GEORGIA BOARD OF PHARMACY
Conference Call
2 Peachtree Street, NW, 6th Floor
Atlanta, GA 30303
June 17, 2020
8:00 a.m.

The following Board members were present:
Lisa Harris, President
Mike Faulk, Vice-President
Carrie Ashbee
Michael Azzolin
Michael Brinson
Hal Henderson
Bill Prather
Dean Stone

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

Visitors:
Becca Hallum, GHA
Bethany Sherrer, MAG
John Rocchio, CVS Health
Stephanie Kirkland, Eldercare
Annalise Anise
Lindsay Burckhalter, Public Pharmacy
Stephen Georgeson
Helen Sloat
Chuck Page, Kroger
Tim Koch, Walmart

Open Session

President Harris established that a quorum was present and called the meeting to order at 8:06 a.m.

Ms. Battle 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 announced that this would be Ms. Battle's last meeting with the Board as she was retiring. President Harris stated that it has been a pleasure to work with Ms. Battle over the years. She further stated that Ms. Battle has done an excellent job as Executive Director. President Harris wished Ms. Battle well and stated that she will be greatly missed. Ms. Battle commented that for those members that have been around a while, the task of moving from the Secretary of State's Office to the Department of Community Health was no small task. She stated that with the team she has, it was done seamlessly. She further stated that it has been a pleasure to work with everyone.

Approval of Minutes

Mr. Brinson made a motion to approve the Public and Executive Session minutes from the May 6, 2020 Conference Call and the minutes from the May 12, 2020 Conference Call. Mr. Stone 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 issue. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

Rule Variance Petition from Immucor Inc., PHWH000582: President Harris explained that this facility is requesting a waiver of Rule 480-7-.03(7)(c). She stated that this facility supplies only one product. Director Troughton stated that they only have the one product that does not require humidity; however, he stated that if a waiver is granted, the facility could get any product they want to. Mr. Henderson inquired as to how difficult it was to comply. Director Troughton responded that he does not think it would be a tremendous financial burden for people. President Harris stated that she believed this would not cost thousands of dollars or be a financial hardship for the facility and they need to comply with the rule requirement. Discussion ensued. Mr. Henderson and Mr. Stone suggested granting the waiver as long as the facility only has this one drug. Mr. Changus commented that the rule requires all prescription drugs or chemicals to be stored at appropriate temperatures and under appropriate conditions in accordance with requirements. He stated that an appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs. He further stated that for this drug, it seems they are using what is necessary to keep the drug in that condition. Mr. Changus stated that in order for the Board to grant the waiver, the facility has to prove a substantial hardship. Mr. Azzolin made a motion to deny the rule variance petition, but also inform them that as long as it is that one drug, a variance would not be required. Mr. Prather seconded. Discussion was held by Director Troughton. He stated when GDNA does an inspection for every new wholesaler, they look for this. He asked if there is a caveat should a facility not stock drugs that have temperature and humidity requirements, is the Board good with that. He added that a wholesaler is not a facility that gets a routine inspection. President Harris responded that GDNA would need to point out that humidity checkers are required if the facility has drugs that require it. With no further discussion, the Board voted unanimously in favor of the motion.

Rule Waiver Petition from AU Medical Center Inpatient Pharmacy, PHH003623: President Harris stated that this facility is asking for the Board's approval of their Omnicell XR2 picking robot. Director Troughton commented that the last sentence of O.C.G.A. § 26-4-60(j) reads, *"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."* Mr. Henderson asked how would that work with an omnicell. He stated that he was trying to determine the difference with the person putting it in a robot and putting it in an omnicell. Director Troughton responded that he was just pointing out what the law said. He stated that an omnicell is like having floor stock and the pharmacy is not dispensing that drug. He further stated that there is a separate law covering what is dispensed out of a RAMS machine. Mr. Azzolin stated that the Board needs to know more about this device. Director Troughton responded that GDNA would be glad to go look at it and report back to the Board with the details as to what their process is. Mr. Changus commented that this petition is requesting a waiver of Rule 480-15-.05(a)(6). He stated that he understands the body of the petition has discussions about an omnicell and that may be worth exploring, but asked what is the Board's pleasure in terms of waiving the rule itself? Mr. Stone responded that the facility is saying when it comes out of the robot the pharmacist does not have to check. Mr. Azzolin commented that the technician is probably the one that is overseeing the device and they may be asking for a waiver so that the pharmacy tech can retrieve the final product from the device. Discussion was held regarding tabling the matter to allow time for further review. Ms. Battle commented that due to the time parameters, the Board could not table the petition because it would not be within the required time by law to wait until the next meeting. Mr. Faulk made a motion to deny the rule waiver petition. Mr. Stone seconded. Discussion was held. Mr. Azzolin stated that he agreed with the denial, but asked if the Board could give the facility some feedback stating that the Board had to deny the petition, but it needed more information. Mr. Prather and Mr. Brinson agreed. With no further discussion, the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Valdosta State Prison, PHPR003519: Mr. Brinson made a motion to grant the petition. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Correspondence regarding regulations pertaining to pharmacy closure

The Board considered this correspondence regarding a pharmacy that closed abruptly. The correspondence stated that notice was given to the Board, as required; however, customers who showed up for his/her prescriptions were met by a gated closed pharmacy. The correspondence suggests the Board revise its regulations that would require customers to be notified of the impending pharmacy closure at the same time they notify the Georgia Board of Pharmacy. President Harris stated it would be a good idea to notify the public. Director Troughton responded by stating that the rule only speaks to notifying the Board. He stated that it is up to the Board if it would like to change that. He further stated this was not a violation by the pharmacy because they did notify the Board of the closure. President Harris commented that it may not be financially feasible for everyone to send letters to their customers, but suggested they may be able to post it. Mr. Henderson agreed. He commented that the pharmacy can post it that they or closing or direct their patients to the nearest pharmacy. Mr. Prather commented that he believes it is better patient care for a store to let its patients know it will be closing so the patients can make arrangements to get his/her medication elsewhere. Mr. Azzolin suggested the pharmacy posting the closure somewhere in its community informing people that the pharmacy was closed, or for the Board to list it on its website. Mr. Stone commented that is a good gesture, but he does not think there is anything the Board can do. President Harris responded that the Board could amend its rule to say that the pharmacy is to notify the Board of the closure and also post it in a public place. Mr. Prather stated that he does not recall this issue ever being brought to the Board before. He suggested the Board take it as information for now and if it comes up again in the next month or two, the Board can deal with it then. The Board agreed.

Correspondence from Richard B. Davis, Quarles & Brady, LLP

The Board considered this correspondence asking if the delivery of gene therapy medications that must be delivered to the pharmacy at a hospital or other medical institution's pharmacy for administration was permissible. The Board directed staff to respond by stating that this was permissible provided that all applicable laws and rules are followed.

Correspondence from Sabena Furman

The Board considered this correspondence regarding conflicting information between Rule 480-27-.09(3) and Rule 480-31-.01(a)(3). Rule 480-27-.09(3) states a patient record shall be maintained for a period of not less than five years whereas Rule 480-31-.01(a)(3) states a patient record shall be maintained for a period of not less than two years. President Harris suggested this matter going on the Board's list of items that need correcting. Discussion about the length of time was discussed by the Board. Ms. Emm commented that the law requires two year maintenance. She stated that staff respond to inquiries regarding such by stating two years, but also suggest he/she check with CMS and Medicaid because they have their own requirements for their patients. The Board recommended amending Rule 480-27-.09(3) to reflect two years.

Correspondence from MasterPharm, PHNR000836

The Board viewed this correspondence for informational purposes only.

Correspondence from Kaitlyn George

The Board considered this correspondence requesting clarification regarding drug destruction on behalf of a long-term care facility. Ms. George's inquiry asks if the vendor pharmacy that provides the medication for these long-term care facilities is handling compliance packaging, are the pharmacy personnel authorized to waste discontinued medications? Mr. Henderson commented that the Board does need to do something about this because the way the rule is written now the facilities cannot destroy the medications

onsite like they did years ago. He mentioned considering a rule change to allow the vendor to take them back, isolate them and then send them to a reverse distributor for destruction. Mr. Henderson stated that in today's world, we do not think that is legal because we do not have licenses to transport those drugs to get them back to the pharmacy. He asked why it is the pharmacy's responsibility to destroy the medication after they have dispensed it. He suggested the Board review the rule and update it. Mr. Azzolin commented that it seems logical to him that a reverse distributor should be able to go to a long-term care facility because it is a licensed entity and can take anything that is out of date, that is waste and remove it. He further stated if this is the case, the nursing home would not have to be responsible for it. Mr. Azzolin stated that it seems logical, but he does not know if the rule prevents that. President Harris asked if nursing homes can deal directly with a reverse distributor. Mr. Henderson affirmed they could.

