquiry regarding prescription hardcopy storage requirements. The Board recommended tabling this matter pending receipt of additional information from GDNA.

Miscellaneous

Pharmacy location changes: Mr. Stone discussed pharmacy location changes. He stated this subject has been discussed at previous meetings. He commented that when a facility moves down the street, the facility is required to obtain a new license number. Mr. Stone inquired as to how patient safety would be affected if the facility is only moving a block away and must obtain a new license number. He stated that O.C.G.A. § 26-4-111(c) states, "*Pharmacy licenses issued by the board pursuant to this chapter shall not be transferable or assignable.*" He further stated that Rule 480-10-.06(1)(c) states, "*Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business.*" Mr. Stone commented that he would like for the Board to amend this rule. Mr. Brinson agreed and stated that there is a lot involved with changing a location. Mr. Azzolin commented that he has been through a move with a retail pharmacy permit. He stated that the location moved to a different town about 20 miles away. He further stated the space had to be inspected by GDNA, but the license number did not change. Mr. Stone stated that he understands the number changing if there is a change in mode of operation or mode of business. Mr. Lacefield commented that a few years ago there was a policy change. He stated that at the time, if there was only a change in location, a new license number was not issued; however, the Board changed its policy and that is how it has proceeded since that time. Mr. Azzolin stated that when a new pharmacy opens, an individual has to get a new license, new PBM, new DEA registration, etc. He further

stated that could be detrimental to a business that is moving. Mr. Stone added that patients cannot be serviced as well. Mr. Lacefield stated that this is a board rule which can be amended. Mr. Changus commented that O.C.G.A. § 26-4-111 states that pharmacy licenses shall not be transferrable or assignable, which means it is not supposed to be moved over. He stated that at some point the rule came into place. He stated that he assumes it was put into place for a valid reason, but as Mr. Lacefield stated, what is done on the administrative side is dependent on this rule. Mr. Changus commented that there may be reasons some felt a new license is required for a change in location. Mr. Changus asked Mr. Prather if he recalls the situation. Mr. Prather stated that Mr. Stone's point is very well taken. He stated that he has received numerous calls throughout the years from individuals that are moving the facility just a few yards away and because a new license number has been issued, he/she is having to redo all contracts, obtain a new DEA registration, etc., which puts the business on hold. Mr. Prather stated that he does not think the Board can solve this issue today, but it definitively needs to look at it closer and readjust the rule or law, if necessary. President Harris agreed and stated the Board can revisit this matter at a future meeting.

Rule 480-34-.15 Epidiolex

Mr. Prather made a motion to post Rule 480-34-.15 Epidiolex. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Rule 480-34-.15 ~~Additional Compounds under Schedule V~~ Epidiolex

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule ~~places an additional~~ removes the compound as specifically identified here under from Schedule V of the Georgia Controlled Substances Act, Section 16-13-29 and reclassifies it as a Dangerous Drug under the Dangerous Drug Act, Section 16-13-71 as follows:

- (a) Removes §16-13-29(1.5) Epidiolex: A drug product in finished dosage formulation in its original container that has been approved by and labelled in compliance with the U.S. Food and Drug Administration (FDA) that contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.
- (b) Adds §16-13-71(332.89) Epidiolex: A drug product in finished dosage formulation in its original container that has been approved by and labelled in compliance with the U.S. Food and Drug Administration (FDA) that contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

(2) This rule is based on the following findings of the Board:

(a) that the FDA approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is an oral solution that contains CBD extracted from the cannabis plant.

~~(b) that the U.S. Drug Enforcement Administration (DEA) did seek a medical and scientific evaluation or scheduling recommendation from the U.S. Department of Health and Human Services (HHS) with respect to the Epidiolex formulation. In responding to that request, HHS advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and therefore, recommended that if DEA concluded that control of the drug was required under the Single Convention, Epidiolex should be placed in Schedule V of the Federal Controlled Substance Act (CSA).~~

(b) that on August 21, 2020 the U.S. Drug Enforcement Administration (DEA) put forth an interim final rule which "removes from control in schedule V under 21 CFR 1308.15(f) a "drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-

benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols.””

(c) that the Board has considered, based on available information, the potential for abuse; scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; and the potential of the drug to produce psychic or physiological dependence liability.

A motion was made by Mr. Stone, seconded by Mr. Brinson, and the Board voted that the formulation and adoption of this proposed rule does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board also voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this proposed rule will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Mr. Prather made a motion and Mr. Brinson seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(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

- R.A.F.
- A.M.G.

Georgia Drugs and Narcotics Agency – Dennis Troughton

- J.D.A.M.H.

