GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St, NW, 5th Floor
Atlanta, GA 30303
October 10, 2018
9:00 a.m.

The following Board members were present:
Bill Prather, President
Michael Brinson
Mike Faulk
Lisa Harris
Hal Henderson
Bob Warnock

Staff present:
Tanja Battle, Executive Director
Dennis Troughton, Director, GDNA
Ronnie Higgins, Deputy Director, GDNA
Michael Karnbach, Special Agent, GDNA
Michael Poblet, Special Agent, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst I

Visitors:
Stephanie Kirkland, ElderCare
Amanda Roberson, ElderCare
Ted A. Green, ElderCare
Christiana Craddock, MAG
Greg Reybold, GPhA
Angelique Turner, Walgreens
Rena Estep, Walgreens
Young Chang, Walgreens
Brian Looby, MWC
Carla Winkles, Mercer
Alicia Palombo, CVS Health
Amy Krieg, GHA
Vince Obsitnik, GVMA
Jeenu Philip, Walgreens
John Rocchio, CVS
Beth Jarrett, Walmart
Stephen Snow, Bendin, Sumrall & Ladner
Helen Sloat, Kaiser Permanente, Hemophilia of GA
Elizabeth Newcomb, Frogue Clark
TJ Kaplan, JLM
J. Basile
Stephen Mellen

Open Session

President Prather established that a quorum was present and called the meeting to order at 9:04 a.m.

Miscellaneous

Emergency Policy Discussion: Michael Brinson made a motion to amend its Policy #14 and approve the following Statement of Interpretation Relating to Emergency Prescription Refills for Evacuees Due to Hurricane Michael. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

STATEMENT OF INTERPRETATION RELATING TO EMERGENCY PRESCRIPTION REFILLS FOR EVACUEES DUE TO HURRICANE MICHAEL

Policy #14 of the Georgia Board of Pharmacy ("Board") provides for the refills of certain medication for up to 30 days for persons in the areas covered by a State of Emergency declared by the Governor of the State of Georgia. This policy is consistent with O.C.G.A. Section 26-4-80(j) and the Governor's Emergency Declaration. The Board is clarifying that persons who are evacuated from those emergency areas may also receive a 30-day refill of medication by a Georgia pharmacy or pharmacist without risk of disciplinary action by the Board so long as:

- The refill is not for a controlled substance;
- In the pharmacist's professional judgment, the prescription drug is essential to the maintenance of the patient's life or to the continuation of therapy;
- The pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "emergency refill prescription," and maintains the record as required by state and federal law and as required by state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency;
- The pharmacist informs the patient or the patient's agent at the time of dispensing that the prescription drug is being provided without the practitioner's authorization and that authorization of the practitioner is required for future refills; and

As emergency conditions permit, the pharmacist notifies the practitioner that the refill occurred.

Policy #14: Public Emergencies

Section 1. Purpose and Scope

The primary purpose of this policy is to enable pharmacists and pharmacies to assist in the management and containment of a public emergency or similar crisis within the confines of a regulatory framework that serves to protect the welfare and health of the public. The Board will consider petitions for rule waivers or variances regarding record-keeping, minimum physical area, and minimal equipment requirements related to the state of emergency in the declared disaster areas and affected areas on an emergency basis, pursuant to a written request in a manner consistent with the Board's authority under state law and/or the Governor's State of Emergency.

Section 2. Definitions.

For the purposes of this policy, the following definitions apply:

(a) "Affected Areas" include areas covered by the state of emergency.

(b) "Declared Disaster Areas" are areas designated by state or federal authorities as those that have been adversely affected by a natural or man-made disaster and require extraordinary measures to provide adequate, safe, and effective health care for the affected population.

(c) "Mobile Pharmacy" means a pharmacy that is self-propelled or movable by another vehicle that is self-propelled.

(d) "State of Emergency" means a governmental declaration issued by the Governor of the State of Georgia or the President of the United States which may suspend certain normal functions of

government, alert citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.

(e) "Temporary Pharmacy Facility" means a facility established as a result of a state of emergency to temporarily provide pharmacy services within or adjacent to declared disaster areas.

Section 3. Emergency Refill Dispensing

(a) For the duration of the state of emergency issued in the affected area and consistent with O.C.G.A. §26-4-80(j), a pharmacist may dispense a 72 hour refill supply of a prescription drug repeatedly to a patient, but in total not more than a thirty (30) day supply, without practitioner authorization if:

(1) The refill is not for a controlled substance;

(2) In the pharmacist's professional judgment, the prescription drug is essential to the maintenance of the patient's life or to the continuation of therapy;

(3) The pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "emergency refill prescription," and maintains the record as required by state and federal law and as required by state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency;

(4) The pharmacist informs the patient or the patient's agent at the time of dispensing that the prescription drug is being provided without the practitioner's authorization and that authorization of the practitioner is required for future refills; and

(5) When emergency conditions permit, the pharmacist notifies the practitioner that the refill occurred.

Section 4. Temporary Recognition of Non-Resident Licensure

(a) When a state of emergency is declared and consistent with O.C.G.A. §26-4-43:

(1) A pharmacist not licensed in this state, but currently licensed in another state, may obtain a temporary license to dispense prescription drugs in areas affected by the declared disaster during the time that the state of emergency exists if:

(i) The Board can verify current licensure in good standing of the pharmacist directly with the state or indirectly via a third-party verification system; and

(ii) The pharmacist is engaged in a documented relief effort.