Director Troughton commented that he believes part of the problem is in O.C.G.A. § 26-4-5(38) which reads, *"Reverse drug distributor" means a person, firm, or corporation which receives and handles drugs from within this state which are expired, discontinued, adulterated, or misbranded, under the provisions of Chapter 3 of this title, the "Georgia Drug and Cosmetic Act," from a pharmacy, drug distributor, or manufacturer for the purposes of destruction or other final disposition or for return to the original manufacturer of a drug."* Director Troughton stated this may have been why that original rule said the drugs have to go back to the pharmacy based on the definition. Mr. Azzolin responded by stating it does not say you *cannot* do it from a nursing home, it only says where you *can* do it from.

Discussion was held regarding controlled substances and non-controlled substances. Mr. Henderson stated that he is only referring to non-controls. He stated there is already a process for inventory with witnesses of controlled substances that are to be destroyed in the nursing home. He further stated most facilities have containers and they put them in to neutralize them and that is an acceptable way to destroy those. Mr. Henderson stated to his knowledge they are not brought back to the pharmacy. He stated that the issue is with the volume of non-controls and bringing them back and transporting them, when they should not be transporting as he does not think it is the pharmacy's responsibility. President Harris asked what the Board should do. Mr. Azzolin responded by stating it can remove the rule that requires the pharmacy to pick them up and then let the reverse distributor get it. He stated that the pharmacy would not be required to get it. He added that if that is a workflow that is appropriate for some businesses, let them do it. Mr. Henderson commented that he does not think it is a good practice to take them back to the pharmacy. He stated the cleanest way to do is to eliminate that option. Ms. Emm commented that the Board would need to amend its rule, but she would need to further look at it first and compare it to what the law says. Mr. Changus asked Ms. Emm if it was just the definition she was looking at. Ms. Emm responded that she thinks the only other place in the law that addresses it is in the section about obtaining licensure. Mr. Changus stated that he and Ms. Emm would need to review it to see if the law would get in the way of the rule because part of the problem is because the definition of what a reverse distributor was contemplating was a very different field of pharmacy. He stated that he does not know when this was originally enacted, but it has been some time. Mr. Henderson asked if the Board licenses reverse distributors now? Ms. Emm responded that it is not a matter of whether or not the Board licenses them because a reverse distributor does have to have a Georgia license if they are going to work with the pharmacies. She stated that the problem is in the definition of a reverse distributor where it says they can select a pharmacy, drug distributor or manufacturer. Mr. Azzolin commented that the Board may need to take this matter to the legislature next year and inform them that due to changing times can they please add language stating, "nothing shall prohibit a reverse distributor from picking up drugs from a licensed nursing home".

Director Troughton discussed O.C.G.A. § 26-4-113(b) which states in part: *"Except where otherwise permitted by law, it shall be unlawful for any type of manufacturer, wholesale distributor, reverse drug distributor, outsourcing facility, or third-party logistics provider to distribute or deliver drugs or devices to or receive drugs or devices from any person or firm in this state not licensed under this chapter; provided, however, that out-of-state firms that conduct intracompany transfers of drugs…"* Ms. Emm

agreed and stated that nursing homes are not licensed under the pharmacy chapter. Mr. Changus stated that what Director Troughton was referencing probably formed the basis of what the rules state and probably put some limitations on the Board may be able to do via rule. President Harris requested Ms. Emm and Mr. Changus review and report back to the Board.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA has conducted 2357 inspections and received 411 complaints for FY2020.

Director Troughton reported that he meets weekly with the agents. He added that all of the agents are police officers. He stated they are doing a great job. He stated that they are not uniformed, but sometimes have to identify themselves as law enforcement.

Director Troughton stated when he was appointed as Director, Ms. Battle helped ease him into the position several years ago. He added that she has been very patient with him and has been a tremendous help. He expressed how much he will miss working with her. Ms. Battle thanked Director Troughton and stated the feeling was very mutual.

Attorney General's Report – Max Changus

Mr. Changus stated that at the Board's last meeting there was discussion about a proposed approach to the Georgia Composite Medical Board and looking to partner with them in terms of changing rules or approaching legislature on collaborative practice. He stated that he has spoken with Mr. Azzolin and Mr. Henderson and has also brought it up with the Chair and Executive Director of the Medical Board. Mr. Changus stated that the Medical Board is willing to entertain some discussion on this, which probably could be done at the next board meeting. He stated that as soon as the Medical Board schedules an in person meeting, a pharmacy board member could go speak to them about this matter.

Executive Director's Report – Tanja Battle

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

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
6/2020 - 12/31/2020	1	The Medical Center, Navicent Health	Medication Safety	2020-2007
7/14/2020 & 7/20/2020	3	Northside Hospital Cancer Institute	Annual Clinical Oncology Disease States Education 2020: Lung Cancer, Gynecologic Malignancies & Lymphomas	2020-0008

Legal Services – Kimberly Emm

No report.

Discussion Topics

Future of the Practical Examination: Ms. Battle stated that the Board did waive the practical examination for the remainder of the year due to the public health crisis; however, some board members expressed wanting to revisit this matter to discuss the future of the practical examination. Mr. Brinson commented that he is all for continuing the practical exam in some form, maybe not a traditional wet exam, but thinks the Board should continue with some form of practical with errors & omissions and calculations. He suggested setting up the candidates in a large room and give them 15 minutes per prescription in order to come up with the answer. He also suggested interviewing them like the Board has done previously for

the patient profile portion. Mr. Azzolin suggested the Board not bring the practical examination back and rely on the MPJE and NAPLEX. He stated that he is a firm believer in data and understanding why we do things. Particularly things that can have that level of impact relative to pharmacists having to wait two months to take the exam in order to obtain a position with a company and then losing that opportunity. Mr. Azzolin stated that the data he would like to see is data regarding the candidates that fail the first time and what percentage of them fail a second or third time. How often has the Board not allowed a candidate to get a license because he/she failed indefinitely? He stated that if the candidate passes a second time and did not the first time, there are only a few questions on that exam. He further stated that the Board cannot judge from those few questions if the candidate will be a knowledgeable pharmacist to the extent the NAPLEX can. Mr. Azzolin commented that the candidates have graduated from an accredited school of pharmacy and passed the NAPLEX and MPJE. He stated that he does not see the point of the practical exam. Mr. Azzolin stated that he thinks the practical exam is antiquated and does not see that a candidate making a mistake on the exam should be something that should prevent the candidate from being a pharmacist.

President Harris stated that it would be interesting to know who has been denied licensure because he/she could not pass the exam and knowing why did he/she did not pass it. She asked if it was because the individual did not have a calculator, which has been her point of contention. President Harris commented that she somewhat agrees with Mr. Azzolin, but does not want to give up the practical examination yet. She stated that she does believe it needs to be modified.

Mr. Prather commented that he is opposed to doing away with the practical examination. He stated that in his years on this board and attending many NABP meetings, he has never spoken to a board member who stated they were glad they gave up their practical. Mr. Prather stated that he thinks it serves as a valuable tool. He stated that he is concerned about a pharmacist who cannot do sixth to eighth grade math without a calculator. He further stated that he understands calculators are used now; however, the Board is not asking the candidates to do quadratic equations. Mr. Prather stated that it is straightforward addition and subtraction and there are just some things that are expected of some professionals. He stated that he agreed that some things may need to be changed on the examination. Mr. Prather stated that if all of the former board members were asked about the examination, the Board would have a tremendous amount of support in keeping the practical.

President Harris stated that when the Board discussed what to do with practical over the summer, she called North Dakota. She stated that they do a dry practical. She asked if the candidates were allowed to use calculators. She stated that the response was “no” because most people have calculators on his/her phones and that they do allow a phone because when the pharmacist is out in practice, he/she will have a phone. President Harris stated that the Board wants to see how these people can problem solve when they are in a real practice setting. She stated that sixth grade was a long time ago and we are all acclimated to using technology, especially these students. She stated that she feels like that is a bit of an unfair advantage. President Harris stated that with USP 800 coming, she does not know if the Board needs to do a wet practical because most places are not going to be doing compounding, but does feel the candidates need to know how to do calculations. Mr. Azzolin responded that he would like to know that the candidates can do calculations too, but they have already proven that they can. He added that he does not have any doubts if someone graduates from an accredited school, he/she can do the math. Mr. Azzolin stated that when the candidate comes to the practical, he/she has no idea as to what kind of question(s) will be asked and on top of that, they have no references. He stated that in regards to NABP board members saying not to give up the practical, one thing he would like to see is how many licensed pharmacists in the state that are licensed in Georgia would state to give it up or keep?

