GEORGIA BOARD OF PHARMACY
Board Meeting
Mercer University College of Pharmacy
3001 Mercer University Drive
Atlanta, GA 30341
March 4, 2020
9:00 a.m.

The following Board members were present:
Lisa Harris, President
Mike Faulk, Vice-President
Michael Azzolin
Michael Brinson
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
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst I

Visitors:
Lea Winkles, Mercer University
Stephen Georgeson, GRA
Chuck Page, Kroger
Mariam Saba, Mercer & Walgreens
Shauna Markes-Wilson, Walgreens
Sasha Kaniga, TCSG
Becca Hallum, GHA
Bijal Patel, Walgreens
Leigh Anne Jacobson, Publix
Stephanie Kirkland, Eldercare
Amanda Roberson, Eldercare
Josh Brannon, WCRMC
Michelle Pasqualetti, WRMC & Clinch
Patrick McGlynn, Clinch Memorial Hospital
Steven Carder
Lana Manatrizio

Open Session

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

Approval of Minutes

Mr. Prather made a motion to approve the Public Session minutes from the February 12, 2020 meeting with the changes noted by Mr. Azzolin. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

In the same motion, the Board approved the Executive Session minutes from the February 12, 2020 meeting.

Report of Licenses Issued
Mr. Stone made a motion to ratify the list of licenses issue. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance
Mr. Brinson made a motion to grant the rule waiver petition First Choice Primary Care, Inc. Mr. Faulk seconded and the Board voted unanimously in favor of the motion.

The Board recommended tabling discussion on the rule variance petitions submitted by Clinch Memorial Hospital and Washington County Regional Medical Center.

Correspondence from Julie Wickman, PCOM
The Board considered this correspondence requesting clarification regarding interns and externs. The Board recommended responding to Ms. Wickman's questions as follows:

1. Intern/extern seems to pop up often on rotations and I know the law says 1 RPh can oversee 1 extern and 1 intern at a time, but some have asked could they "technically" have 2 students at a site even if they "technically" are both externs? *Interns and externs are defined separately in the Pharmacy Practice Act O.C.G.A. § 26-4-5(16) and (19). An extern is assigned by the school to that spot as part of their clinical rotation. A pharmacist may only supervise one intern and one extern.*

2. Our students now have service learning hours and faculty would like to offer health fairs to students, however does the 1 RPh to 1 extern 1 intern rule affect events like health fairs? Technically, students are not earning experiential education hours, but it would be part of the curriculum. Is there a difference between interns/externs now? *The laws and rules regarding technicians apply to all locations where a pharmacist is supervising interns/externs. If the school intends to designate students as externs and/or interns, the pharmacist must comply with the supervision ratios.*

3. Last, we have had physicians want to have students for an "elective" rotation. Are MDs or DOs (or any other HC professional) allowed to have interns/externs? ACPE is pushing for this and encouraging students to work with other HC providers on rotations (no pharmacist). *The intern/extern can work there; however, as far as abilities to do extern/intern duties, those would not travel with them to that setting because they are not under the direct supervision of a licensed pharmacist. The MD or DO would be responsible for all activities performed by the intern/extern in that setting.*

Correspondence from Accreditation Council for Pharmacy Education
The Board viewed this correspondence for informational purposes only.

Correspondence from Focus Treatment Center
The Board considered this correspondence requesting the Board consider Focus Treatment Center as a board-approved treatment facility. The Board recommended inviting a representative from Focus Treatment Center to the Board's next available meeting to further discuss.

Correspondence from Mindy Rogers, Pharmacy Benefit Management Certified Technician Program
The Board considered this correspondence requesting inclusion on the Board's website as a recognized Pharmacy Technician Certification Program. The Board recommended inviting Ms. Rogers to the Board's next available meeting to further discuss.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA has received 44 more complaints and has conducted 495 more inspections than at this same time last year.

Attorney General's Report – Max Changus

Mr. Changus discussed the prescription pick-up locker that was previously presented to the Board by Ms. Karen Nishi. Mr. Changus stated there were multiple questions from the Board about whether or not this could be utilized. He added that he has spent some time going through various code sections. Mr. Changus stated that the Board's definition of a pharmacist means a pharmacist that is licensed in Georgia. He stated that some of the design, as he understands it, is to outsource the counseling aspect of it. He explained that when the patient comes in to retrieve his/her prescription the pharmacist pops up on the screen. He further explained that the design of the system is to pull the prescription out of its designated slot. Mr. Changus stated that the security aspects of it are that the patient will have a secure code to use to retrieve the prescription. He stated that, in reviewing the pharmacy code section, these laws were written before the concepts of technology.

Mr. Changus stated O.C.G.A. § 26-4-110 discusses "hours of operation" and states that every pharmacy licensed pursuant to this chapter shall have a prescription department under the personal supervision of a duly licensed pharmacist who shall have personal supervision of not more than one pharmacy at the same time. He stated that the rules talk about direct supervision and some that talk about being open for business and the closure of a prescription department. Mr. Changus stated that this pick up locker is designed to be accessed 24 hours a day and located on the outer walls. He stated this brings us to the sanctity of the licensed pharmacy, or what is supposed to happen in the pharmacy. He explained that Rule 480-10-.19 talks about access within the licensed pharmacy and the term "within" means inside and not something on an outer wall that faces out. He stated it is something directed within. Mr. Changus stated there are a couple of issues with the pick-up locker. One is the laws in Georgia suggest access to the pharmacy is during business hours. He stated that the idea of taking it outside of hours where you do not have a pharmacist supervising the practice does not align with how the statute was written. The other issue is the automated system can be used, but it needs to be used inside the pharmacy department. Mr. Changus asked can they use this locker? Can they have it there? He stated yes, but to the extent to access it after hours poses some problems with the way the law is currently written. Mr. Azzolin asked if this was in a law or rule that medications can only be accessed during hours of operation. Mr. Changus responded that O.C.G.A. § 26-4-110 discusses hours of operation. Mr. Changus stated that he thinks we would agree that one of the aspects of pharmacy is counseling. He further stated if the patient is accessing this after hours, that is not being done under the supervision of the pharmacist-in-charge. Mr. Azzolin responded that there are times when the pharmacist-in-charge is not there that day. Mr. Changus commented that there is a licensed pharmacist there. Mr. Azzolin stated that a duly licensed pharmacist to him fits the requirements especially in modern times. Mr. Changus stated that he agrees if a licensed pharmacist in Georgia is providing that service, then you have the counseling aspect of that covered. Mr. Azzolin commented that, in Georgia, if he had a patient that lives 30 miles away, and wants to mail medication when the pharmacy is closed, he just broke the law because it is after hours, based on Mr. Changus's interpretation. He stated that unless the law specifically says medications can only be dispensed during the hours of operation, he does not think it precludes a pharmacy from dispensing outside business hours. He added that to him it is a patient care issue if the patient cannot get that medication.