(2) A pharmacy technician or pharmacy intern not registered or licensed in this State, but currently registered or licensed in another state, may assist the pharmacist in dispensing prescription drugs in affected disaster areas during the time that the state of emergency exists if:

(i) The Board can verify current registration or licensure in good standing of the pharmacy technician or pharmacy intern directly with the state or indirectly via a third-party verification system; and

(ii) The pharmacy technician or pharmacy intern is engaged in a documented relief effort.

(b) The temporary recognition of non-resident pharmacist licensure and pharmacy intern licensure shall cease at end of the month following the third board meeting conducted after the issuance of such license and shall not be renewed. The temporary recognition of non-resident pharmacy technician registration shall registration shall cease with the termination of the state of emergency.

Section 5. Temporary Pharmacy Facilities or Mobile Pharmacies

(a) Consistent with the authority in O.C.G.A. §26-4-110, and if necessary to provide pharmacy services during a state of emergency, pharmacies located in declared disaster areas and non-

resident pharmacies may arrange to temporarily locate or relocate to a temporary pharmacy facility or mobile pharmacy if the temporary pharmacy facility or mobile pharmacy:

(1) Is under the control and management of the pharmacist-in charge or designated supervising pharmacist;
(2) Is located within the declared disaster area or affected areas;
(3) Notifies the Board of its location, subject to approval by the Board in accordance with (b);
(4) Is properly secured to prevent theft and diversion of drugs;
(5) Maintains records in accordance with laws and regulations of the state in which the disaster occurred; and
(6) Ceases the provision of services with the termination of the state of emergency, unless it is successfully licensed by the Board of Pharmacy in accordance with the Georgia Pharmacy Practice Act and applicable rules.

(b) The Board shall have the authority to approve or disapprove temporary pharmacy facilities and mobile pharmacies and shall make arrangements for appropriate monitoring and inspection of the temporary pharmacy facilities and mobile pharmacies on a case-by-case basis. Approval of temporary pharmacy facilities and mobile pharmacies will be based on the need, type, and scope of the state of emergency, as well as the ability of the temporary pharmacy facilities or mobile pharmacies to comply with state and federal drug law.

(c) A temporary pharmacy facility wishing to permanently operate at its temporary site must be licensed by the Board in accordance with the Georgia Pharmacy Practice Act and applicable Board rules.

(d) Mobile pharmacies, placed in operation during a state of emergency, may not operate permanently, unless approved by the Board.

Approval of Minutes

Lisa Harris made a motion to approve the Public and Executive Session minutes from the September 12, 2018 meeting. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Michael Brinson made a motion to ratify the list of licenses issued. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

The Board discussed the rule waiver petition submitted from CVS Health. Mr. Rocchio was present at the meeting and spoke to the Board regarding the petition. Mr. Rocchio explained that CVS Health is seeking a waiver of Rule 480-36-.03(4). In the documents provided by Mr. Rocchio, it says CVS Health believes the existing language of 480-36-.03(4) places an additional level of responsibility on the pharmacist verifying the accuracy of the product dispensed, which exceeds the expectations placed on a pharmacist performing the same task within a single pharmacy location. Assigning responsibility of prescription order entry accuracy to the pharmacist at the primary dispensing pharmacy negates the purpose of pharmacy workload sharing. They believe the language of 480-36-.03(5) sufficiently outlines the responsibility of the pharmacist at the secondary remote entry pharmacy, which encompasses the accuracy of order entry. After further discussion by the Board, the Board recommended tabling consideration of this matter until its November meeting to allow additional time to review.

Bob Warnock made a motion to grant the rule waiver petition from Jefferson Hospital Pharmacy-Corp, PHH003567. Michael Brinson seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion to deny the rule waiver petition from SCILEX Pharmaceuticals, Inc. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

The Board discussed the rule waiver petition from Taylor Regional Hospital, PHH005070 and The Medical Center of Peach County, PHH007937. President Prather stated that he received input from Ms. Arnold regarding this request and she felt strongly that the Board should grant waiver requests regarding Class I and Class II balances and he is unsure why. Mr. Brinson commented that, in his short time of being on the Board, he has seen several requests for such considered by the Board. He asked if the Board could amend its rule regarding this requirement. President Prather requested Ms. Emm review Rule 480-11-.04 for possible amendments. President Prather stated that he appreciates Ms. Arnold's thoughts on this, but is hesitant to put another burden on the hospitals to buy something they do not need. Mr. Warnock agreed. He stated that he does not believe it is in the rule to prescribe how the facility is to weigh IV's. Mr. Faulk commented that the Board needs to be consistent, regardless. Michael Brinson made a motion to grant the rule waiver petition from Taylor Regional Hospital, PHH005070 and The Medical Center of Peach County, PHH007937. Hal Henderson seconded and the Board voted unanimously in favor of the motion. Discussion was held regarding possibly notifying previous petitioners to resubmit their requests.