Mr. Stone commented that he sees taking the practical as a rite of passage. He stated that he also knows that the Board may be prohibited on some of the things it is facing now such as COVID. He further stated

that if the Board is able to start the practical again, there may be a problem with offering the test to as many candidates that it has in the past. Mr. Stone stated he is concerned about the budget and also sees that technology has changed the way we do things. He stated that when he is in his every day practice and he sees something that he has never seen before, he has references and is able to look up things. Mr. Stone stated that he also has concerns with the time it takes for someone to get licensed in this state because after August the individual has to wait until January. He stated that he is also interested in knowing who is failing the exam and are they in-state or out-of-state graduates.

President Harris asked Mr. Lacefield if he was able to give the Board some statistics. Mr. Lacefield responded that he does have statistics on total passing rates for in-state versus reciprocity candidates. Mr. Azzolin asked if Mr. Lacefield could give the total vs first time exams? Mr. Lacefield responded that he could provide that information, but it is not readily available. President Harris commented that it would be interesting to see the number of people that failed the test, but who also failed NAPLEX. Ms. Battle stated that she understands why that information is important, but because staff have not tracked it before, that would be quite an undertaking. Mr. Lacefield added that staff would have to go into candidates' records individually. Mr. Azzolin suggested speaking with NAPLEX to see if they can extract that information. Mr. Stone inquired about the budget as that is a concern. Ms. Battle responded that the budget will have an impact. She stated that if the Board does not make any changes with the practical, it will be paying for travel for former board members. President Harris stated that the Board does not have to make a decision today; however, it does need to determine what changes need to be made. She stated with USP coming, she does not feel a wet lab is necessary and thinks that would save money. Mr. Stone responded that the Board would then have to figure out when it would test as he does not think that the Board would be able to test in January. He stated that if the Board changes the practical, it needs to have at least a four month lead time to plan out and work through it. Vice-President Faulk commented that the Board needs to look at updating the test and then be ready to discuss it further come September.

Mr. Lacefield reported that in 2019, the total passing rate for candidates in January was 85%, in March 84%, and June 97%. He added that for those coming in by reciprocity the passing rate in January was 84%, in March 83% and in June 94%. President Harris suggested for the ones that fail the exam, in a couple of months pull them up and see what their scores were on NAPLEX and MPJE. Mr. Azzolin suggested the Board look at those three exams to see if the 15% that failed the first or second exam pass the third exam. President Harris responded that would be something to look at. She suggested doing that and then compare the pass/fail rate with the candidates that failed when they took NAPLEX and MPJE.

Chart Orders as Valid Prescriptions: Mr. Henderson stated that he has brought this issue up several times. He stated that in a long-term care pharmacy typically it has been standard practice that they use chart orders. He explained that physicians do not typically write prescriptions in a long-term care environment. Mr. Henderson stated that there is a nurse documenting, one is managing and one is administering the drugs. He stated this is the standard of practice everywhere. He explained that the problem is with audits by third parties. Mr. Henderson stated that they come in and ask for a copy of the prescription, which they do not have. He stated that they have the chart order, but what it lacks in what a prescription is required to have is quantities, number of refills, etc. He stated those are the main things that come to mind. Mr. Henderson stated that in a skilled environment, the orders are written by the doctor and they are standing orders typically for 30 or 60 days. He stated that refills are not needed as long as you have an active order and the nurse can reorder the medication. He further stated that the quantities are not necessary because based on the dispensing system, they may send one day, seven day or 30 days, but as long as there is an active order on the chart, it can be refilled. Mr. Henderson stated that he is requesting chart orders be considered valid prescriptions in institutional facilities. President Harris asked if the patient can be dismissed from the facility and take the chart order with them? Mr. Henderson responded that the order is void once they leave the facility. President Harris asked if it would be enough for the Board to say it is a valid prescription if a PMB was doing an audit. Mr. Henderson responded by stating if the Board

says chart orders are valid prescriptions and list what is required to be on them, then the PBM would have to accept them as prescriptions. Mr. Brinson agreed with Mr. Henderson. He commented that he sees this all the time. He explained that with their chart orders, if they have a discharge, the doctor writes out discharge prescriptions and they either fill or send the prescriptions to where the patient is going.

Ms. Emm commented that there is no separate licensure between long-term care and retail. She added that all long-term care facilities are licensed as retail facilities. She stated that if the rule was amended to say that chart orders are considered valid prescriptions in institutional facilities, any pharmacy can accept a chart order. Mr. Henderson responded that it would not be a problem. He explained that it is the location of where the resident is that determines whether or not you have a chart order. He stated that in a skilled nursing facility or similar environment, they work off of chart orders. He further stated that someone else is responsible for managing and administering the drugs. Mr. Henderson stated the Board could define the location where a chart order is acceptable. Mr. Azzolin suggested amending the nursing home rules to say that nothing shall prohibit a chart order from constituting a valid prescription in a nursing home licensed in the state of Georgia, so you are limiting where a chart order can be considered to within a nursing home.

Discussion was held by Ms. Emm regarding a practitioner drug order under Rule 480-27-.01(q) which states, "*Practitioner Drug Order. A drug order written in an institutional practice/setting in a patient's chart for a specific patient. It is not necessary to reduce to writing as required for a prescription drug order."* Ms. Emm stated that a practitioner drug order is not defined by law, nor is it referenced anywhere else in Board's rules. Mr. Stone asked if the rule could be amended to state, "In the settings of a long-term care nursing home, a practitioner drug order is acceptable." Ms. Emm responded by stating that the Board would also need to include what information is required on a practitioner drug order. Mr. Prather asked if there could be one definition of a prescription that was in a nursing home setting and one definition in retail setting where both are recognized by the Board as prescriptions. Mr. Henderson affirmed that would be sufficient. Mr. Prather commented that the simplest solution would be to come up with the definition of a prescription in a nursing home setting and what is included on that prescription, as opposed to retail and list two separate definitions. Mr. Henderson stated that it seems there are not any board members opposed to this recommendation. He stated that he will work with Ms. Emm regarding the matter.

Mr. Stone suggested having a committee to work on rules and present back to the Board. Ms. Emm responded that any sort of committee meeting discussing rules has to be a public meeting.

Appearance

Appearance by Mr. Andrew Turnage, Executive Director, Medical Cannabis Commission: Mr. Turnage stated that he appreciated the Board allowing him to speak to its members. Mr. Turnage explained that he was in his fourth week in his new role as Executive Director. He stated that with a brand new law, the primary focus for this commission is to promulgate rules. He added that he would be available to answer any questions the Board has. Mr. Changus commented that one of the questions the Board had was just trying to get a sense of the timeframe as far as moving these rules. Mr. Turnage responded that one thing is they are waiting on is to see what happens with the budget. He stated that as far as timing, it depends of availability and what pace the Commission wants to set. He added that the Commission's goal is to make applications go live in the new fiscal year. President Harris asked what the Board's responsibilities would the Board be as far as discipline. Mr. Turnage suggested the Board review O.C.G.A. § 16-12-206 as a primary reference regarding such. He stated that it is his take the Board of Pharmacy will develop rules and regulate dispensing in the state. Ms. Battle added that the disciplinary functions would fall to the Board as well. Mr. Turnage stated it would be a joint effort. Mr. Prather commented that this is still a Schedule I narcotic and quite frankly, there will be legal questions as to how we work our way through that. He stated that he would like to see pharmacy involved with this distribution. He added that he does not know how the Board and the Commission will deal with that. Mr. Azzolin agreed with Mr. Prather and stated that he does not see how one can dispense this drug from any other place than a pharmacy. Mr.

Prather commented that of the states that have legalized this, there are five states that require the involvement of pharmacists directly. He stated that he knows the Commission has been looking at several states and how they handle cannabis and how pharmacy is involved. He added that the Commission has not met virtually or otherwise since the public health crisis began. Mr. Turnage stated that, in reference to the items mentioned, it is important to note all states that have put a cannabis program in place are operating with a safe harbor law. He added that many are under a misconception about how that works. He stated that the difference with cannabis is that it is based entirely on a doctor's written certification. Mr. Brinson asked if the dispensaries are not really pharmacies? Mr. Turnage stated that was correct. He added that they are not required under the law to be a licensed pharmacy and would fall under the Commission.