Mr. Faulk made a motion to respond to Ms. Nishi by stating that, based on the information provided, the Board raised concerns that the usage of this product, especially after hours, would potentially run afoul of O.C.G.A. § 26-4-110(i) (requiring a pharmacist to personally supervise the pharmacy during hours of operation) and the corresponding Board Rules 480-10.-02(4)(b)(4)(" No prescription shall be dispensed in the absence of a licensed pharmacist.") and 480-10-.19 (requiring an automated system to be <u>within</u> the pharmacy or pharmacy department). Based on these concerns, the Board could not give blanket approval

to the use of the prescription pick up locker. Discussion was held. Mr. Prather commented that if a patient needs a medication, the pharmacist would meet the person there and dispense that medication in the proper way as there was never any issues doing it that way. Mr. Azzolin responded that he appreciates that and respects it. Mr. Brinson commented that the pharmacist also carries the prescription to the patient in a lot of cases. Mr. Azzolin stated that times are different and while the Board may disagree with the concept, as long as they are not violating the law, he disagrees with telling Ms. Nishi no. Bill Prather seconded the motion. Additional discussion was held by the Board. Mr. Stone expressed his concerns. He stated that he feels there is potential for abuse. Mr. Changus stated that Rule 480-10.-02(4)(b)(4) states that no prescription shall be dispensed in the absence of a licensed pharmacist. He added that he thinks that handing over medications precludes that. Mr. Azzolin stated he understands everyone's concerns, but asked does the law preclude it though. He added that the Board needs to be careful about its opinions on how a business model is submitted.

Mr. Changus stated that O.C.G.A. § 26-4-110(i) states in part, "During hours of operation, every pharmacy licensed pursuant to this chapter shall have a prescription department under the personal supervision of a duly licensed pharmacist who shall have personal supervision of not more than one pharmacy at the same time…" He stated that is the crux here. He added that the way the statute is written it is contemplating a pharmacy with hours of operation with a pharmacist present. Mr. Azzolin stated to let the business model prove or disprove itself. Mr. Changus added that again he is just reading what the law says. He asked will there be a duly licensed pharmacist during those after hour periods. Mr. Azzolin asked if they have a virtual pharmacist, does that meet the requirements? Mr. Changus asked what would the virtual pharmacist be doing? He stated that from what he recalls with the pick-up locker, the patient hits a button and the pharmacist is available for the call and is not present in the way the statute seems to suggest. President Harris commented that mail order has separate rules than retail, so they are covered for hours outside of operation where the pick-up locker is going to be at a retail establishment. Mr. Changus stated that the first statement under O.C.G.A. § 26-4-110(i) is what, for retail purposes, was envisioned by the legislature at that time and Ms. Nishi is asking for something different where there would be 24 hour access. He added that the pharmacist would not be on duty during the hours of operation. Mr. Azzolin asked when a patient accesses that bin, is the pharmacist notified? He stated that the reason he asks is anytime something is accessed, a notification can be sent to the pharmacist. He added that he knows it does not meet the definition in law, but in reality, when he picks up a prescription he is not counseled. Mr. Azzolin stated that having a button there to press is different; however, he understands the Board has to go with what the law reads. There being no further discussion, the motion passed. Mr. Azzolin opposed the motion.

Next, Mr. Changus discussed two correspondences that were referred to him for advice. The first correspondence was from Pam Wilkinson regarding Medication Therapy Management (MTM). He stated that the correspondence asked does the pharmacist doing the MTM work need to be licensed in Georgia, or just licensed in North Carolina where the dispensing pharmacy is located? Mr. Changus stated that a Georgia license is required and suggests she refer to O.C.G.A. § 26-4-110.1 for more information.

Lastly, Mr. Changus discussed correspondence from Jan Howell regarding a Pharmacy Benefits Manager (PBM) conducting MTM. Ms. Howell's inquiry asks the following questions:

From the Georgia Board of Pharmacy perspective, is a pharmacist conducting MTM of Georgia residents in a non-pharmacy (PBM office) setting required to be licensed in Georgia, or is it sufficient to be a pharmacist licensed in the state where the PBM offices reside?

In addition, are PBMs performing MTM required to be licensed as retail pharmacies in Georgia when they do not reside in Georgia and are performing their duties from a different state?

Mr. Changus stated that O.C.G.A. § 26-4-110.1 states that a license is required. President Harris commented that if they are licensed in Georgia, then they fall under the purview of the Board of Pharmacy. Mr. Azzolin stated that O.C.G.A. § 26-4-110(a) reads, "All facilities engaged in the manufacture, production, sale, or distribution of drugs or devices utilized in the practice of pharmacy or pharmacies where drugs or devices are dispensed or pharmacy care is provided shall be licensed by the board and shall biennially renew their license with the board. Where operations are conducted at more than one location, each such location shall be licensed by the board." Mr. Azzolin commented that if the PBM is doing MTM work, then they are engaging in pharmacy care, which by definition is something that needs to be licensed.

Mr. Changus discussed two bills that are looking to clarify that what a PBM does is different from the practice of pharmacy. Mr. Azzolin stated that the way the law is written now, they are providing pharmacy care. He further stated that O.C.G.A. § 26-4-80(a) states, "All persons engaging in the practice of pharmacy in this state must be licensed by the board."

Mr. Faulk made a motion to direct staff to respond to Ms. Wilkinson and Ms. Howell per the direction of Mr. Changus. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Executive Director's Report – Tanja Battle

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

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
03/07/2020	6	Northside Hospital	COPD Symposium (Chronic Obstructive Pulmonary Disease)	2020-0002
03/03/2020	2	Northside Hospital	An Update on Medication Administration in Enternal Nutrition Patients	2020-0003

Renewal fee for Durable Medical Equipment Suppliers: Mr. Brinson made a motion to set the renewal fee for Durable Medical Equipment Suppliers to $400. Mr. Faulk seconded and the Board voted unanimously in favor of the motion.

Proposed Budget: Ms. Battle reported that the proposed budget does have an approximate cut of $31,000 for the Board, which is significant. She stated that this board has a small budget to begin with. Ms. Battle stated that in regards to conferences, the Board usually has 4-5 members attend. She requested that the Board discuss any future travel plans before making any arrangements. Mr. Stone asked if this were to stop any member from paying his/her own way for a conference. Ms. Battle responded that this would not stop the member from doing so; however, the Board would likely not be able to reimburse the members for travel. Mr. Brinson discussed the GPhA conference and possibly paying for one night instead of three. Ms. Battle responded that the Board may need to vote on sponsoring one person instead of five. President Harris stated that the GPhA conference is typically a Q&A with the Board. Ms. Battle commented that this was just something the Board needed to be aware of.