Cognizant’s Report – Mike Faulk

- GDNA Case # B33407
- GDNA Case # T33423
- GDNA Case # T33429
- GDNA Case # A33378
- GDNA Case # A33400
- GDNA Case # A33387
- GDNA Case # A33449
- GDNA Case # B33385
- GDNA Case # T33439
- GDNA Case # B33398
- GDNA Case # B33363
- GDNA Case # B33340
- GDNA Case # B33241
- GDNA Case # B33373
- GDNA Case # B33384
- GDNA Case # A33035

- GDNA Case # B33208

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- K.H.G.
- R.W.C.
- D.D.S.S.
- T.P.
- G.P.S.G.

Mr. Changus discussed pending disciplinary cases related to failure to properly notify the board of location changes.

Mr. Changus discussed the following cases:

- G.L.B.
- P.P. & P.P.
- T.C.
- P.M.P.
- Z.U.
- K.I.

Executive Director's Report – Eric Lacefield

No report.

Legal Services – Kimberly Emm

- J.L.

Applications

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

- L.A.L.
- A.A.N.
- J.E.C.
- O.L.S.
- R.T.E.
- B.H.S.I.
- M.S.S.
- C.M.S.I.
- E.U.
- U.S.S.F.

Correspondences/Requests

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

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

Open Session

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

Appearances

- | | | |
|----------|----------------------------------|--------------------------------|
| • R.A.F. | Pending Reinstatement | Refer to the Department of Law |
| • A.M.G. | Request to discuss reinstatement | Refer to the Department of Law |

Georgia Drugs and Narcotics Agency – Dennis Troughton

- | | | |
|--------------|-----------------------------------|------------------|
| • J.D.A.M.H. | Request re ambulatory care center | Approved request |
|--------------|-----------------------------------|------------------|

Cognizant's Report – Mike Faulk

- | | |
|----------------------|--------------------------------------|
| • GDNA Case # B33407 | Accept Signed Voluntary Surrender |
| • GDNA Case # T33423 | Accept Signed Voluntary Surrender |
| • GDNA Case # T33429 | Accept Signed Voluntary Surrender |
| • GDNA Case # A33378 | Accept Private Interim Consent Order |
| • GDNA Case # A33400 | Accept Signed Voluntary Surrender |
| • GDNA Case # A33387 | Refer to the Department of Law |
| • GDNA Case # A33449 | Close with letter of concern |
| • GDNA Case # B33385 | Close with no action |
| • GDNA Case # T33439 | Close with letter of concern |
| • GDNA Case # B33398 | Close with no action |
| • GDNA Case # B33363 | Close with no action |
| • GDNA Case # B33340 | Close with no action |
| • GDNA Case # B33241 | Close with no action |
| • GDNA Case # B33373 | Close with no action |
| • GDNA Case # B33384 | Close with no action |
| • GDNA Case # A33035 | Refer to the Department of Law |
| • GDNA Case # B33208 | Refer to the Department of Law |

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- | | |
|-----------------------------|--------------------------------|
| • K.H.G. | Private Consent Order accepted |
| • R.W.C. | Private Consent Order accepted |
| • Davids Drug Surgical Shop | Public Consent Order accepted |
| • Taylorsville Pharmacy | Public Consent Order accepted |
| • Guardian Pharm South GA | Public Consent Order accepted |

Mr. Changus stated more discussion was warranted regarding vaccinations and the conflict between federal law and state law.

Mr. Changus discussed pending disciplinary cases related to failure to properly notify the board of location changes.

Mr. Changus discussed the following cases:

- | | |
|---------------|---|
| • G.L.B. | Update provided |
| • P.P. & P.P. | Table pending receipt of additional information |
| • T.C. | Close with no action |
| • P.M.P. | Close with no action |

- Z.U. Close with no action
- K.I. Close with no action

Executive Director’s Report – Eric Lacefield

No report.