Discussion Topics – Continued

Collaborative Practice: Mr. Changus stated that he touched on this topic earlier. He stated that Mr. Azzolin and Mr. Henderson may want to elaborate. Mr. Stone commented that he believes this may tie in to something he wanted to discuss, which is drug therapy protocols and retail pharmacy. He stated that he is looking at drug therapy protocol and how it applies to a retail pharmacy setting. He stated there is training and working close with doctors to be able to care for patients seen monthly, doing assessments, etc. Mr. Stone stated that he is wanting to know more about how that relates to a community pharmacy. He asked if it was addressed in a rule or is that allowed? Mr. Henderson commented by stating that is exactly what he and Mr. Azzolin were trying to accomplish with the Medical Board. He added that location should not matter. He stated that as currently written, "Drug Therapy Management" needs to be broadened considerably. Mr. Azzolin commented that ultimately the way they decided to approach it is to make sure the Medical Board understands the Board's intention is not to change the scope of a pharmacist, but to make it easier for a physician to work with a pharmacist. He stated that the physicians would have more flexibility to care for his/her patients and the idea is to help them understand the Board wants to give them more control and freedom. He added that it would probably be most applicable to retail pharmacists. Mr. Stone responded by stating that currently the way he reads everything is that retail could not do this. Mr. Azzolin stated that the way he understands it is retail could, but they would have to have a drug therapy protocol with each doctor and each patient they want to do it with, and then they have to get it approved by the Board which is impractical considering modern services and the frequency of eligibility changes for those services for patients. Mr. Prather asked if the nurse practitioners have an agreement with a doctor they work under? Mr. Changus commented that the idea behind nurse practitioners and physician's assistants is that they are called physician extenders. He stated that O.C.G.A. § 43-34-24 does not give them the freedom to do what they need to do. He added that there is a protocol and understanding between nurse practitioners, physician's assistants and physicians. Mr. Changus stated that his understanding is the current law does not allow the flexibility to accomplish what the Board is needing.

E-Kit by an Out-of-State Pharmacy: Mr. Henderson stated this topic was previously discussed several months ago. Director Troughton commented that GDNA received a letter from an out of state pharmacy that was a servicing nursing home in Georgia. Mr. Henderson stated that Director Troughton's question to the Board at that time was could the out of state pharmacy put an e-kit in the facility. He stated that the Board voted to not allow them to do it because they were out of state and in doing so, the Board was penalizing the patients. President Harris asked why the Board did not allow it. Director Troughton responded by stating that O.C.G.A. § 26-4-114.1 states, *"Any person, pharmacy, or facility located outside this state may apply to the board for a nonresident pharmacy permit which shall entitle the holder thereof to ship, mail, or deliver dispensed drugs, including but not limited to dangerous drugs and controlled substances, into this state. The board shall establish an application and require such information as the board deems reasonably necessary to carry out a background investigation of applicants and to ensure that the purposes of this Code section are met."* Director Troughton stated that an e-kit is not a dispensed drug. He stated that he agrees it is a critical piece to have in the nursing home. Mr. Henderson asked if the code section prohibited an e-kit from being allowed. Mr. Changus commented that Director Troughton is

focusing on the term that says "dispensed drugs". He stated that the facility is shipping something into the state that has a prescription. He further stated that this non-resident pharmacy would be sending drugs into the state for the purposes of establishing an e-kit. Director Troughton responded by stating that is the hurdle he was pointing out and it is his job to make sure people are in compliance. Mr. Henderson discussed how an e-kit was critical to a nursing home. Mr. Brinson stated that he does not see any reason why the Board cannot allow it. Mr. Changus stated that the Board has discussed items that need to be corrected by statute or rule. He stated that it does not seem with the way the statute is written that it can come from a non-resident pharmacy. He further stated that it may be something that is a restriction that no longer has a purpose, but it was put into the statute. Mr. Changus stated that adjusting the rules does not get around that stumbling block. Discussion was held regarding dispensing. Ms. Emm stated that "dispensing" is defined on its own in O.C.G.A. § 26-4-5(10) and states, *"Dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient, patient's caregiver, or patient's agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient."*

Vice-President Faulk commented that Mr. Henderson is correct and the Board should allow it, but the statute prevents the Board from allowing it. Mr. Azzolin asked if the Board had a mechanism to deliver items to the legislature. Mr. Changus responded by stating that the Georgia Pharmacy Association would be the sort of entity that would bring those matters before legislature. He added that members are not supposed to lobby in a sense. He stated that he does not know if there has been a formal approach in the past. Mr. Prather responded that, traditionally, the Board has used the Georgia Pharmacy Association who have lobbyists that would go to the legislature, but in this case the Georgia Pharmacy Association is not representing pharmacies from outside the state of Georgia. President Harris stated the National Hospital Association could represent out of state vendors on the Board's behalf, but this is a legislative matter.

Temporary Licenses: Ms. Battle asked if there were any unresolved issues. There were none. Ms. Battle commented that this topic was added to the agenda just in case the Board needed to talk about it. She added that the public health emergency will expire July 12th.

Pharmacy Technicians: Mr. Brinson stated that he presented information to the Board in September concerning certification and continuing education for pharmacy technicians and at that time, the Board recommended tabling the matter. He stated the Board discussed three options. Option #1 would require all technicians to obtain 10 hours of continuing education for each renewal. He stated that the Board held a lengthy discussion about not having personnel to conduct audits. Mr. Brinson stated Option #2 would require all pharmacy technicians to be certified by 2025. He stated Option #3 would require any new technician registered by the Board after June 30, 2021 to become certified within two years of being registered. Mr. Brinson stated this option would allow any technicians who are not certified to continue working, but newly registered technicians would have to obtain certification. He suggested the Board table for another six months because it is unsure about the budget at this time. President Harris commented that she liked the idea regarding requiring continuing education and asking all incoming techs to be certified by 2023. Mr. Brinson responded that he did not think the Board had the manpower to perform these audits. Ms. Battle commented that it would be difficult to do such. Mr. Prather stated that he understood the piece about continuing education and the budget constraints; however, he asked for the Board's thoughts on going forward with requiring technicians to be certified as there seems to be more and more responsibility added on to the technicians. Mr. Brinson commented that he liked the idea of requiring new technicians to be certified by 07/01/2023. Mr. Prather stated that he thinks sooner or later the Boards need to require technicians be certified if the national stage continues to heap more responsibilities on them. Mr. Brinson agreed, but stated there are many independent pharmacies that have technicians that have worked there for 20 years and will not pass a certification. He stated that he does not feel it would be fair for the Board to mandate the technicians either be certified by a certain date or the individual could not work in a pharmacy. Mr. Henderson stated that the Board does not distinguish between non-certified versus certified

in their responsibilities. He stated that he thinks Mr. Prather was saying there would be two different levels of technicians and the ones who were certified would be able to do more than the non-certified. Mr. Stone commented, while he understands it is in the statute, he thinks it may be time to increase the technician ratio. He stated that technicians are valuable and they help him every day.

Diversion and Fines: Mr. Stone stated that he wants to make sure the Board is being reasonable and fair when it comes to issuing fines. He stated that he is not saying the Board should do away with fines, but feels the Board should educate pharmacists more. Mr. Azzolin commented that the DEA says if the diversion is not reported, the DEA will issue a fine. He stated that when diversion is reported to the Board, the Board issues a fine. Mr. Stone stated that he constantly tells pharmacists to make sure they do certain things. President Harris stated that she does not want to discourage individuals from turning in those who are diverting. Mr. Prather asked if he was hearing some members say the Board should allow someone to allow drugs to be taken and not do anything to them in the way of punishment when the law clearly states the PIC or pharmacist is totally in charge of what goes on in that pharmacy. Mr. Stone responded by stating that he is not suggesting the Board not fine them. He suggested giving the pharmacists guidelines as the Board does not give them any. Mr. Prather asked if the laws and rules that were in place were sufficient, as they are very specific about what a PIC's duties are. President Harris commented that what Mr. Stone is trying to say is the person may not be consciously doing it and may not catch where there has been diversion until inventory is done. Mr. Prather stated that he appreciates what Mr. Stone has to say, but if the Board does not have rules or a law that give parameters that outline the duties for PIC's and pharmacists that the Board does not enforce, why even have the law. Mr. Azzolin commented that if one were to look at medication errors and how those errors are to be identified, the standard of practice is to remove punitive action from the equation. He stated that instead what they do is they look at system processes and why that error occurred and fix the why and not the who. Mr. Prather stated that Mr. Azzolin is talking about drug diversion and misfills. He asked if the Board plans to enforce the law or not. He further stated that it is the pharmacist's job to know what his/her duties are as a PIC. Mr. Azzolin asked where the law states that the Board will fine someone for doing this. Vice-President Faulk commented that the problem lies if a good number of medications are diverted. He added that then there would be a fine. He stated that it is unfortunate if you have a good pharmacist.