Legal Services – Kimberly Emm

Correspondence from Ayanna Wilson: Ms. Emm discussed this correspondence asking if a DME supplier license is needed for nebulizer equipment and oxygen equipment. The Board directed staff to respond by stating a DME license is not needed for nebulizer equipment and oxygen equipment as long as there is no prescription required for it.

Miscellaneous

Medical Cannabis Commission: Mr. Prather stated that the Board of Pharmacy will issue licenses to pharmacies that want to dispense cannabis. He stated that he was recently asked when the Board would make these licenses available. Ms. Battle responded that the law requires the Commission to promulgate rules jointly with the Board of Pharmacy. She asked Mr. Prather if the Commission has discussed that yet. She stated that the setting up the license is not hard from an administrative perspective, but the Board will need to impart what the requirements are. Mr. Prather responded that the Commission will not have any say so on what the license will entail. Ms. Emm commented that the law requires the Board of Pharmacy and the Commission come together to promulgate rules and figure out how it will be dispensed before the Board can issue a license. She stated that the Board cannot issue a license without rules. Mr. Prather stated that the legislature was asking when the Board was going to start issuing licenses. He stated he does not see what the commission has anything to do with giving a license to a pharmacy. Ms. Emm responded by stating that is how that pharmacy will dispense that product. She stated that those rules should be the same for dispensaries as well. Mr. Prather stated that it would be impossible to have the exact same rule for pharmacies and dispensaries. He further stated that he would like for the Board President to appoint one board member to meet with the Medical Cannabis Commission to discuss this further. President Harris appointed Mr. Brinson to meet with the Commission.

Central Filling Regulations: Mr. Georgeson, who was present at the meeting, spoke to the Board regarding proposed revisions from Georgia Retail Association (GRA). Mr. Georgeson stated that last fall when the Board was considering a regulation regarding central fill, GRA submitted comments. He stated that after speaking with Mr. Prather, it was suggested they submit additional comments later. He further stated that he knows the Board's practice has been to refer to a committee that the President would appoint and since this is not an urgent matter, he feels that would be the proper course here. The Board recommended appointing Mr. Faulk to the Committee and bring back suggestions to the Board.

Rule 480-36-.03 Personnel and Supervision: Ms. Emm stated that the Board discussed this rule in February and the consensus was to remove section (4). Mr. Prather commented that he is not in agreement with this amendment. He stated that he believes the purpose of this Board is to protect the citizens of Georgia. He added that the more supervision there is and the more pharmacists looking at a prescription the better. Mr. Changus refreshed the Board on the initial proposal. He then stated it would be to explicitly remove the responsibility from primary pharmacist to look at anything. He added that it was a suggestion from him to delete subsection (4) and allow the board to determine if that pharmacists was involved in the incident, if a case were to come in, the Board could examine it to determine who was responsible and what course of action to take. Mr. Changus stated that it was a compromise from the language proposed about which the Attorney General's office had issues. He stated that the proposed language had prompted some concern. Mr. Azzolin commented that he thinks it has multiple benefits. He stated that the primary pharmacist does not have to fear that a mistake by the remote pharmacist would be primarily on his/her shoulders. He further stated that it allows for that business entity to makes its own decision over workflow. Mr. Stone commented that he feels it was making everybody responsible. He added that now it is more fairly spread out. President Harris stated that she is in agreement with it as long as the primary pharmacist has access. Mr. Faulk commented that if a prescription comes in from a remote pharmacy, is dispensed by the primary pharmacist and there is an error, he stated that Mr. Prather's concern is about the safety of the patient. He stated that if the prescription comes in and this person is relieved of that responsibility, is that person absolved from responsibility? Mr. Azzolin responded by stating that leaving subsection (4) in there you are saying the only one responsible is the primary pharmacist. Mr. Azzolin stated that relative to the patient care issue, both of these individuals have to be licensed in Georgia. He stated that this gives the Board more ability to determine where the actual error is. Mr. Faulk responded by asking if the person dispensing is not free of liability, he/she is just not solely responsible. Mr. Changus stated that this was referred to him as a proposal to expressly limit the responsibility of the primary dispensing pharmacist. He stated that he brought this matter back to the

Board for discussion in September. He stated that at that time, Mr. Henderson's comment was this happens in a pharmacy location all the time. Mr. Changus stated that at the end of that discussion, the Board was at a stalemate. At that point, the Board wanted to continue forward. Mr. Changus stated that he did not issue a memo of authority, so the rule did not move forward. He stated that his suggestion was to remove section (4) so now the Board is not expressly saying the primary pharmacist is not responsible for the dispensing of the product. He continued by stating that the idea was that, if there was an issue, the Board could make a determination of who is responsible for purposes of disciplinary action. Mr. Changus stated that the idea to make it explicit was the original intent of the rule sent over to his office was to ensure the right pills were in the bottle. He stated in lieu of that, he suggested the Board take out this subsection all together. Discussion on liability was discussed. Mr. Changus stated that if the Board made a determination that the primary pharmacist should have done something and did not, it can discipline for such. He stated that the rule proposed previously was taking that discretion away from the Board. Mr. Faulk stated he was in agreement. With no further discussion, Mr. Stone made a motion to post Rule 480-36-.03 Personnel and Supervision. Mr. Brinson seconded and the Board voted in favor of the motion, with the exception of Mr. Prather who opposed.

Rule 480-36-.03. Personnel and Supervision

(1) The primary dispensing pharmacy shall have a licensed pharmacist on site during business hours and his/her shall duties shall include the verification of the validity of all prescriptions. Such pharmacist shall be responsible for obtaining and recording all information needed. This shall include but not be limited to the following patient information: biographical information, medication history, drug allergies, and other information as required. Pharmacy technicians and pharmacy interns/externs may assist a pharmacist located at the primary dispensing pharmacy with remote prescription drug order processing. Such pharmacies shall comply with Georgia laws and rules set forth pertaining to ratios and the supervision of pharmacy technicians and pharmacy interns/externs.

(2) The secondary remote entry pharmacy shall have a pharmacist on duty, licensed in this State, who is physically present and personally supervising all pharmacy activities. Remote prescription drug order processing in a retail pharmacy without the direct supervision of a pharmacist is prohibited.

(3) Pharmacy technicians and pharmacy interns/externs may assist a pharmacist located at the secondary remote entry pharmacy with remote prescription drug order processing. Such pharmacies shall comply with Georgia laws and rules set forth pertaining to ratios and the supervision of pharmacy technicians and pharmacy interns/externs.