Correspondence from Dr. Lois Lassiter

The Board considered this correspondence regarding pharmacy regulations pertaining to compounded medications prescribed by veterinarians. Dr. Lassiter's letter states that she has been informed by her compounding pharmacies that she is prohibited, especially in the case of controlled substances, from dispensing compounded medications to her patients although they are not prohibited from administering them to patients in the hospital or prescribing them. Director Troughton mentioned a previous discussion the Board had regarding this matter. He explained that the Board considered a request to amend Rule 480-11-.02(f) to allow veterinarians to dispense compounded medications to their clients in urgent and emergency situations. He stated the amended rule could allow for emergency dispensing, but it did not go forward as it would take a legislative change to accomplish what was being requested.

Dr. Vincent Obsitnik spoke to the Board. He stated that the Board does have a letter before them regarding concerns. He stated the letter is not from the Georgia Veterinarian Medical Association (GVMA). He stated GVMA has been in discussions with the Georgia Pharmacy Association. Dr. Obsitnik stated what they want to do is to dispense from a compounded hospital supply in emergent or urgent situations. He stated he understands there is an opioid situation and trying to do something like that in this current environment is not doable. He stated they take certain drugs, now in compounded form, and dispense to some of their patients. The issue is that they use a lot of compounded drugs and many of their practices are open late; however, the local pharmacy is not open late when the practice is still open. He asked if there is a way to do that from a Board perspective. If there is not, GVMA will be in discussions about addressing this need legislatively. Discussion of emergency kit quantities was discussed.

Mr. Brinson asked Dr. Obsitnik specifically what-the request is. Dr. Obsitnik responded by stating to be able to dispense compounded medications from the hospital supply in emergent situations. He stated it is more of a dispensing issue regarding compounded drugs from the hospital supply. Discussion ensued. President Prather directed staff to respond to Dr. Lassister by stating that the Board is working to resolve this matter. President Prather requested Mr. Brinson work with Director Troughton to review the rule and bring back to the Board's next meeting for discussion. Mr. Changus asked about the issue of the controls that would require a legislative change. President Prather stated that when the Board can come up with a fix for this, it can tell GVMA what they need to take to the legislature.

Correspondence from Dhara Patel

The Board considered this correspondence regarding CBD oil. Director Troughton responded by stating when there is an inquiry regarding CBD oil, if that oil has THC in it, his understanding is that it is not legal except under the circumstances listed on the Department of Public Health's "Low THC Oil Registry Page". He stated that the CBD oil itself is a very unregulated industry and what GDNA has been advising is if it has THC it cannot be distributed in Georgia except under the circumstances listed on the registry. Mr.

Changus commented that legislation provided that the individual can obtain an identification card. He stated in terms of them getting the product to the consumer, there is nothing in the law saying that it is allowed. He stated if it has THC in it, it is illegal for sale. Ms. Harris asked how would one know a product does not have THC? Director Troughton responded that that is the risk you are taking when selling such products. He stated if the Board would like to hear what the GBI is facing, they would be glad to come in and speak to the Board. Director Troughton stated that the specific drug Epidiolex was recently approved by the FDA and rescheduled by the DEA as a Schedule V controlled substance.

Mr. Snow asked how many decimal points before it is considered as no THC? Mr. Changus responded by stating that maybe it would be helpful for the Board to hear from the GBI. He stated the problem is that is there is insufficient direction from the General Assembly. After further discussion, the Board directed staff to respond to Ms. Patel by stating that it suggests she refer to the Regulation of Low THC Oil law (O.C.G.A. Title 16, Chapter 12, Article 8) and to please note that the Board is still reviewing this matter. Additionally, be advised that the specific drug Epidiolex was recently approved by the FDA and rescheduled by the DEA as a Schedule V controlled substance.

Correspondence from Sylvia Kornegay

The Board considered this correspondence regarding safe handling standards. The Board directed staff to respond by stating that the Board and Georgia Drugs and Narcotics Agency ("GDNA") have jurisdiction over USP-NF standards. Additionally, GDNA does have the authority to inspect independent physician practices and substantiated violations of USP-NF standards in such settings would be reported to the Georgia Composite Medical Board.

Correspondence from Wesley Colston

The Board considered this correspondence regarding therapeutic substitutions. The Board directed staff to respond by referring Mr. Colston to O.C.G.A. § 43-34-24 Drug therapy management; modification by pharmacist and Chapter 480-35 Pharmacist Modification of Drug Therapy for more information.

Correspondence from Sachin Kalaria

The Board considered this correspondence regarding state mail order pharmacies. The Board directed staff to respond by stating that it appreciates Mr. Kalaria for his concerns regarding this matter.

Correspondence from Melissa Hansen

The Board considered this correspondence requesting clarification as to where assisted living facilities fell within the law. Mr. Warnock commented that the Board has always interpreted long term care as skilled nursing. He had a conversation with the previous director of GDNA who stated if it were an institutionalized patient, he was not inclined to push the issue. In his mind, he would say they were all institution. Director Troughton agreed by stating that is the way GDNA enforces as well. Mr. Changus suggested responding to Ms. Hansen by stating that assisted living facilities are not considered to be long term care.

Correspondence from Stacie Borngrebe

The Board considered this correspondence regarding the licensing process for medical devices. The Board directed staff to respond to Ms. Borngrebe by suggesting she refer to O.C.G.A. § 26-4-51 and Chapter 480-7B Durable Medical Equipment Suppliers for more information.

Correspondence from Jeenu Philip, Walgreen Co.