Mr. Stone commented that he has mentioned before requiring a biannual inventory. He stated that someone could steal a certain amount of tablets of anything. He further stated that, as a Board, it should help patient care and what is expected of pharmacists. Vice-President Faulk stated that the Board does try to be consistent with its fines. Mr. Azzolin stated that he appreciates consistency, but he agrees with Mr. Stone. He stated that he does not see how a person who has a livelihood should be held accountable when he or she finds out that a rogue tech or pharmacist was able to divert drugs. Mr. Azzolin stated that if he does not report to the DEA, he would be fined and when he reports to Board, he would also be fined. He stated the Board has a method of punishing folks instead of rewarding them for reporting diversion. President Harris asked if a pharmacist allowed someone under his/her watch to divert, should the Board require any sort of continuing education? Mr. Changus commented that on the case-by-case matters, those will be discussed in Executive Session. He stated that all concerns raised by all parties are important to consider. He added that he will have some more thoughts from Attorney General's office on this matter. Mr. Changus commented that imposing additional requirements upon checking was mentioned. He stated that requires the rule process and agreement on what is appropriate in terms of asking a pharmacist what to do. He added that this is was a difficult issue, but certainly an interesting topic for him. Mr. Changus stated he appreciated listening to the viewpoints, but will have more comments for the Board in Executive Session.

Point-of-care Testing: Mr. Stone stated that point-of-care testing was something he has been looking at for years. He stated that years ago he purchased equipment that was CLIA waived and never used it. Mr. Stone stated in regards to point-of-care testing being nasal, pharyngeal swabs, etc., it is not clearly defined

if a pharmacist can do that. He discussed testing patients and saying it is flu or strep and reporting that information to the patient's physician. Mr. Stone stated he wanted to see where this was addressed and asked for the Board's thoughts. He added that he believes pharmacists are poised in a good way to do these things. Mr. Azzolin commented that he had a conversation with Greg Reybold about throat swabs and according to Mr. Reybold, pharmacists cannot do those because it is not a CLIA waived test. Ms. Emm directed the Board to O.C.G.A. § 26-4-4 which states: *"The "practice of pharmacy" means the interpretation, evaluation, or dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care; performing capillary blood tests and interpreting the results as a means to screen for or monitor disease risk factors and facilitate patient education, and a pharmacist performing such functions shall report the results obtained from such blood tests to the patient's physician of choice; and the responsibility for compounding and labeling of drugs and devices."*

Extern/Intern Ratio: Mr. Stone stated he knows the ratio is limited by statute. Director Troughton referred Mr. Stone to O.C.G.A. § 26-4-82(e).

Rules Review: Mr. Stone stated that he was going through rules as some are outdated. He previously mentioned having a committee review the rules, but found out the meeting regarding such would need to be held in Open Session to the public. He stated that the Governor is wanting to get rid of unnecessary regulations and believes the Board needs to get rid of outdated rules. President Harris responded by stating that GDNA has started a list of rules that are in conflict or need tweaking. Mr. Azzolin suggested putting that list on Sharepoint so that members can add comments to it. Director Troughton stated that what GDNA is reviewing is the conflict in the rules regarding maintaining records for two years and five years. President Harris stated that it could be a running list.

Counseling: Mr. Stone stated that he personally offers counseling; however, he wanted to discuss further with the Board due to all the technology and the reality of it. He stated the Board previously discussed this matter concerning mailing or delivering and having a personal offer of counseling. He added that he is not stating there is a conflict, but just wanted to revisit the topic. He asked how does technology play in to that and the offering of counseling. Ms. Emm responded that the rule that the Board voted to amend in January is currently being reviewed for statutory authority by the Attorney General's office. She stated that if statutory authority is received, the Board may be able to move forward with the public hearing. Ms. Emm stated that the Board voted to amend Rule 480-31-.01(c)(1) which states in part, *"Upon receipt of a Prescription Drug Order and following a review of the patient's record, the dispensing Pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. <u>The personal offer to counsel may be made verbally or in written format; a written offer must provide a telephone number and business hours during which the dispensing pharmacist can be reached.</u>"*

Remote Prescription Drug Order Processing: Mr. Stone commented that with the pandemic, this is about technicians and where data entry is taking place. He stated that he does not think there is anything the Board can do. He further stated that O.C.G.A. § 26-4-82(c) talks about the technology and personally supervising that data entry. Mr. Stone stated that a lot of system data entry is done by the technician and is then reviewed by the pharmacist. Ms. Emm stated that the Board has an emergency rule in place based on an executive order suspending the direct supervision requirement for that specific practice [Executive Order 03.31.20.04]. Mr. Azzolin asked where is it defined that data entry by a non-registered person is prohibited? Ms. Emm responded by stating that the code section is O.C.G.A. § 26-4-82(c)(3), which expressly states that when utilizing electronic systems, a pharmacy technician may enter information. Mr. Azzolin commented that right now there is a major health crisis. He stated that by allowing it to go back to

the way it was, the Board is saying when there is less of a need, it will make it harder for technicians to support pharmacists. President Harris and Mr. Brinson agreed.

340B Contract Pharmacy: Mr. Azzolin directed the Board to a handout he provided regarding this particular issue. He stated that he appreciated the Board looking at it and would be happy to elaborate on it when the Board sees fit.

At 12:09 p.m. the Board recessed for lunch. The meeting resumed at 12:45 p.m.

Rules Review/Discussion

Rules referencing a balance requirement: Ms. Emm stated that at a previous meeting the Board requested she review and adjust the rules that mention the balance requirement to bring them in line with the hospital rule. Those rules were Rule 480-10-.12 Minimum Equipment for Prescription Departments, Rule 480-11-.04 Facilities and Equipment, Rule 480-18-.05 Physical Requirements and Equipment, and Rule 480-33-.05 Physical Requirements. After further discussion, the Board requested Ms. Emm adjust the wording in each to read: *"If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance;"* Ms. Emm stated that she will make the changes and post them on Sharepoint for the Board to review.

Conflict between O.C.G.A. § 26-4-83.d and Rule 480-27-.09 Patient Records: President Harris stated the Board discussed this matter earlier in the day. Ms. Emm responded that the Board directed her to change the rule from five years to two years to make it consistent.

Retail licenses in hospital pharmacy licensed spaces: President Harris stated she has done a lot of thinking about this subject and does not have an issue with it. She asked for the Board's thoughts on waiving the 150 square foot requirement. Mr. Brinson commented that if someone wants a retail license to start dispensing, he does not have an issue with having it in the same space and does not have a problem with having the drug all together. He stated that he does have an issue with nurses coming into the pharmacy after hours due to past experiences. He further stated if nurses are allowed, he would like for there to be some type of video surveillance. President Harris responded by asking if it says somewhere in the rule about a nurse not being able to enter a retail pharmacy without the presence of the pharmacist? She stated the rule would need to be changed to reflect that. Director Troughton stated that was the conflict originally. He asked how GDNA would enforce that. Mr. Azzolin responded by stating language could be added to Rule 480-10-.02(4). Director Troughton commented that if the issue is solved with amending the rule, GDNA will enforce it. Vice-President Faulk asked if retail is in the same space as the hospital, will they be exempt from the same rules? Mr. Azzolin responded by stating there are a couple of ways to handle that. Mr. Azzolin discussed a scenario where he was on call and multiple burn patients presented to the ER and the nurses ran out of irrigation fluid. He stated that they called because they were scared to enter the pharmacy because they had been instructed to limit access in the past. Mr. Azzolin approved their entry to the pharmacy based on the rule allowing nurses to do so if the situation would otherwise harm the patient and the fact that it would have taken him 20 minutes to present to the pharmacy. Mr. Brinson commented that one of the main reasons he had to leave the pharmacy when he had both was with a "code blue", but he always had someone available to cover for him. He stated no prescriptions were dispensed or sent out until he returned.