~~(4) The pharmacist on duty at the primary dispensing pharmacy shall be responsible for assuring the accuracy of all filled or dispensed prescriptions including those prepared through the use of remote prescription drug order processing. This shall include, but not be limited to, viewing and verifying the hardcopy or electronic prescription.~~

(~~5~~4) The pharmacist on duty at the secondary remote entry pharmacy shall be responsible for assuring the accuracy of prescriptions for which he/she performed or supervised remote prescription drug order processing. This responsibility shall exclude the compounding, preparation, dispensing, and counseling for prescriptions for which he/she has performed remote prescription drug order processing. The pharmacist shall verify the data entered into the computer system is consistent with the prescription. The pharmacist shall conduct a drug regimen review for each prescription. Any activity requiring the exercise of professional judgment shall be performed by the pharmacist on duty and shall not be delegated to pharmacy technicians. The pharmacist on duty at the secondary remote entry pharmacy shall be responsible for verification of all activities performed by pharmacy technicians, or pharmacy interns/externs.

Rule 480-13-.06 Drug Distribution and Control: Ms. Emm stated that one thing to note is that perpetual inventory is not necessarily required. Director Troughton added that the exception would be for CII's. He stated that the language may need to be adjusted. Mr. Brinson asked how the Board can make it where all narcotics and controlled substances require a perpetual inventory. Director Troughton responded that the

Board could amend the rule to include that. Mr. Stone commented that all controlled substances must be signed for by a pharmacist. Ms. Emm added that all controls must be signed for by a pharmacist upon receipt. Mr. Prather stated that given the modern technology, the Board is long past due of requiring a perpetual inventory. He asked if the Board can look at requiring this across the board. Ms. Emm commented that the Board's most recent rule was denied by the Governor's office. She stated that the Board needs to take that into account because requiring perpetual inventories would result in a burden and may not pass the review by the Governor's Office. Mr. Changus commented that all of these rule discussions need to be more precise and expansive. He stated that the Board needs to be on record regarding its purpose for the rule so it is clear to anyone reviewing the submission for review. He further stated that anything that appears to looks like it is imposing an additional burden is going to be scant. Mr. Changus stated that the Board would need to say "here is the need for this" and demonstrate that the necessity for the rule should outweigh any impact. He stated that the Board has to lay out when drugs are diverted the potential impacts are significant. The Board recommended tabling this rule.

Rule 480-6-.02 Nonresident Pharmacy Permit: Ms. Emm explained that this is regarding the change discussed a few meetings ago about affiliates. Mr. Azzolin commented that he does not have an issue with the language. He asked if the Board would have an obligation to reach out to any affiliates that it was unaware of and let them know they are practicing pharmacy without the appropriate PBM license. Mr. Changus responded that he thinks the requirement in the statute is for them to report and it does not impose a duty on the board. Mr. Azzolin asked if it gives the Board authority to reach out to these entities who are not licensed. Mr. Changus stated that he would give this question consideration. With no further discussion, Mr. Stone made a motion to post Rule 480-6-.02 Nonresident Pharmacy Permit. Mr. Faulk seconded and the Board voted unanimously in favor of the motion.

Rule 480-6-.02. Nonresident Pharmacy Permit

(1) Effective April 1, 2015, it shall be unlawful for any person, pharmacy, or facility located outside this state to ship, mail, or deliver prescription drugs orders into this state or to advertise its services, personally or through an in-state third party, unless such person, pharmacy or facility holds a pharmacy license pursuant to O.C.G.A. Section 26-4-110.1, or holds a nonresident pharmacy permit pursuant to O.C.G.A. Section 26-4-114.1, or is otherwise exempt from Georgia registration as a matter of Georgia law.

(2) Application for a non-resident pharmacy permit:

(a) Applications must be filed with the Georgia State Board of Pharmacy located at 2 Peachtree Street, NW, 6th Floor, Atlanta, Georgia 30303, along with the required fee.

(b) The Board requires information from each applicant for a nonresident pharmacy permit on its application, including but not limited to, the following:

1. The name, full business address, and telephone number of the applicant;
2. All trade or business names used by the applicant;
3. Address, telephone numbers, and the names of contact persons for each facility used by the applicant for the records, storage, handling, and distribution of prescription drugs into this state;
4. Address, telephone number and name of agent of service for the applicant;
5. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship);
6. The name(s) of the owner and/or operator of the pharmacy, including:
   (i) If a person, the name of the person;
   (ii) If a partnership, the name of each partner and the name of the partnership;
   (iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the incorporation, and the name of the parent company, if any; or
   (iv) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.

7. Where operations are conducted at more than one location by a single pharmacy, each such location shall be permitted by the Board;
8. Proof of a valid, unexpired license, permit, or registration to operate a pharmacy in the compliance with the laws and rules of each state in which the applicant receives and dispenses prescription drug orders;
9. The names and license numbers of the pharmacist-in-charge of each facility involved in dispensing drugs to residents of this state and evidence that the pharmacist(s) are licensed and in good standing in the state where they are located;
10. Information necessary to demonstrate compliance with O.C.G.A. T. 50, Ch. 36;
11. Evidence satisfactory to the Board that the applicant in is compliance with all laws and investigations from each regulatory or licensing agency in which the applicant holds a license; and
12. If dispensing sterile or nonsterile compounding for practitioners to use in patient care in the practitioner's office, a copy of the most recent inspection report that is no older than two (2) years before the date of application was submitted and which is from an inspection conducted by the regulatory or licensing agencies of the jurisdiction in which the applicant is located that indicates compliance with the Board's rules and regulations and compliance with USP-NF standards for pharmacies performing sterile and nonsterile compounding, or another inspection approved by or conducted by the Board.

(3) Registration of a nonresident pharmacy permit will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the GDNA certifying the applicant possesses the necessary qualifications for a permit.

(4) Application fees and renewal fees shall be set by the Board in a fee schedule and shall not be refundable.

(5) Permits may be denied for failure to comply with rules of the Board, for failure to meet the minimum qualifications for a permit, for the conviction by an owner or pharmacist of a felony involving the practice of pharmacy or the distribution of drugs, for false representations on an application, and for any other good cause related to evidence of misfeasance or malfeasance by the applicant.

(6) Permits become null and void upon the sale, transfer or change of mode of operation or location of the business. Prior to the sale, transfer or change in mode of operation or the location of the business, the nonresident pharmacy may apply for such change by submitting a Board- approved application to the Board, and paying a fee. The permits of nonresident pharmacies will not become void if proper application is made and approved prior to the change.

(7) Permits are issued for two years and expire on June 30th of each odd-numbered year, and may be renewed for two years upon the payment of the required fee for each place of business and the filing of a completed application for renewal. Applicants for renewal must submit such evidence as requested by the Board including, but not limited to evidence of certain inspection reports on compounding and the status of the licenses of the pharmacy and pharmacists in the state of location. If the application for renewal is not made and the fee not paid before September 1st of the odd-numbered year, the permit shall lapse and shall not be renewed, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.