Legal Services – Kimberly Emm

- J.L. Request re revoked tech registration Denied request

Applications

- Victoria Fitzgerald Pharmacy Technician Approved for registration
- Emily R. Clausing Pharmacy Technician Approved for registration
- Aisa S. Jones Pharmacy Technician Approved for registration
- Bryan G. Bowden Pharmacy Technician Approved for registration
- Krystal L. Stone Pharmacy Technician Approved for registration
- Kelecha R. Wadley Pharmacy Technician Approved for registration
- Haley M. Enterkin Pharmacy Technician Approved for registration
- Tiffany J. Stephens Temporary Pharmacy Technician Approved for registration
- Brian C. Hanberry Pharmacist Intern Approved application
- Brian Galeano Pharmacist Intern Approved application
- Eric A. Moses Pharmacist Intern Approved application
- Fadi A. Abdallah Pharmacist Intern Approved application
- Kyana C. Grimball Pharmacist Intern Approved application
- Shiv K. Bhagat Pharmacist Intern Approved application
- Troy L. Ashe Pharmacist Intern Approved application
- C.L.S. Pharmacist Intern Approved request for extension
- B.M.C. Pharmacist Reciprocity Approved to sit for the exam
- D.E.K. Pharmacist Reciprocity Approved to sit for the exam
- G.S.G. Pharmacist Reciprocity Approved to sit for the exam
- J.R.H. Pharmacist Reciprocity Approved to sit for the exam
- L.S.I. Pharmacist Reciprocity Approved to sit for the exam
- L.A.L. Pharmacist Reciprocity Approved to sit for the exam
- Amber A. Newell Pharmacist Certification of DTM Approved application
- Jamie E. Coates Pharmacist Certification of DTM Approved application
- Olivia L. Steltenpohl Pharmacist Certification of DTM Approved application
- Reuben T. Elliott Pharmacist Certification of DTM Approved application
- B.H.S.I. Durable Medical Equipment Table pending receipt of additional information
- M.S.S. Durable Medical Equipment Table pending receipt of additional information
- C.M.S.I. Durable Medical Equipment Overturn denial and approve
- E.U. Researcher Pharmacy Refer to the Department of Law
- U.S.S.F. Manufacturer Pharmacy Refer to the Department of Law

Correspondences/Requests

- A.P. Notice of Discipline No action
- M.C.P. Notice of Discipline No action
- H.F.P.A.S. Notice of Discipline No action
- H.P.I. Notice of Discipline No action

| | | |
|------------|--|---|
| • I.R. | Notice of Discipline | No action |
| • I.A.T. | Notice of Discipline | No action |
| • M.B. | Notice of Discipline | No action |
| • O.P. | Notice of Discipline | No action |
| • O.C.S. | Notice of Discipline | No action |
| • M.F.V. | Notice of Discipline | No action |
| • M.F.V. | Notice of Discipline | No action |
| • O.S. | Notice of Discipline | No action |
| • S.V.P. | Notice of Discipline | No action |
| • S.P.I.I. | Notice of Discipline | No action |
| • T.S.M.I. | Notice of Discipline | No action |
| • C.V.S.P. | Request to terminate probation | Approved request |
| • A.E.M. | Request to terminate consent order | Approved request |
| • C.N.S. | Request to terminate supervised practice restriction | Approved request |
| • A.M.S. | Correspondence | The Board viewed this correspondence for informational purposes only. |
| • K.J.B. | Request for 4 th attempt at MPJE | Approved request |
| • S.A.P. | Request for 6 th attempt at MPJE | Approved request |
| • L.T.B. | Correspondence | The Board viewed this correspondence for informational purposes only. |
| • A.S.M.P. | Remote order entry | Approved |
| • G.S.P. | Remote order entry | Approved |
| • A.S.P. | Remote order entry | Approved |
| • M.G.C.C. | Remote order entry | Approved |
| • G.D.C.P. | Remote order entry | Approved |
| • P.S.P. | Remote order entry | Approved |
| • M.S.P.P. | Remote order entry | Approved |
| • V.S.P. | Remote order entry | Approved |
| • L.A.C.I. | Remote order entry | Approved |

Mr. Brinson seconded and the Board voted in favor of the motion, with the exception of President Harris, who recused herself from the vote regarding GDNA Case # A33449.

Miscellaneous

Mr. Azzolin inquired as to the status of in person meetings. Mr. Lacefield responded that the Board will be required to conduct virtual meetings until further notice. Mr. Azzolin commented that the reason he asked was because he was appointed to a committee, along with Mr. Henderson, to discuss protocol agreements with the Georgia Composite Medical Board. Mr. Azzolin stated that he reached out to Mr. Stone and asked if he would be interested in joining the committee in place of Mr. Henderson. Mr. Stone commented that he would be willing to join the committee if the Board approved such. The Board was in agreement with Mr. Stone joining the committee. Mr. Changus commented that, given the fact that it may be a while before the Georgia Composite Medical Board meets in person, if Mr. Azzolin and Mr. Stone would be interested in meeting virtually, he will reach out to the Board to see if that would be an option.

Mr. Azzolin requested the Board discuss what intern/externs are allowed to do in a remote environment.

Mr. Brinson requested the Board discuss increasing the pharmacy technician ratio at its next meeting. Ms. Emm commented that the ratio is set by statute. Mr. Brinson responded that he is aware of such, but would like for the Board to recommend or stand in unison with increasing the ratio. Mr. Stone added that he would like to see this for interns and externs as well.

Mr. Prather reported that the Georgia Medical Cannabis Commission will meet on Saturday, September 19, 2020 at 9:00 a.m.

There being no further business to discuss, the meeting was adjourned at 3:35 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, October 14, 2020 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6th floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I

Minutes edited by Eric Lacefield, Executive Director