Mr. Brinson asked how the Board came up with "five minutes" as mentioned in Rule 480-10-.02(4)(a)(1). Mr. Prather responded that this rule was changed because the Board was trying to redefine direct supervision. He stated that the way it had been interpreted before was if the pharmacist went out onto the floor to answer a question for someone, he/she could be in violation. Mr. Prather stated the Board was just trying to ease the burden on the pharmacist. Mr. Stone responded that he appreciated the Board making that change, but if he were to go out and counsel a patient and the person kept talking, it may take more

than five minutes to get back in the pharmacy. Discussion was held regarding if the pharmacist was outside the pharmacy providing pharmacy care, he/she would not be in violation of the rule.

The Board discussed Rule 480-13-.05 Physical Requirements.Amended and Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed. President Harris asked does hospital square footage count? Mr. Azzolin stated that if they exist in the same platform, it would count. President Harris asked Director Troughton if he had any issues regarding this matter. Director Troughton responded that GDNA will enforce board rules as written. He stated that once the Board changes that to allow it to be a coexisting space, there would not be a need to have two of everything. Discussion was held about inventory and tracking the records. Mr. Azzolin commented that there is nothing in the rules that speaks to using a refrigerator with two different licenses. He stated that he thinks the Board could specify the retail inside the hospital space, and that it is okay for nurses to go in only in certain instances. Discussion was held regarding modifying Rule 480-10-.02(4) to read, "*Except for pharmacy benefit manager retail pharmacies and retail pharmacies located in the same space as hospital pharmacies, a Licensed Pharmacist shall be present and on duty in a licensed retail pharmacy as follows:"*

Discussion was held regarding deleting subsections (2)(a)(3)(4)(5)(6)(8) and (2)(b) of Rule 480-13-.05. Ms. Emm stated she will review the requested changes and report back to the Board.

Rule 480-24-.04 Drug Distribution: Mr. Azzolin discussed section (7)(d), which states, *"An emergency drug kit must be inventoried at least once a month by a pharmacist from the provider pharmacy and sign a card attached to the kit indicating the date it was inspected. The provider pharmacy must maintain an adequate record of such inspections."* He pointed out that some emergency drug kits are electronic and the information of inspections are available in the database indicating the inspection dates. He requested the Board consider altering the language to eliminate the requirement of the manual signature and card on these types of kits. Deputy Director Karnbach discussed language that was similar. Specifically, the last line in Rule 480-33-.04(d)(4), which reads, "*Labeling - exterior. The exterior of emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by the Board, the GDNA or one of their agents;"*

Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders: Mr. Azzolin stated he had some "cleanup" suggestions. He stated that the last few words were truncated in section (3). He requested a change to allow electronic documents to be acceptable for files for prescriptions. If paper scripts are obtained, request for allowance of scanning in and attaching to the pharmacy information system data for retrieval as this would eliminate the need for extra paper storage of documents which are costly to retain and inefficient to reference. He stated the data required in section (4) should be retrievable from the pharmacy information system. Director Troughton commented that federal regulations state that if you are receiving a paper copy of a prescription for a controlled substance, then you have to keep that paper copy and it be readily retrievable. He added that if it is an electronic prescription that is okay. Mr. Azzolin asked about non-controlled substances. Director Troughton responded that the DEA does not require a copy for non-controlled substances. President Harris commented that it is electronic, the pharmacist does not have to print it.

Rule 480-27-.05 Record-Keeping When Utilizing an Automated Data Processing System: Mr. Azzolin discussed section (b)(2) of Rule 480-27-.05, which states, *"When utilizing electronic daily prescription fill and refill records, each pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the prescription information entered by him or her into the computer that day has been*

reviewed by him or her and is correct as shown." Mr. Azzolin asked what the intent of this portion of the rule was as it looks to be requiring a daily log of all the pharmacists working that day. He asked if this allows for daily prescriptions audits to be eliminated from physical hard copy print or saving to a file. Director Troughton responded that when they were printing out the daily logs, if they do not do that any longer, then there is a wet signature daily in a log. Mr. Henderson asked how the log tells you any different than what is on the printout. Director Troughton responded that they do the printout and would sign it. He stated that is their wet signature. He added that one way or the other that pharmacist has to sign something attesting they were there.

Rule 480-36-.03 Personnel and Supervision and Emergency Rule 480-36-0.36-.08 Remote Order Verification for Retail Pharmacy Permits: Mr. Azzolin stated that he understands this is currently allowed because of the State of Emergency and would require a legislative change. Ms. Emm affirmed that was correct.

Use of RAMS: Mr. Azzolin discussed nurses wanting to use a dispensing cabinet. He stated that in the feedback he has received, it is safer and more accurate. Mr. Azzolin provided the Board with suggested language that could be utilized. Mr. Henderson asked if Mr. Azzolin was speaking about something that labels the items with a patient's name? Mr. Azzolin responded that he was not. Mr. Henderson stated that Mr. Azzolin was talking about a Pyxis. Mr. Henderson mentioned the Board previously discussing this matter and thought the Board allowed the facility to get a hospital license. Mr. Azzolin responded that if the Board did that, it would be in violation of law or rule. He stated that the definition of a hospital pharmacy requires you to be a licensed hospital. Mr. Henderson asked Director Troughton if he recalled the situation. Director Troughton responded that it was an in-patient facility that did have facility licensure through the Department of Community Health. Mr. Azzolin asked Mr. Henderson if any of his facilities have access out of a dispensing cabinet. Mr. Henderson responded that he is a believer in labeling it and thinks that in a hospital environment, patients are only there for a few days. He stated that in that case, that system works well.

Mr. Henderson stated that the rules do not match what the law states. He stated that Rule 480-37-.03(l) reads, *"The stocking or restocking of a dangerous drug or controlled substances shall only be completed by a Georgia pharmacist or a pharmacy intern/extern under the direct on-site supervision of a Georgia licensed pharmacist."* Whereas O.C.G.A. § 26-4-28(12.1)(B) states, "*The regulation and establishment of minimum standards for the use and operation of remote automated medication systems by the board as provided for in subparagraph (A) of this paragraph shall permit a pharmacy technician registered pursuant to this chapter to fill a remote automated medication system. If the remote automated medication system utilizes radio frequency identification or bar coding in the filling process, the pharmacy shall retain an electronic record of the filling activities of the pharmacy technician. If the remote automated medication system does not utilize radio frequency identification or bar coding in the filling process, a pharmacist shall supervise continuously the filling activities of the pharmacy technician through a two-way audiovisual system."*

Mr. Azzolin suggested that Rule 480-37-.03(1) be amended to read, "*The stocking or restocking of a dangerous drug or controlled substances shall only be completed by a Georgia pharmacist, a pharmacy technician under the direct on-site supervision of a Georgia licensed pharmacist, or a pharmacy intern/extern under the direct on-site supervision of a Georgia licensed pharmacist., a Georgia registered nurse with a witness or a Georgia licensed practical nurse with a witness. The system shall maintain a readily retrievable electronic record to identify all witnesses of each transaction when restocking occurs by a Georgia registered nurse or a Georgia licensed practical nurse."* Vice-President Faulk commented that he does not see how nurses could be added to the rule as they do not fall under purview of Board. Mr. Azzolin stated that he would love to see how many RAMS are licensed in Georgia as he believes they are way under-utilized. Ms. Emm stated that RAMS has its own license type. Mr. Changus stated that the

statute calls for the use of the system and thinks to Mr. Henderson's point, its limitations are imposed by the statute. Ms. Emm added that the statute specifically states who can fill a rams. She stated that the Board does not have the ability to say a nurse can fill a RAMS. She continued by stating that the rule does need to be updated to match the law and that would be a matter that is added to the "errors list". Mr. Azzolin stated that would be a start. He asked Mr. Henderson if that would promote utilization better? Mr. Henderson responded that it would help.

Rules referencing a balance requirement: Ms. Emm informed the Board that she updated Rules 480-10-.12 Minimum Equipment for Prescription Departments, Rule 480-11-.04 Facilities and Equipment, Rule 480-18-.05 Physical Requirements and Equipment, and Rule 480-33-.05 Physical Requirements with the changes noted per the Board's request. Mr. Stone made a motion to post Rules 480-10-.12 Minimum Equipment for Prescription Departments, Rule 480-11-.04 Facilities and Equipment, Rule 480-18-.05 Physical Requirements and Equipment, and Rule 480-33-.05 Physical Requirements. Mr. Azzolin seconded and the Board voted unanimously in favor of the motion.