(8) The denial of a nonresident pharmacy permit and the denial of the renewal of a nonresident pharmacy permit shall not be considered a contested case under the provisions of O.C.G.A. T. 50, Ch. 13, but the applicant shall be entitled to an appearance before the Board.

(9) Nonresident pharmacy permit holders shall comply with all the recordkeeping requirements of the state in which they are located and licensed for all prescriptions shipped, mailed or delivered to patients or practitioners in the State of Georgia, but shall be maintained a minimum of two (2) years. Nonresident pharmacy permit holders shall notify the Board of each location where the required records are being maintained, and such records must be readily retrievable and produced to the Board within fifteen (15) business days, upon written request.

(10) In addition to labeling requirements required by the state where the nonresident pharmacy is located, the permit holders shall label the drugs dispensed with the following minimum information:

(a) The name and address of the dispenser;
(b) The serial number and date of the prescription or of its filling;
(c) The name of the prescriber;
(d) The name of the patient;
(e) The name of the drug dispensed;
(f) The direction for use and cautionary statements; and
(g) Identification of the pharmacist filling the prescription.

(11) Nonresident pharmacy permit holders shall comply with the Board's rules and regulations on delivery of prescriptions by mail in Board Chapter 480-48.

(12) Nonresident pharmacy permit holders shall comply with the laws and rules and regulations of the state where such pharmacies are located.

(13) Nonresident pharmacy permit holders who compound drugs must comply with the federal compounding laws as required in Board Chapter 480-11.

(14) Nonresident pharmacy permit holders shall maintain a toll-free telephone number operational during the permit holder's regular hours of operation, but not less than six days per week for a minimum of 60 hours per week, in order to provide patient counseling. Such toll-free number shall be capable of receiving inbound call from patients to the permit holder, and such number shall be on file with Board and shall be included on the label affixed to each container of all dispensed and distributed drugs sent into the State of Georgia.

(15) Nonresident pharmacy permit holders must notify the Board within five (5) business days of the receipt of any final order or decision by any other licensing board or federal agency of the imposition of disciplinary action or restriction by such other licensing board or federal agency. A final order or decision includes a consent order or agreement and is any decision, regardless whether there still exists an appellate right to the state or federal courts. Any revocation or suspension of a state or federal license or permit will result in the immediate suspension of the nonresident pharmacy permit pending a final decision by the Board.

(16) Within 72 hours, nonresident permit holders must update the Board of any change in pharmacist-in-charge of shipping into Georgia by completing forms provided by the Board and including such pharmacist licensure information and criminal history. Where a criminal background check cannot be completed within the seventy-two (72 hours) contemplated by this section, nonresident pharmacy permit holders must still update the Board of any change in pharmacist-in-charge of shipping into Georgia by completing forms provided by the Board and including such pharmacist licensure information, but shall have up to fifteen (15) business days to provide criminal history information.

(17) Nonresident pharmacy permit holders shall cooperate with the Board in any investigation involving prescription drugs distributed by such permit holder into this state or related to the permit holder's compounding practices. The permit holder shall respond within ten (10) business days to all communications from the Board or its designee. Failure to respond or cooperate with the Board shall be grounds for the immediate suspension of the nonresident pharmacy permit, pending a hearing on further disciplinary action by the Board. Failure to cooperate with the Board is grounds for disciplinary action by the Board.

(18) Notices to nonresident pharmacy permit holders shall be made on the agent of record with the Board. If notices are returned as undeliverable or unclaimed, service shall be made on the Executive Director., and any disciplinary proceedings shall proceed, or if a final decision, the decision shall become effective.

(19) If, in the course of investigation of a nonresident pharmacy permit holder or applicant, an onsite inspection by the Board or its designee is required, the permit holder or applicant shall be responsible for the cost of such onsite inspection.

(20) A nonresident pharmacy permit may be revoked or suspended or otherwise disciplined for any reason that a permit may be denied, for failure to comply with this rule, for disciplinary action by other

states and federal agencies, for conduct causing bodily or psychological injuries to a resident of this state, and for failure to comply with Board laws and other applicable rules as provided herein.
(21) If a nonresident pharmacy holder has an affiliate as defined by O.C.G.A. § 26-4-119, it shall annually file a disclosure statement identifying all such affiliates no later than June 30 every year.

Rule 480-10-.01 Controlled Substances and Dangerous Drugs: The Board recommended tabling this rule.

Rule 480-10-.18 Pharmacy Anti-Steering and Transparency Act and Affiliates: Ms. Emm discussed the proposed amendments with the Board. Mr. Prather made a motion to post Rule 480-10-.18 Pharmacy Anti-Steering and Transparency Act and Affiliates. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Rule 480-10-.18 Pharmacy Anti-Steering and Transparency Act and Affiliates
If a retail pharmacy has an affiliate as defined by O.C.G.A. § 26-4-119, it shall annually file a disclosure statement identifying all such affiliates no later than June 30 every year.

Mr. Brinson made a motion and Mr. Stone seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and § 43-1-2(k) to deliberate and to receive information on applications, investigative reports and the Assistant Attorney General's report. Voting in favor of the motion were those present who included Michael Azzolin, Michael Brinson, Mike Faulk, Lisa Harris, Bill Prather and Dean Stone.

Executive Session

Miscellaneous
The Board discussed board member recusal from applications/investigative matters.

Appearances
- C.M.H.
- W.C.R.M.C.
- S.P.C.

Georgia Drugs and Narcotics Agency – Dennis Troughton
- A.B.
- The Board discussed O.C.G.A. § 26-4-28 and O.C.G.A. § 16-13-45.

Cognizant's Report – Mike Faulk
- GDNA Case # T33226
- GDNA Case # A33230
- GDNA Case # B33113
- GDNA Case # A33115
- GDNA Case # B33140
- GDNA Case # B33155
- GDNA Case # B33161
- GDNA Case # B33176
- GDNA Case # B33178
- GDNA Case # B33190
- GDNA Case # B33193
- GDNA Case # B32980

Attorney General's Report – Max Changus

Mr. Changus discussed the following:

- G.H.

Executive Director's Report – Tanja Battle

No report.

Legal Services – Kimberly Emm

No report.

Applications

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

Correspondences/Requests

- D.S.P.D.
- I.R.
- A.R.W.P.
- H.F.P.A.S.
- T.P.
- F.M.C.
- A.P.S.P.
- A.I.S.
- I.R.
- P.I.
- K.C.P.
- C.P.
- H.W.
- T.A.P.
- T.A.P.
- A.I.
- D.P.S.
- D.P.S.
- H.I.L.C.O./T.H.C.
- W.P.N.
- W.P.N.
- A.H.I.
- A.H.I.
- A.H.I.