The Board considered this request for a waiver regarding Rule 480-15-.03 Use of Registered Technicians and Other Pharmacy Personnel. Walgreens recently purchased all Rite Aid Pharmacies in this state and will be transitioning the Rite Aid pharmacy computer systems to Walgreens computer systems. The request is regarding whether or not Rule 480-15-.03 allows non-Georgia licensed technicians and non-

Georgia licensed pharmacists to serve as "trainers". Discussion was held by the Board regarding the request. Mr. Warnock stated that he can understand why they would want to do it and why it would be the most efficient way to switch over to a new computer system. Ms. Emm stated that they are talking about non-licensed Georgia personnel. President Prather stated that this appears to be a business decision that Walgreens would have to make.

Mr. Philip was present at the meeting and spoke to the Board regarding his request. He explained that they have asked their Rite Aid pharmacists and pharmacy technicians to undergo training and shadowing. He stated the best way for the pharmacist and the technician to complete training is to have someone readily available to answer questions in the pharmacy department. Mr. Philip stated the intent of the "trainers" is to support the development of their previous Rite Aid technicians and pharmacists with adapting to a new system. He stated as part of this process, they are requesting clarification on Rule 480-15.03, specifically may non-Georgia licensed technicians and non-Georgia licensed pharmacists be leveraged to serve as "trainers" under this rule? Mr. Philip stated that they believe the rule does allow a "trainer" to serve as "other pharmacy personnel" under 480-15-.03(c). He stated they do not get involved from the patient standpoint. He explained that the "trainers" would only be in the pharmacy to assist from the system standpoint and to make sure training is being accomplished the right way. Mr. Philip stated they will be there for about two (2) weeks.

President Prather stated that he wanted to reiterate there is no such thing as a "trainer" in Georgia. He deferred to Mr. Changus. Mr. Changus read Rule 480-15-.03(c) which states, *"Registered pharmacy technicians and other pharmacy personnel, i.e. clerks, cashiers, observers, etc., in the prescription department shall be easily identifiable by use of a name badge or other similar means which prominently displays their name and the job function in which the personnel are engaging at that time. Any pharmacy personnel or other person present in the pharmacy department must be under the direct supervision of a licensed pharmacist."* Mr. Changus stated they could have someone identified as an observer as trainer is not a term that is utilized. Ms. Emm added that if the person is labeled as an observer, there is restriction of access, which states a pharmacy observer shall not be present in the pharmacy for more than eight (8) hours per day and in no circumstance for more than forty (40) hours.

Mr. Philip explained in terms of having Rite Aid technicians and pharmacists and having the ability to continue having patients be served, they want to be sure this continues to run smoothly through this process. Ms. Harris stated that she personally does not have an issue with it. She explained that it is hard going from one software to another. She said having a pharmacist that does not understand the software is not a good thing. She stated that having someone there not waiting on customers, not giving advice, just there to observe and train, and that is a good thing. She stated you have to follow the 40-hour requirement for the observer.

The Board discussed ratio. Ms. Harris stated the pharmacist would be considered the observer. Mr. Philip commented that they will be sure to maintain the ratio. President Prather stated the idea of having an observer was to accommodate a student. Mr. Changus stated the observer is a bit of a false trail. Kim read definition of "observer" in Rule 480-15-.06 and why that would exclude the pharmacist from being an observer. President Prather discussed what bothers him about non-licensed Georgia pharmacists in the pharmacy. He asked if they were bound by HIPAA. Mr. Philip stated no. President Prather stated his biggest concern was theft. Mr. Faulk asked how does this differ from going to a new system and him bringing someone in and showing him how to use it. He stated this happens all the time. Mr. Brinson stated that you have to have that expertise in order to make that transition go smoothly. President Prather asked from Director Troughton's thoughts. Director Troughton stated a pharmacist on duty will be responsible if there are thefts. He stated his understanding is an authorized person by the pharmacist would be in there. If they see people labeled as whatever, they can ask pertinent questions such as "how long do you plan on being in here" and include that information on the inspection form. He stated that if there is an

issue GDNA would bring it back to the Board. Director Troughton stated from an investigative standpoint, GDNA could provide the Board with the information if they were doing things differently from what they said they would. However, they are not in these pharmacies all the time. Mr. Warnock asked Mr. Philips if he could you provide GDNA with a "rollout schedule". A representative with Mr. Philip stated that is something that could be provided if it would be helpful. Mr. Philip thanked the Board for its time and stated he wanted to make sure the Board and GDNA were aware of what their plan was. President Prather stated he appreciated them coming in and that the Board is not opposed to this. They just want to make sure it is done correctly.

Correspondence from Paul Carpenter, St. Joseph's/Candler Hospital

The Board considered this correspondence concerning St. Joseph's/Candler health system in Savannah building a "micro hospital" about 20 miles from St. Joseph's Hospital. In Mr. Carpenter's letter, he requests a waiver from the Board that would allow the facility to maintain a pharmacy license at this location for the purpose of medication delivery from Cardinal Health without the presence of a physical pharmacy. Mike Faulk made a motion to deny the request. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

Correspondence from Julie Wellman, RPH015621

The Board considered this correspondence from Ms. Wellman requesting it remove the public documents related to her license from the Board website. Mike Faulk made a motion to deny the request. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

Correspondence from Beth Gorse, Wayne Memorial Hospital

The Board considered this correspondence regarding a chemo infusion center for Wayne Memorial Hospital. Ms. Gorse is requesting to know if an additional pharmacy license for this addition is needed or can the facility operate under its inpatient pharmacy license. Mike Brinson made a motion to deny the request for the facility to operate under its inpatient pharmacy license. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Correspondence from Dana M. Richens

The Board considered this correspondence requesting a written statement from the Board to submit to other states' pharmacy boards regarding DME licensure. The Board directed staff to respond by stating after consideration of the request, it declines the request as it believes the law is clear. Additionally, please review O.C.G.A. § 26-4-51. Durable medical equipment supplier license; requirements; exemptions; rules and regulations.