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

(1) No pharmacy licensed in accordance with O.C.G.A. T. 26, Ch. 4, shall engage in the practice of filling, compounding or dispensing prescriptions unless it shall possess the following items:
  (a) Copies of and/or computer or electronic access to current reference materials appropriate to the individual pharmacy practice. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.
  (b) The telephone number of a poison control center. This number shall be conspicuously posted within the prescription department.
  (c) Current copies of and/or computer or electronic access to the following:
    1. Georgia Pharmacy Practice Act, O.C.G.A. T. 26, Ch. 4;
    2. Georgia Controlled Substances Act & Dangerous Drug Act, O.C.G.A. T. 16, Ch. 13; and
    3. Official Rules of the Georgia State Board of Pharmacy.
  (d) Equipment (appliances):
    1. Refrigerator in operating condition with a thermometer; and
    2. Sink in working condition with both hot and cold running water.
  (e) Weighing and labeling:
    1. ~~Class A Balance, Class I or II Electronic Balance, or as approved in writing by the Board~~ If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance;
    ~~2. Assortment of weights: metric and apothecary, only if utilizing a Class A Balance;~~
    ~~3~~2. Appropriate prescription labels consistent with the requirements of the Georgia Drug and Cosmetic Act, O.C.G.A. Title 26, Chapter 3; and
    ~~4~~3. Appropriate auxiliary labels that should be used in the pharmacist's professional judgment.
  (f) Other equipment:
    1. Graduates of assorted sizes;
    2. Two mortars and pestles of assorted sizes;
    3. Two spatulas;
    4. One pill counting tray;
    5. Ointment slab, tile or ointment paper pad;
    6. Stirring rods;
    7. Typewriter, word processor or computer with label-printer; and
    8. Any other equipment necessary for a specialized practice setting where such a specialized practice takes place.

(g) Adequate supply of drugs most commonly prescribed (ONLY to be on hand after a permit has been issued by the Board).
(h) Assorted sizes and types of child-resistant dispensing containers.

(2) The pharmacist-in-charge of a facility may submit to the Georgia State Board of Pharmacy a typed request for a variance to these provisions relating to minimum equipment requirements. Stated reasons for application for variances must be included in submitted request. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for doing so which relate to the necessary or efficient delivery of health care.
(a) Any variance granted by the Board must be in writing, and this variance must be posted in the pharmacy next to the current Board issued permit/renewal certificate.

Rule 480-11-.04. Facilities and Equipment

(1) Facilities.
(a) Pharmacies engaging in compounding shall have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile preparations shall be separate and distinct from the area used for the compounding of non-sterile drug preparations. The area(s) used for compounding of drugs shall be maintained in a good state of repair.
(b) Bulk drugs and other chemicals or materials used in the compounding of prescription drug orders must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.
(c) Adequate lighting and ventilation shall be provided in all drug-compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute to contamination of any compounded drug preparation. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air dryers or single-use towels.
(d) Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

(2) Equipment.
(a) Equipment used in the compounding of drug preparation shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug preparations shall be of suitable composition so that surfaces that contact components, in-process materials, or drug preparations shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond that desired.
(b) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug preparation beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug preparations, cleaning, sterilization, and maintenance procedures as set forth in Board Rules.
(c) Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.
(d) Automatic, mechanical, electronic, or other types of equipment other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug preparations. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(3) Physical requirements for pharmacies compounding sterile parenteral preparations.

(a) A pharmacy compounding or preparing sterile parenteral preparations shall have a designated area for preparing compounded, sterile parenteral preparations as defined in USP 797. This area shall be physically separate from other areas and should be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile parental preparations.

(b) Equipment and supplies for compounding sterile parenteral preparations. A equipment and supplies:

1. Laminar airflow hood (ISO 5) located within a clean room, or barrier isolator as described in USP 797;
2. Infusion pumps, if appropriate;
3. Sink, in working condition, with hot and cold running water, which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;
4. Facility for light/dark field examination;
5. Appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapy agents;
6. A Class II, vertical flow biological safety cabinet or appropriate barrier isolator, if chemotherapy agents are routinely prepared;
7. Refrigerator/freezer in working condition;
8. ~~Class I or II electronic balance, or as approved in writing by the Board~~ If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance;
9. Disposable needles, syringes and other supplies needed for aseptic admixture;
10. Disinfectant cleaning solutions;
11. Handwashing agent with bactericidal action;
12. Disposable, lint free towels or an automatic hand dryer;
13. Appropriate filters and filtration equipment;
14. Disposable masks and sterile, disposable gloves, gowns, hair and shoe covers and goggles when indicated;
15. An oncology drug spill kit, if chemotherapy agents are routinely prepared.
16. For the purpose of emergency or immediate patient care, compounded sterile preparations are exempted from the requirements as outlined in USP 797.

(4) Minimum equipment for pharmacies compounding non-sterile preparations.

(a) A compounding pharmacy must have all equipment required of a pharmacy in Chapter 480-10 of the Board Rules.

(b) Additionally, a compounding pharmacy must have the appropriate equipment for use in compounding as defined in USP Chapters 795 and 797.

(5) References. In addition to references required of a pharmacy, pharmacies compounding sterile pharmaceuticals shall also have a current edition of or electronic access to an established reference on IV stability and incompatibility, such as, Handbook on Injectable Drugs or King's Guide to Parenteral Admixtures, current Federal requirements for sterile compounding and other reference material including but not limited to:

(a) "USP Pharmacists Pharmacopeia",

(6) Variances.

(a) The pharmacist-in-charge may submit to the Georgia State Board of Pharmacy a typed request for a variance to the provisions relating to minimum equipment requirements. The reasons for the request for a variance must be included in the submitted request. A variance shall be granted by the Board only when, in the judgment of the Board, there are sound

reasons for doing so that relate to the necessary or efficient delivery of health care. After consideration by the Board, the requestor will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as proof of the Board's approval for the variance indicated in the letter, and must be posted next to the inspection report.

Rule 480-18-.05. Physical Requirements and Equipment

(1) Physical Area. An OTP clinic pharmacy shall have within the clinic which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed space, and which meet the other requirements of this section, the Georgia Pharmacy laws, and other applicable state and federal laws and rules. Such space shall be at a minimum 150 square feet. Such space shall include all areas which are assigned and under the direct control of the Director.

(2) Minimum equipment. No OTP clinic pharmacy licensed in accordance with O.C.G.A. Title 26, Ch. 4 shall engage in the practice of filling, compounding or dispensing prescription drugs for an OTP Clinic unless it shall possess the following items:

(a) Copies of and/or electronic access to current reference materials appropriate to the practice of pharmacy related to OTP. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(b) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be posted or readily available in areas both inside and outside of the pharmacy where drugs are stored or patients are being cared for.

(c) Current copies or electronic or computer access to the following:

1. The Georgia Pharmacy Practice Act/Drug and Cosmetic Act, O.C.G.A. §§ 26-4 and 26-3;
2. The Georgia Controlled Substances Act/Dangerous Drug Act, O.C.G.A. § 16-13;
3. The official rules of the Georgia State Board of Pharmacy.

(d) Equipment:

1. Sink in working condition with both hot and cold running water;
2. Two spatulas;
3. One oral solid counting tray;
4. Typewriter, word processor or computer with label printer;
5. A refrigerator in working order with a thermometer.
6. Any other equipment the Board may deem necessary for a specialized practice setting where such a specialized practice takes place.

(e) Weighing and labeling:

1. Appropriate prescription labels consistent with the requirements of O.C.G.A. §§ 16-13, 26-3 and 26-4; and
2. Appropriate auxiliary labels that should be used in the pharmacist's professional judgement.
3. ~~A class A balance with metric and apothecary weights or an electronic class I or II balance~~ <u>If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance</u>.

(f) An adequate supply of drugs used in an OTP Clinic setting.

(g) Assorted sizes and types of appropriate dispensing containers.

(3) The Director in an OTP clinic pharmacy may submit to the Board a typed request for a variance to the provisions relating to the minimum equipment requirements.

(a) The reason for requesting each variance must be included in the typed request;

(b) A variance shall be granted by the Board only when, in the judgement of the Board, there are sound reasons for doing so which relate to the necessary or efficient delivery of health care.

(c) Any variance granted by the Board shall be in writing, and the variance must be posted in the pharmacy next to the current Board issued license certificate.

Rule 480-33-.05. Physical Requirements

(1) Area. An outpatient clinic pharmacy shall have within the clinic which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this section and the Georgia Pharmacy Laws. The outpatient clinic pharmacy space requirements shall be a minimum of 150 square feet. Such space shall include all areas which are assigned and under the direct control of the pharmacist-in-charge.