- A.H.I.
- A.H.I.
- A.H.I.
- A.H.I.
- A.H.I.
- D.C.R.I./P.C.A.
- N.H.D.N.G.G.R.C.
- F.N.
- J.E.W.
- J.J.C.
- J.H.L.
- K.A.L.

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

Open Session

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

Miscellaneous
The Board discussed board member recusal from applications/investigative matters.

Appearances

• C.M.H.	Denied Retail Pharmacy Applicant	Uphold denial
• W.C.R.M.C.	Denied Retail Pharmacy Applicant	Uphold denial
• S.P.C.	Request to discuss reinstatement	Refer to the Department of Law

Georgia Drugs and Narcotics Agency – Dennis Troughton
- A.B. Pharmacist Exam Applicant
- The Board discussed O.C.G.A. § 26-4-28 and O.C.G.A. § 16-13-45.

Cognizant's Report – Mike Faulk
- GDNA Case # T33226 Accept Voluntary Surrender
- GDNA Case # A33230 Accept Private Interim Consent Order for Assessment
- GDNA Case # B33113 Refer to the Department of Law
- GDNA Case # A33115 Here they voted to extend rph's probation…not sure what to put for action taken
- GDNA Case # B33140 Refer to the Department of Law
- GDNA Case # B33155 Close with no action
- GDNA Case # B33161 Close with no action
- GDNA Case # B33176 Close with no action
- GDNA Case # B33178 Close with no action
- GDNA Case # B33190 Close with no action
- GDNA Case # B33193 Close with no action
- GDNA Case # B32980 Refer to the Department of Law

Attorney General's Report – Max Changus
Mr. Changus discussed the following:
- G.H. Deny counterproposal

Executive Director's Report – Tanja Battle
No report.

Legal Services – Kimberly Emm
No report.

Applications

• Kameron D. Francis	Pharmacy Technician	Approved for registration
• Jonathan C. Sanchez	Pharmacy Technician	Approved for registration
• Alana M. Willis	Pharmacy Technician	Approved for registration
• M.W.	Pharmacist Intern	Denied application
• J.N.H.	Pharmacist Exam	Approved to sit for the exam
• L.B.C.	Pharmacist Reciprocity	Approved to sit for the exam
• R.A.F.	Pharmacist Reinstatement	Schedule to meet with the Board
• G.T.L.	Nuclear Pharmacist	Approved application
• M.W.S.	Nuclear Pharmacist	Approved application
• O.O.	Correspondence	Table pending receipt of additional information
• National Seating & Mobility	Durable Medical Equipment	Approved application
• H.S.E.	Wholesaler Pharmacy	Refer to the Department of Law

Correspondences/Requests

• D.S.P.D.	Notice of discipline	No action
• I.R.	Notice of discipline	No action
• A.R.W.P.	Notice of discipline	No action
• H.F.P.A.S.	Notice of discipline	No action
• T.P.	Notice of discipline	No action
• F.M.C.	Notice of discipline	No action
• A.P.S.P.	Notice of discipline	No action
• A.I.S.	Notice of discipline	No action
• I.R.	Notice of discipline	No action
• P.I.	Notice of discipline	No action
• K.C.P.	Notice of discipline	No action
• C.P.	Notice of discipline	No action
• H.W.	Notice of discipline	No action
• T.A.P.	Notice of discipline	No action
• T.A.P.	Notice of discipline	No action
• A.I.	Notice of discipline	No action
• D.P.S.	Notice of discipline	No action
• D.P.S.	Notice of discipline	No action
• H.I.L.C.O./T.H.C.	Notice of discipline	No action
• W.P.N.	Notice of discipline	No action
• W.P.N.	Notice of discipline	No action
• A.H.I.	Notice of discipline	Table pending receipt of additional information
• A.H.I.	Notice of discipline	Table pending receipt of Additional information
• A.H.I.	Notice of discipline	Table pending receipt of

		additional information
• A.H.I.	Notice of discipline	Table pending receipt of additional information
• A.H.I.	Notice of discipline	Table pending receipt of additional information
• A.H.I.	Notice of discipline	Table pending receipt of additional information
• A.H.I.	Notice of discipline	Table pending receipt of additional information
• A.H.I.	Notice of discipline	Table pending receipt of additional information
• D.C.R.I./P.C.A.	Notice of discipline	No action
• N.H.D.N.G.G.R.C.	Remote order entry	Approved request
• F.N.	Request for extension of application	Approved request
• J.E.W.	Request for 4th attempt at MPJE	Approved request
• J.J.C.	Request for 4th attempt at MPJE	Approved request
• J.H.L.	Request for 5th attempt at MPJE	Approved request
• K.A.L.	Request to lift supervised practice	Approved request

Mr. Stone seconded and the Board voted in favor of the motion, with the exception of Mr. Azzolin, who opposed the recommendation for G.H., and recused himself from the votes regarding C.M.H. and W.C.R.M.C.

Miscellaneous

Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security and Rule 480-13-.06 Drug Distribution Control. Mr. Brinson made a motion to post Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security and Rule 480-13-.06 Drug Distribution Control. Mr. Stone seconded. Discussion was held. Mr. Azzolin commented that per GDNA comments, there is no statistical evidence, and less than 2% of diversion happens prior to drugs being checked in. He added that this will affect workflow. Mr. Brinson asked how. Mr. Azzolin responded that the Board should not be dictating to a pharmacy how it manages its workflow. Mr. Stone commented that the DEA already says schedule IIs must be checked in and the Board is just adding schedule IIIs, IVs and Vs. He added that they are already doing this in part and does not see how it can effect workflow. Mr. Azzolin expressed his concerns and stated it is not a massive workflow issue, but every little thing the Board does effects workflow and he does not like dictating what a pharmacy should do regarding such. With no further discussion, the motion passed. Mr. Azzolin opposed the motion.

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

(1) Every retail pharmacy, possessing or having possessed any controlled substances and/or dangerous drugs, within a period of two years, and/or possessing any record related to the same, which is required to be kept by O.C.G.A. T. Ch. 16-13, shall exercise diligent care in protecting such controlled substances and/or dangerous drugs and/or records related to the same from loss or theft.

(a) Every licensed retail pharmacy shall ensure that all controlled substances and/or dangerous drugs are purchased from and/or returned to firms holding a current permit issued by the Georgia State Board of Pharmacy (Board). This requirement can be met by a pharmacy maintaining a copy of such firms' current Georgia Board permit.

(b) It shall be the responsibility of the pharmacist on duty to sign for all controlled substances upon receipt.

(2) All controlled substances and/or dangerous drugs shall be kept in the prescription department, accessible only to an authorized person, except where contained in a collection receptacle compliant with state and federal law and regulation.
(3) The Georgia Drugs and Narcotics Agency (GDNA) shall have the authority to conduct inspections of any place or premises used by any such licensed retail pharmacy in relation to such controlled substances and/or dangerous drugs and/or any records pertaining to their acquisition, dispensing, disposal, or loss.
(4) The GDNA shall have the authority to examine, copy, or remove all such records, and to examine, copy, remove, or inventory all such controlled substances and/or dangerous drugs.