Correspondence from Michael Wynne, Piedmont Walton Hospital

The Board considered this correspondence requesting a new DEA certificate for its endoscopy center to be associated with Piedmont Walton Pharmacy's license and for the existing DEA certificate tied to Monroe HMA's pharmacy license to be terminated. The Board directed staff to respond to Mr. Wynne by stating he needs to contact the DEA regarding this request.

Correspondence from GAMES

The Board considered this request for an appearance to discuss durable medical equipment. The Board recommended approving the request.

Correspondence from Angela Dennis

The Board considered this correspondence seeking clarification on multiple scenarios involving a nurse receiving, delivering, and/or storing prescription medications. The Board directed staff to respond to Ms. Dennis by stating that her questions are too general for the Board to respond to and suggest she review the law and rules located on its website for more information.

Correspondence from Alan C. Wright, RPH023701

The Board considered this correspondence regarding continuing education. The Board directed staff to respond by stating the Board accepts courses that are approved by the Accreditation Council for Pharmacy Education ("ACPE"). If the providers of the courses Mr. Wright has taken are willing to contact ACPE to have the courses reviewed and acquire ACPE approval, the Board would accept the continuing education.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA will hire a new agent effective November 1st. He stated with the new hire, that will give GDNA ten (10) agents.

Director Troughton reported that GDNA has conducted 551 inspections and received 84 complaints for FY2019.

Director Troughton stated that opioid litigation has begun. He stated that GDNA has received open records requests regarding such.

Director Troughton stated he did have a question on the DME rule amendment. He is aware that the rule has not been signed by the Governor. He stated the question is concerning the language in 480-7B-.03(1), which states *"Where operations are conducted at more than one licensed place of business by a DME supplier, each licensed place of business by a DME supplier shall have at least one designated representative present."* He stated this seems to be open-ended. He asked if one (1) person overseeing seven (7) stores would be acceptable. Director Troughton asked if this is something the Board can answer now or should it wait until the Board receives a response from the Governor's office. He stated that this may be something the Board needs to clarify for GDNA when they do inspections.

Attorney General's Report – Max Changus

Inquiry from Palmetto GBA: Mr. Changus stated that the Board has received inquiries and has previously discussed the issue of durable medical equipment and supplies listed on the National Suppliers Clearinghouse List. Mr. Changus advised that the Board's charge is not to provide business guidance for pharmacies. Palmetto GBA has received a contractor that has been tasked with putting a list together that applies nationally concerning DME requirements. He stated there have been a couple of inquiries asking the Board to comment on the list. When that has been brought to the Board, the Board has declined. Mr. Changus stated he has spoken with Palmetto and they are, for all intents and purposes, Medicare and they are to administer reimbursements. Regarding Ostomy and urological products the Board would not typically consider such as DME. Mr. Changus stated the Board's previous response was to refer the facility to the law and rule and they can make their own determination. He stated that Palmetto has made their determination and it goes against where the Board would fall. He stated that given the fact Palmetto has a whole classification with the ostomy and urological products that does not fit in the Board's law and rules, the Board would need to reach out to the clearinghouse and notify it of the Board's position, in order for this list to change. After discussion was held by the Board, Mr. Changus stated that Palmetto has reviewed the Board's law and rules. He stated if the Board wants to give them guidance, reviewing the national clearinghouse list may be appropriate. Ms. Emm commented that this issue has come before the Board several times. She stated it is an ongoing quarterly review request. Mr. Warnock asked if the Board reviews it, if the Board would keep getting it quarterly? Ms. Emm responded that it would. Mr. Changus suggested having a member of the Board to review the list to see what it looks like. President Prather requested Mr. Henderson review the list and report back to the Board.

Executive Director's Report – Tanja Battle

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

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
08/23/18	1	The Medical Center, Navicent Health	Biostatistics Refresher	2018-0011
09/20/18	0.5	Kaiser Permanente	Anticoagulation Refresher Training	2018-0012
10/02/18	1	Kaiser Permanente	Fostering transgender-inclusive care with a focus on hormone therapy	2018-0013
09/27/18	0.05	Kaiser Permanente	Clinical Pharmacy Information Series Direct Oral Anticoagulant (DOAC) Surveillance	2018-0014
09/25/18	1	Kaiser Permanente	PrEP-aring for the Unexpected	2018-0015

2019 Proposed Meeting Dates: Discussion of the proposed 2019 practical exam and meeting dates was held. The Board requested the proposed August 2019 date at PCOM be moved to mid-August instead of the first week in August. A representative from Mercer University stated that it could accommodate the Board up until August 12th. Hal Henderson made a motion to approve the 2019 practical exam dates and meeting dates, except for the proposed August date. Mike Faulk seconded and the Board voted unanimously in favor of the motion. Ms. Battle stated that staff will research and bring back to the Board in November.