(2) Minimum Equipment. No outpatient clinic pharmacy licensed in accordance with Title 26, Chapter 4 of the Official Code of Georgia Annotated shall engage in the practice of filing, compounding or dispensing prescription drugs unless it shall possess the following items:

(a) Copies of and/or electronic access to current reference materials appropriate to the individual pharmacy practice. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(b) The telephone number of a poison control center. This number shall be conspicuously posted within the pharmacy and at other locations within the clinic facility.

(c) Current copies of or computer or electronic access to the following:

1. The Georgia Pharmacy Practice Act, O.C.G.A. Title 26, Chapter 4;
2. The Georgia Controlled Substances Act/Dangerous Drug Act, O.C.G.A. Title 16, Chapter 13;
3. Official Rules of the Georgia State Board of Pharmacy.

(d) Equipment (appliances):

1. Refrigerator in operating condition and a thermometer; and
2. Sink in working condition with both hot and cold running water.

(e) Weighing and labeling:

1. ~~Class A Balance, Class I or II Electronic Balance, or as approved by the Board~~ If compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance;
2. ~~Assortment of weights: metric and apothecary;~~
3. 2. Appropriate prescription labels consistent with the requirements of the Georgia Drug and Cosmetic Act, O.C.G.A. Title 26, Chapter 3; and
4. 3. Appropriate auxiliary labels that should be used in the pharmacist's professional judgment.

(f) Other equipment;

1. Graduates of assorted sizes;
2. Two mortars and pestles of assorted sizes;
3. Two spatulas;
4. One oral solid counting tray;
5. Ointment slab, tile or ointment paper pad;
6. Typewriter, word processor or computer with label printer; and
7. Any other equipment necessary for a specialized practice setting where such a specialized practice takes place.

(g) Adequate supply of drugs most commonly prescribed.

(h) Assorted sizes and types of appropriate dispensing containers.

(3) Variances.

(a) The pharmacist-in-charge in an outpatient clinic facility may submit to the Georgia State Board of Pharmacy a typed request for a variance to these provisions relating to minimum equipment requirements. The reasons for the request for the variance must be included in the submitted request. A variance may be granted by the Board only when, in the judgment of the Board, there are sound reasons for doing so that relate to the necessary or efficient delivery of health care. After consideration by the Board, the requester will be notified of the Board's decision in writing.

(b) If approved, said letter(s) will serve as the proof of the Board's approval for the variances indicated in the letter, and must be posted next to the facility's inspection report.

(4) The compounding, admixture, and quality control of large volume parenterals is the responsibility of a pharmacist and shall be prepared under a laminar flow hood within the pharmacy. Other licensed healthcare professionals who are authorized by law to prepare or administer large volume parenterals must have special training to do so. These functions of compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas, emergency situations, and during unattended hours of the pharmacy department. The pharmacist-in-charge shall be responsible for providing written guidelines and for approving the procedure to assure that all pharmaceutical requirements are met when any part of the above functions (preparing, sterilizing and labeling parenteral medications and solutions) is performed within the clinic by other licensed healthcare professionals who are authorized by law to prepare parenteral medications and solutions.

(5) Storage. All drugs shall be stored in designated areas within the clinic pharmacy which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage areas shall be locked or otherwise secured when health care professionals are not present.

(6) Controlled drug storage for Schedule II drugs. An enclosed controlled room or space with limited access capable of showing forced entry is preferable. However, a safe or metal cabinet that can be locked and that is permanently affixed to the structure is acceptable.

(7) Unattended areas. Whenever any area of a clinic pharmacy is not under the personal and direct supervision of authorized personnel, such areas shall be locked.

(8) Security. All areas occupied by a clinic pharmacy shall be capable of being locked by key or combination, so as to prevent access by unauthorized personnel by force. The director of pharmacy shall designate in writing, the name and specific area, of persons who shall have access to particular areas within the pharmacy. These areas shall meet the security requirements of Federal and State Laws and Regulations. Only those persons so authorized shall be permitted to enter these areas.

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

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

Rule 480-13-.06 Drug Distribution Control: Mr. Azzolin discussed a scenario of when a nurse retrieves medication from a dispensing cabinet, takes it to a patient's room and the patient refuses it. He stated the seal is unbroken, the nurse scans it and places it back in the cabinet and it is removed from the patient's profile. Mr. Azzolin stated that the GDNA agent stated the nurse could not put the medication back in the cabinet. Director Troughton commented that he spoke to the pharmacist Mr. Azzolin is referring to. He stated that the rule says before a drug can be returned to stock, it has to be verified by the pharmacist. Mr. Azzolin read Rule 480-13-.06(4)(b) which states, *"In accordance with the policies and procedures developed by the Director of Pharmacy, discontinued non-controlled substances dispensed to hospital patients shall be returned to the pharmacy and evaluated by the licensed pharmacist to assure the integrity of the medication. If the integrity can be assured, the medication may be returned to the hospital's drug distribution s system for re-issue. When the integrity cannot be assured, the medication must be separated immediately from the regular drug inventory and destroyed or transferred to a reverse distributor with a current license issued by the Board. The following method of destruction of non-controlled substances is approved by the Board for medications dispensed to hospital patients or patients residing in nursing homes or long term care units which are part of a hospital facility;"* Director Troughton responded that is the basis for which GDNA enforced that. Mr. Azzolin stated that it is not a discontinued drug. He stated that it is usually refused by the patient or not needed for some other reason. Discussion was held regarding a discontinued drug being different than a refused dose. Director Troughton commented that there are all kinds of reasons the patient may not get it. He stated that the point is the nurse went into the patient's room, the patient refused it. The question is if it is okay for the nurse to put it back. Mr. Azzolin stated that with controlled substances, when an item is removed or returned, it requires a nurse witness. He stated that he/she could not access that medications drawer without having another nurse witnessing that. Director Troughton stated that he can instruct the agents the medication can be returned to the particular cabinet they were in by the nurses, if the Board agrees. He stated this would not require a change in the rule. The Board agreed.

Ms. Battle stated that the Board will need to talk about Executive Session items. She stated that she had anticipated the Board meeting until 5:00 today. Ms. Battle stated that, currently, the Board may not have another Open Session tomorrow with the public. She stated that there was an appearance scheduled for 9:00 a.m. She further stated the public could join the call for Open Session tomorrow at 10:00 a.m. since there are additional rules to discuss. The Board agreed to start the next day's meeting, which will be in Executive Session, at 8:30 a.m. and the public could join for Open Session discussion at 10:00 a.m.

Mr. Stone 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), § 43-1-2(k) and § 50-14-3(b)(2) 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, Hal Henderson, Bill Prather and Dean Stone.

Executive Session

Miscellaneous

- C.M.H.

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Cognizant's Report – Mike Faulk

- GDNA Case # T33350
- GDNA Case # T33320
- GDNA Case # T33357

- GDNA Case # A33070
- GDNA Case # B33142
- GDNA Case # A33157
- GDNA Case # B33171
- GDNA Case # A33179
- GDNA Case # A33214
- GDNA Case # A33238
- GDNA Case # B33237
- GDNA Case # A33250
- GDNA Case # B33254
- GDNA Case # A33291
- GDNA Case # B33204
- GDNA Case # B33282
- GDNA Case # B33243
- GDNA Case # A33338
- GDNA Case # B33301
- GDNA Case # A33310
- GDNA Case # B33068
- GDNA Case # B33169
- GDNA Case # B33174
- GDNA Case # B33177
- GDNA Case # B33242
- GDNA Case # B33217
- GDNA Case # B33252
- GDNA Case # B33253
- GDNA Case # T33294
- GDNA Case # A33197
- PHAR2000090

Attorney General's Report – Max Changus

Mr. Changus presented the following orders for acceptance:

- J.M.M.
- B.Z.A.
- B.D.F.
- C.V.S.P.
- S.L.W.S.
- A.P.P.
- R.C.S.
- V.H.
- T.A.D.S.C.
- A.P.

Mr. Changus discussed the following cases:

- M.C.
- P.P.P.
- C.T.M.S./C.M.C.

Applications

- A.I.J.
- E.L.K.
- D.T.R.
- A.S.B.
- R.F.L.
- M.R.S.
- S.C.L.
- D.Y.
- S.D.P.
- E.N.W.
- K.M.A.
- D.L.K.
- D.N.P.

Executive Director's Report – Tanja Battle

- C.N.C.

Miscellaneous

The Board discussed staffing matters and the Executive Director vacancy that resulted from Ms. Battle's retirement.

Executive Session suspended.

There being no further business to discuss, the meeting was adjourned at 5:30 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Thursday, June 18, 2020 at 8:00 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 Tanja D. Battle, Executive Director