(a) It shall be the responsibility to such person possessing such controlled substances and/or dangerous drugs and/or records to make the same available for such inspection, copying, examination, or inventorying by said GDNA.

(b) At the conclusion of an inspection, the GDNA personnel examining said drugs and/or records shall have the responsibility of providing to such retail pharmacy a copy of an inspection report on which any deficiencies or violations are made along with any recommendations, if any, concerning the satisfactory storage, keeping, handling and security of controlled substances and/or dangerous drugs.

(5) Any person possessing controlled substances and/or dangerous drugs and/or records may request that such an inspection be made, and upon receipt of such written request, the GDNA Director shall make, or cause to be made, without reasonable delay, an inspection in compliance with said request.

Rule 480-13-.06. Drug Distribution Control

(1) General. A drug distribution system is the entirety of that mechanism by which a prescription drug order is executed, from the time the practitioner transmits the order either orally or in writing to an authorized health professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration.
(2) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the hospital shall cooperate with the Director of Pharmacy in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials to achieve this purpose. The Director of Pharmacy shall establish written procedures for the distribution of parenteral medications to achieve this goal. Accordingly, the Director of Pharmacy shall be responsible for, at a minimum, the following:

(a) 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 or utilizing such other equipment to protect the integrity of the product, within the pharmacy department. Individuals who prepare or administer large volume parenterals must have special training to do so. These functions of IV admixture compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas such as Intensive Care Units, Cardiac Catheterization Laboratories Intensive Care Units, etc., during emergency situations, or during unattended hours of the pharmacy department. When any part of the above functions (preparing, sterilizing, and labeling parenteral medications and solutions) is performed within the hospital but not under direct pharmacist supervision, the Director of Pharmacy shall be responsible for providing written guidelines and for approving the procedures to assure that all pharmaceutical requirements are met;
(b) All drugs must be identified up to the point of administration;
(c) All controlled substances must be signed for by a pharmacist upon receipt;
(~~c~~d) The pharmacy must receive a direct copy, electronic or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by hospital stat order policy;
(~~d~~e) Utilization of a pharmacy-generated patient profile. The patient profile shall be the official record of medications dispensed to the patient. The patient profile or the ability to generate such

profile electronically shall be under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:

1. Given and last name of the patient;
2. Age;
3. Sex;
4. Provisional diagnosis;
5. Room number;
6. Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;
7. Identification or differentiation of controlled substances;
8. Intravenous therapy;
9. Selected medical data;
10. Drug history interview (when possible); and
11. Sensitivities and allergies to drugs and foods;

~~(e) No more than a 72-hour supply of a patient's medication shall be available at the patient-care area at any time except for those drugs in bulk packages which cannot be repackaged in unit-dose containers;~~

(f) Manufacture of drugs, if applicable;

(g) Establishment of specifications or use of compendia specifications for procurement of drugs, chemicals, devices and biologicals, subject to approval of the appropriate committee of the hospital;

(h) Participation in the development of a drug formulary for the hospital;

(i) filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;

(j) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs. Current antidote information, telephone numbers of regional poison control center(s) and other emergency assistance organizations, and other material and information as may be deemed necessary shall be maintained;

(k) Records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over the accountability for all pharmaceutical drugs, devices and materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;

(l) Participation in those aspects of the hospital patient care evaluation program which relate to pharmaceutical drug, device and material utilization and effectiveness; and

(m) Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.

(3) Labeling.

(a) For use inside the hospital, all drugs dispensed by a hospital pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.

(b) For use outside the hospital, all drugs dispensed by a hospital pharmacy to patients about to be discharged or on leave of absence shall be labeled with the following information:

1. Name, address, and telephone number of the hospital pharmacy;
2. Date and identifying serial number;
3. Patient's give n and last name;
4. Name of drug, (brand or generic) and strength;
5. Directions for use by patient;
6. Name of prescribing practitioner;
7. Required precautionary information regarding controlled substances; and
8. Such other and further accessory cautionary information as may be required or desirable for proper use by and safety of the patient.

(c) Drugs added to parenteral solutions. Wherever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a licensed pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and the identity of the person so adding.

(4) Discontinued drugs. The Director of Pharmacy shall develop and implement policies and procedures to insure that outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(a) Full doses of controlled substances prepared for administration and not given must be destroyed by a licensed pharmacist or a licensed nurse and one witness. Any portions of controlled substances discontinued and taken from a medication delivery device shall be destroyed by a licensed pharmacist or a licensed nurse and one witness. The two persons witnessing the destruction must sign the destruction record at the time of destruction. The destruction record shall be returned to the pharmacy and must be signed by the pharmacist who is ultimately responsible for the accuracy of the information contained therein.

(b) 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;

1. Placed in a secure storage area at the facility separated from other medications. The drugs may be destroyed at the facility by the pharmacist and another licensed healthcare practitioner designated by the facility. However, before the destruction can take place, it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction and the inventory for a two year period. This record shall include at a minimum the date, time, and personnel involved with the destruction and the method of destruction; or

2. If the drugs are to be transferred to a reverse distributor with a current license issued by the Board, a record of the following must be maintained by the hospital pharmacy for a minimum of two years:

(i) An inventory of the drugs to be transferred including the names of the drugs; the dosage form(s) of the drugs and the quantity of the drugs; the inventory shall be verified by a pharmacy representative and a representative of the reverse distributor;

(ii) The date and time the drugs were taken from the pharmacy;

(iii) The name, Board permit number, address and telephone number of the destruction firm removing the drugs;

(iv) The name and signature of the responsible person representing the reverse distributor who is physically removing the drug(s);

(v) The name and signature of the pharmacist representing the pharmacy transferring the drug(s) to the reverse distributor.

(c) The following methods of destruction of controlled substances are approved by the Board of Pharmacy:

1. A securely attached wooden or metal cabinet within a locked limited-access area shall be used to store the drugs until the drugs are destroyed. When controlled drugs are discontinued or the patient expires, the medication shall be pulled from the active stock immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional. The inventory must be recorded into a permanent record and the

drugs shall then be placed in the aforementioned cabinet. This medication shall remain within the locked cabinet until such time as it is removed for destruction.

2. The pharmacist shall establish a form, which shall include the following data:
   (i) Date of discontinuance or inventory date;
   (ii) Name of patient;
   (iii) Name of pharmacy;
   (iv) Identifying serial numbers;
   (v) Name and strength of the drug; and
   (vi) Quantity of the drugs in container(s) at the time of inventory.