Paid Advertisements on Prescription Orders: Ms. Battle stated that when Jim Bracewell was on the Board he had a concern about paid advertisements on prescription orders and the Board recommended sending a letter to the Georgia Composite Medical Board regarding such. With the abrupt shift in board membership, the letter was not finalized. Ms. Battle asked if the Board had any objections to the letter presented. Ms. Harris stated that she remembered the Board discussing this matter and agreed with Mr. Bracewell. She stated that she can forward an example of a redacted prescription showing such advertisement to send with the letter. Bob Warnock made a motion to direct staff to send the letter and example to the Georgia Composite Medical Board. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Legal Services – Kimberly Emm

No report.

Miscellaneous

Cleanroom Design, LLC: A representative from this company spoke to the Board at its September meeting. The Board voted to table its decision to review the documentation submitted by Cleanroom Design, LLC. President Prather stated there are no objections to what they have proposed. Mr. Changus asked if it would be fair to say the plans themselves do not raise any objections at this point and that ultimate approval would be subject to compliance with the law and rules. Director Troughton responded by stating that from everything they have sent, he does not have the qualifications to look at design plans, but does not see any issues that would raise a red flag. President Prather stated as long as their plan adheres to the regulations of USP 797, the Board would not object, but, ultimately, the Board would not know about the total finished product. Mr. Changus suggested responding by stating if they are compliant with USP797, there are no issues that raise a red flag.

Rule 480-10A-.01 Central Filling of Prescriptions: Hal Henderson made a motion to post Rule 480-10A-.01 Central Filling of Prescriptions. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Chapter 480-10A. Central Filling Regulations

Rule 480-10A-.01 Central Filling of Prescriptions

(1) Definitions

(a) “Board” shall mean the Georgia Board of Pharmacy
(b) “Originating Pharmacy” shall mean the licensed retail pharmacy outsourcing the prescription filling services. This pharmacy shall be considered the dispensing pharmacy.
(c) “Central Fill Pharmacy” shall mean a pharmacy which is permitted by the state in which it is located to prepare prescription orders for dispensing pursuant to a valid prescription transmitted to it by an originating pharmacy and to return the labeled and filled prescriptions to the originating pharmacy for delivery to the ultimate user.
(2) All pharmacies providing central prescription filling services to retail pharmacies in Georgia must be appropriately licensed in Georgia.
(3) A central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of an originating pharmacy only if the originating pharmacy and central fill pharmacy have a contractual relationship for such activities or are under common ownership.
(a) The contract or agreement shall outline the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and states laws and regulations.
(4) Each pharmacy engaging in or utilizing central prescription filling services shall be jointly responsible for properly filling prescriptions.
(5) The originating pharmacy’s pharmacist is responsible to perform a drug utilization/regimen review of prescriptions received from a central fill pharmacy prior to delivering prescriptions to the ultimate user as well as patient counseling.
(6) A licensed retail pharmacy that desires to provide and/or use central prescription filling services must maintain policies and procedures, which are readily retrievable for submission to the Board or Georgia Drugs and Narcotics Agency (“GDNA”) upon request.
(a) The policies and procedures must include:
1. A clear description of the activities in the prescription filling process to be performed by each pharmacy;
2. An outline of the responsibilities of each pharmacy;
3. An outline of the accountabilities of each pharmacy;
4. A list of the names, addresses, telephone numbers, and all license/registration numbers for the pharmacies participating in the central fill prescription filling;
5. Guidelines for:
(i) Protection of the confidentiality and integrity of patient information;
(ii) Maintenance of appropriate records to identify the names, initials, or identification codes and specific activities of each pharmacist who performed any processing;
(iii) Compliance with all federal and state laws, regulations, and rules;
(iv) Operation of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolved and identify problems; and
(v) Annual review of the written policies and procedures and documentation of such review.
(7) Central prescription filling of controlled substances requires compliance with all Drug Enforcement Administration (“DEA”) regulations permitting a central fill pharmacy to fill prescriptions for controlled substances on behalf of an originating pharmacy as well as state laws, rules and regulations
(a) The pharmacist filling a prescription for a controlled substance listed in Schedule II shall affix to the container a label showing the date of filling, the pharmacy name, address, and telephone number, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, expiration date of the dispensed drug, and the directions for use and cautionary statements, if any, contained in such prescription or required by law.
(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the container a label showing the originating pharmacy name, address, telephone number and a unique identifier (i.e. the central fill pharmacy’s DEA registration number) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