3. A licensed pharmacist or licensed nurse and one witness must destroy the drugs.

4. Inventory of the drugs included in the final destruction must be taken with one copy retained by the facility. The inventory shall be certified by the two witnesses present at the destruction in the following format:

"We, whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____ (location) on _____ (date) at _____ o'clock. "

Name of drug

Strength of drug

Dosage form

Quantity of drug

_____

(Signature and Title)

_____

(Signature and Title)

_____

(Signature and Title)

5. The Board and/or the GDNA may prohibit any pharmacist or hospital pharmacy from utilizing this method.

(d) A method of off-site destruction allowable by the Board is as follows:

1. The drugs to be destroyed shall be immediately removed from the active stock and stored in a separate and secure location in the pharmacy until the drugs are transferred. When the drugs are transferred to a reverse distributor licensed by the Board, an inventory must be recorded and include the following information: the names of the drugs, the dosage forms of the drugs and the quantities of the drugs taken and witnessed by an authorized representative of the hospital pharmacy and the responsible person representing the reverse distributor.

2. A receipt including the date and time the drugs were taken from the pharmacy; the name, Board permit number, address and telephone number of the reverse distributor removing the drugs; the inventory of the drugs; the name, signature and title of the responsible person representing the reverse distributor; and the name, signature and title of

the pharmacy representative transferring the drugs. This receipt/record must be maintained by the hospital pharmacy for a minimum of two years.

(5) Prescription drug orders. Drugs may be dispensed from the hospital pharmacy only upon written orders, direct or mechanical copies thereof, of authorized practitioners.

(a) Authorization. The appropriate committee of the hospital shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.

(b) Abbreviations. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.

(c) Requirements - Prescription drug orders for drugs, devices or materials for use by in-patients. Prescription drugs orders for use by in-patients shall, at a minimum, contain:

1. Patient name and room number;
2. Drug name, strength, directions for use; and
3. Date and practitioner's signature.

(d) Requirements - Prescription drug orders for drugs, devices or materials for use by outpatients. Prescription drug orders for drugs, devices or materials for use by outpatients shall, at a minimum, contain all of the information required by Rule 480-13-.06(5)(c), and in addition include:

1. Quantity to be dispensed;
2. Practitioner's address and Drug Enforcement Administration identification code, if applicable, and
3. Patient's address, if applicable.

(6) Accountability of controlled drugs.

(a) Proof of use of controlled drugs on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the hospital, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:

1. Name of drug, strength, and dosage form;
2. Dose administered;
3. Name of authorized practitioner. This shall include, at a minimum, the initial and last name;
4. Given and last name of the patient;
5. Date and time of administration to the patient;
6. Signature of the individual administering, which shall include at a minimum, the initial, last name, and title;
7. Documentation of the destruction of any and all unused portions by two signature verifications;
8. Proof of receipt of the medications that bears identifying serial numbers; and
9. Date the medication was issued and the date that the proof of use form was returned to the pharmacy.

(b) Anesthesia departments that obtain controlled drugs from the hospital pharmacy must show accountability of the controlled drugs by proof of use as defined above.

(c) Use of computer generated hard copy is permitted where such copy meets all other requirements of the law.

(d) Any hospital pharmacy licensed by the Georgia State Board of Pharmacy and in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:

1. The controlled substance is either a whole dose or a partial dose of a single-dosage unit; and
2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.

(e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.

(7) Recall. The Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper disposition.

(8) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering authorized practitioner, the pharmacy, and to the appropriate committee of the hospital. An appropriate entry on the patient's medical record shall also be made.

(9) Records and reports. The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety and welfare. Such records shall be readily available and subject to inspections by the Board of Pharmacy, the GDNA or its employees. These shall include, at a minimum, the following:

(a) Patient profile;
(b) Proof of use;
(c) Reports of suspected adverse drug reactions;
(d) Inventories of night cabinets and emergency kits/crash carts;
(e) Inventories of the pharmacy;
(f) Biennial controlled substances inventories;
(g) Alcohol and flammables reports; and
(h) Such other records and reports as may be required by state Law and the Rules and Regulations of the Board of Pharmacy.

(10) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a hospital for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said hospital or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order. This practitioner's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A record of administration of drugs administered to patients in ancillary areas such as but not limited to the operating room, emergency room, anesthesiology, and x-ray shall be forwarded to the pharmacy and these medications shall be recorded on the patient profile. A survey of usage trends of each standard ward inventory shall be prepared monthly. Such records shall be retained for a period of two years.

(11) Emergency room dispensing. An authorized practitioner may, when drugs or controlled substances are not otherwise available from a licensed pharmacy, dispense an emergency amount of medication, but only sufficient quantities until such time as medication can be obtained from a pharmacy licensed as a retail pharmacy. Nurses or other unauthorized personnel may not dispense medication from the emergency room. The total act of dispensing shall be performed by an authorized practitioner in accordance with Pharmacy Laws, Rules and Regulations. Such medications shall be labeled as required in Section 480-13-.06(3)(b).

A motion was made by Mr. Prather, seconded by Mr. Faulk, and the Board voted that the formulation and adoption of these rule amendments do 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 Variance Petitions from Clinch Memorial Hospital and Washington County Regional Medical Center: Mr. Faulk made a motion to deny the rule variance petitions as there was no substantial hardship

demonstrated. Mr. Prather seconded and the Board voted in favor of the motion, with the exception of Michael Azzolin, who abstained from the vote.

Senate Bill 316/House Bill 914: Mr. Brinson stated that back in July, the Governor signed into law a bill about military and their spouses. He stated he went back and read the minutes and did not see where the Board did anything as a pharmacy board. Mr. Brinson stated that an individual can come in, but he/she must take the practical before the Board will license someone. Mr. Brinson stated that, depending on when someone applies, it could be six months without a license. Ms. Battle responded that the Board is able to provide a remedy, by law, and has a process by which an individual may be eligible for a temporary license. Mr. Brinson commented that he just wanted to make sure the Board was covered. Mr. Stone expressed his concerns over the long wait time between August and January. Mr. Lacefield commented that temporary licensure is not just for the military service members and spouses. He stated that it also applies to applicants that have submitted evidence of an emergency situation justifying such temporary license. Ms. Battle stated that there is an application for a temporary license that is submitted by the applicant. If the applicant is applying based on an emergency, the Board would consider the application and make a determination. She stated in regards to reciprocity, this board decided to require an exam in 2013. Mr. Prather responded that the Board decided it was best to require the exam because of individuals like himself that graduated years ago. Mr. Stone stated that he just feels like August through January is a long time whether it is an emergency or not.

There being no further business to discuss, the meeting was adjourned at 4:28 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, April 15, 2020 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6th floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I
Minutes edited by Tanja D. Battle, Executive Director