(c) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile.
1. The originating pharmacy transmitting the prescription information must:
(i) Write the words "CENTRAL FILL" on the face of the original paper prescription and record the name, address, telephone number, Georgia license number, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the originating pharmacy pharmacist transmitting the prescription, and the date of transmittal. For electronic prescriptions, the name, address, telephone number, Georgia license number, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the originating pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record;
(ii) Maintain the original prescription for a period of two years from the date the prescription was filled;
(iii) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the originating pharmacy employee accepting delivery.
2. The central fill pharmacy receiving the transmitted prescription must:
(i) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, telephone number, Georgia license number, and DEA registration number of the originating pharmacy transmitting the prescription;
(ii) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;
(iii) Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (i.e. private, common or contract carrier).
(d) The pharmacist filling a prescription for a dangerous drug or controlled substance listed in Schedule III, IV, or V shall affix to the container a label showing the pharmacy name, address, and telephone number, the serial number of the prescription, date of initial fill or refill, the name of the patient, the name of the practitioner issuing the prescription, name of supervising physician if applicable, expiration date of dispensed drug, and directions for use and cautionary statements, if any, contained in such prescription as required by law.
(e) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the container a label showing the originating pharmacy name, address, telephone number, Georgia license number, and a unique identifier (i.e. the central fill pharmacy's DEA registration number if the prescription is a controlled substance) indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under (d) of this section.
(f) Prescriptions for dangerous drug or controlled substances listed in Schedule III, IV, or V may be transmitted electronically from an origination pharmacy to a central fill pharmacy including via facsimile.
1. The originating pharmacy transmitting the prescription information must:
(i) Write the words "CENTRAL FILL" on the face of the original prescription and record the name, address, telephone number, Georgia license number, and DEA registration number (if the prescription is a controlled substance) of the central fill pharmacy to which the prescription has been transmitted and the name of the originating pharmacy pharmacist transmitting the prescription, and the date of transmittal;
(ii) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;
(iii) Maintain the original prescription for a period of two years from the date the prescription was last refilled;
(iv) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy employee accepting delivery.
2. The central fill pharmacy receiving the transmitted prescription must:
(i) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, telephone number, Georgia license

number, and DEA registration number (if the prescription is a controlled substance) of the originating pharmacy transmitting the prescription;
(ii) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;
(iii) Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (i.e. private, common or contract carrier).
(8) The originating and central fill pharmacies must share common electronic files or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.
(a) Prescriptions filled at a central fill pharmacy must be reported to the PDMP administered by the Georgia Department of Public Health at least every 24 hours pursuant to § 16-13-59 and must include all required information. It is the responsibility of the dispensing (originating) pharmacy to ensure compliance with PDMP reporting.
(9) The originating pharmacy must have a pharmacist, pharmacy intern, pharmacy extern, or pharmacy technician sign for the receipt of prescriptions delivered from the central fill pharmacy. Such receipts must be maintained as a part of the prescription record.
(10) An originating pharmacy using central prescription filling services is responsible for maintaining records of the processing of all prescriptions entered into their information system including prescriptions filled at a central fill pharmacy.
(a) The pharmacist at the originating pharmacy must comply with the minimum required information for the patient record system and all requirements of a prescription drugs order as outlined in the Georgia law and Board rules prior to sending a prescription to the central fill pharmacy.
(b) The information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the originating pharmacy's prescriptions.
(11) A pharmacy that utilizes central prescription filling services must, prior to outsourcing the prescription, notify patients that prescription filing may be outsourced to another pharmacy.
(a) The patient shall have the choice to not have the prescription outsourced.

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

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

Michael Brinson made a motion and Mike Faulk 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 Brinson, Mike Faulk, Lisa Harris, Hal Henderson, William Prather, and Bob Warnock.

Executive Session

Appearances

- F.K.S.
- S.M.M.

Georgia Drugs and Narcotics Agency – Dennis Troughton
Director Troughton discussed the following:

- T.M.C.N.H.

Cognizant's Report – Dennis Troughton
- GDNA Case # A32655
- GDNA Case # A32672
- GDNA Case # B32571
- GDNA Case # B32625
- GDNA Case #B32619
- GDNA Case # B32644
- GDNA Case # B32643
- GDNA Case # B32585
- GDNA Case #B32629
- GDNA Case #A32613
- GDNA Case # B32618
- GDNA Case # T32666
- GDNA Case # A32541

Attorney General's Report – Max Changus
Mr. Changus discussed the following cases:
- M.C.
- S.P.C.
- S.B.S.
- P.A.S.C.H.C.

Mr. Changus presented the following consent orders for acceptance:
- P.O.D.
- C.V.S.P.
- C.V.S.P.
- A.A.L.
- C.V.S.P.
- T.P.S.
- T.B.R.
- C.S.V.P.

Executive Director's Report – Tanja Battle
- P.P.
- C.S.

Legal Services – Kimberly Emm
No report.

Applications
- C.C.
- A.T.W.
- A.M.C.
- R.M.P.

- Z.O.
- G.E.M.
- L.A.K.
- N.Y.B.
- B.B.
- A.T.B.
- M.J.E.
- D.B.S.
- S.G.
- L.G.T.
- B.H.
- B.A.M.
- E.A.O.
- M.M.W.
- N.T.
- S.M.
- J.B.W.
- W.B.D.
- J.A.S.
- A.L.
- J.L.
- A.E.U.
- C.A.M.
- E.A.W.P.
- M.M
- Z.C.H.
- T.C.C.W.D.

Correspondences/Requests

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

- A.W.T.
- T.K.C.
- R.S.S.
- H.C.L.

Miscellaneous
- Exam administration

No voted were taken in Executive Session. President Prather declared the meeting back in Open Session.

Open Session

Mike Brinson made a motion for the Board to take the following actions:

Appearances

• F.K.S.	Researcher Pharmacy	Table pending receipt of additional information
• S.M.M.	Pharmacist Exam Applicant	Approved to sit for the exam

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton discussed the following:

- T.M.C.N.H. Advise facility they must apply for a retail license.

Cognizant's Report – Dennis Troughton
- GDNA Case # A32655 Accept Private Interim Consent Order
- GDNA Case # A32672 Accept Private Interim Consent Order
- GDNA Case # B32571 Close with no action
- GDNA Case # B32625 Close with no action
- GDNA Case #B32619 Misfill Policy #3
- GDNA Case # B32644 Misfill Policy #2
- GDNA Case # B32643 Close with no action
- GDNA Case # B32585 Close with no action
- GDNA Case #B32629 Close with no action
- GDNA Case #A32613 Schedule for Investigative Interview
- GDNA Case # B32618 Close with no action
- GDNA Case # T32666 Close with a letter of concern
- GDNA Case # A32541 Schedule for Investigative Interview

Attorney General's Report – Max Changus

Mr. Changus discussed the following cases:
- M.C. Update provided
- S.P.C. Deny request for reconsideration
- S.B.S. Close with no action
- P.A.S.C.H.C. Update provided

Mr. Changus presented the following consent orders for acceptance:
- P.O.D. Private Consent Order accepted
- CVS Pharmacy #5353 Public Consent Order accepted
- CVS Pharmacy #3013 Public Consent Order accepted

- A.A.L. Private Consent Order accepted
- C.V.S.P. Public Consent Order to be accepted and signed with express permission upon receipt of the original
- T.P.S. Private Consent Order accepted
- Thomas B. Rollins Public Consent Order accepted
- C.S.V.P. Private Consent Order accepted

Executive Director's Report – Tanja Battle

• P.P.	Records request	Approved request
• C.S.	Open records request	Approved request

Legal Services – Kimberly Emm

No report.

Applications

• Crystal Collins	Pharmacy Technician	Approved for registration
• A.T.W.	Pharmacy Technician	Denied registration
• Ashley M. Cooper	Pharmacy Technician	Approved for registration
• Raven M. Pope	Pharmacy Technician	Approved for registration
• Zurisadai Oliver	Pharmacy Technician	Approved for registration
• G.E.M.	Pharmacy Technician	Denied registration
• Leila A. Kinsey	Pharmacy Technician	Approved for registration
• N.Y.B.	Pharmacy Technician	Denied registration
• Bart Beasley	Pharmacy Technician	Approved for registration
• A.T.B.	Temporary Pharmacist	Denied application
• Marcus J. Ezell	Pharmacist Reinstatement	Approved application
• Douglas B. Smock	Pharmacist Renewal	Approved for renewal
• Shubhra Goyal	Pharmacist Renewal	Approved for renewal
• Laura G. Thomas	Pharmacist Renewal	Approved for renewal
• Benjamin Hightower	Pharmacist Intern	Approved application
• Brian Arana-Madriz	Pharmacist Intern	Approved application
• Ekene A. Oranu	Pharmacist Intern	Approved application
• Mahlet M. Wole	Pharmacist Intern	Approved application
• Noah Tedla	Pharmacist Intern	Approved application
• Shivani Mittal	Pharmacist Intern	Approved application
• J.B.W.	Pharmacist Intern	Schedule to meet with the Board
• W.B.D.	Pharmacist Intern-Correspondence	No action taken
• Jessica A. Scott	Pharmacist Intern	Approved request to extend intern license
• Aaron Little	Pharmacist Intern	Approved application
• Jungseok Lee	Pharmacist Intern	Approved application
• Alyssa E. Utz	Pharmacist Certification of DTM	Approved application
• Caroline A. McNabb	Pharmacist Certification of DTM	Approved application
• Erin A.W. Pace	Pharmacist Certification of DTM	Approved application
• Michelle Morales	Pharmacist Certification of DTM	Approved application
• Zuri C. Hawkins	Pharmacist Certification of DTM	Approved application
• The Compounding Center Wholesale Division	Wholesaler Pharmacy	Approved application

Correspondences/Requests

• D.P.S.	Notice of Discipline	No action taken
• H.W.	Notice of Discipline	No action taken
• O.M.D.	Notice of Discipline	No action taken
• O.M.D.	Notice of Discipline	No action taken
• D.S.I.G.	Notice of Discipline	No action taken
• D.S.I.G.	Notice of Discipline	No action taken
• V.R.	Notice of Discipline	No action taken
• P.F.P.I.	Notice of Discipline	No action taken
• W.P.N.	Notice of Discipline	No action taken
• J.C.N.	Request to terminate consent order	Approved request
• A.L.H.	Request to terminate consent order	Approved request
• L.D.R.	Appearance request	Approved request
• A.E.B.	Appearance request	Approved request
• J.F.C.	Request regarding employment	Denied request
• C.B.S.	Correspondence re misfill course	No action taken
• P.R.W.	Medical Malpractice Claim Report	Table pending receipt of additional information
• J.H.S.	Medical Malpractice Claim Report	Table pending receipt of additional information
• T.M.C.	Remote order entry	Approved request
• H.H.I.	Remote order entry	Approved request
• A.W.T.	Request to lift supervised practice	Approved request
• T.K.C.	Request to lift supervised practice	Approved request
• R.S.S.	Request to lift PIC restriction	Approved request
• H.C.L.	Request to take MPJE a 4th time	Approved request

Miscellaneous

The Board discussed examination administration.

Bob Warnock seconded and the Board voted in favor of the motion, with the exception of Hal Henderson, who recused himself from the vote regarding GDNA #A32541.

There being no further business to discuss, the meeting was adjourned at 3:01 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, November 14, 2018 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5th Floor, Atlanta, GA 30303.

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