GEORGIA BOARD OF PHARMACY
Board Meeting
Mercer University College of Pharmacy
3001 Mercer University Drive
Atlanta, GA 30341
March 6, 2019
9:00 a.m.

The following Board members were present:
Bill Prather, President
Lisa Harris, Vice-President
Vicki Arnold
Carrie Ashbee *(departed @ 10:10/returned @ 11:25 a.m.)*
Michael Brinson
Mike Faulk

Staff present:
Tanja Battle, Executive Director
Eric Lacefield, Deputy Executive Director
Dennis Troughton, Director, GDNA *(arrived @ 10:15 a.m.)*
Michael Karnbach, Deputy Director, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst I

Visitors:
Lea Bonner, Mercer
Sasha Kaniga, TCSG
Stephen Georgeson, GRA
Melissa Robinson, Piedmont Healthcare
Scott McAuley, Piedmont Healthcare
Vince Obsitnik, GVMA
Greg Reybold, GPhA
Adam Schrepp, Walgreens
Becca Hallum, GHA
Stephanie Kirkland, ElderCare
Travis Clark, CAPS
Stacy Burke, Publix
Amanda Roberson, ElderCare
Claudia Lewis, Venable LLP
Joey Sturgeon, Silvergate
John Rocchio, CVS Health
Gary R. Johnson
Jefferson Jones
Philip House
Jim Bartling

Open Session

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

Approval of Minutes

Michael Brinson made a motion to approve the Public and Executive Session minutes from the February 13, 2019 meeting. Carrie Ashbee seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Vicki Arnold made a motion to ratify the list of licenses issued. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

Mike Faulk made a motion to deny the rule waiver petition from Hope Pharmaceuticals, PHWH001782. Carrie Ashbee seconded and the Board voted unanimously in favor of the motion.

Michael Brinson made a motion to deny the rule waiver petition from Skrip Shoppe Pharmacy, PHRE005617. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Correspondence from Michelle Ames, PruittHealth

The Board considered this correspondence regarding nurse practitioners, physician's assistants and controlled prescriptions. In Ms. Ames's email, she states that physician assistants and nurse practitioners are now permitted to write C-II prescriptions in Florida. She asks if there is anything in the Board's regulations that prevent a Georgia pharmacy from filling a C-II script for a Florida nursing home resident from a nurse practitioner or a physician assistant in a state where these prescriptions are valid, the provider is registered with the DEA, and the prescription meets the criteria necessary for a controlled substance prescription. The Board directed staff to respond by stating it suggests she refer to O.C.G.A. § 26-4-80(b), which states, "prescription drugs shall be dispensed only pursuant to a valid prescription drug order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription." As such, there is nothing that would prevent the filling of such a prescription should the pharmacist, in his or her professional judgment, find it to be valid.

Correspondence from Sothea Phon-Xue, University of Findlay

The Board considered this correspondence regarding Medication Therapy Management ("MTM") services. In her inquiry, Ms. Phon-Xue requests guidance on what is needed to complete MTM services for patients in Georgia. The Board directed staff to respond by requesting she provide additional information. Specifically, the Board requested she provide information on exactly what services she wants to offer, how she plans to offer the services, and to whom, etc.

Correspondence from Eddie Williams

The Board considered this correspondence requesting clarification regarding Rule 480-36-.07 Notification to Patients. The Board directed staff to respond to Mr. Williams that the form of notification is ultimately up to the pharmacy. The rule has provided one suggestion, to ensure notice is adequate, which consists of a one-time written consent and a sign. Per subsection (2), regardless of how a pharmacy decides to notify patients, if the pharmacies do not share common ownership written consent is required.

Correspondences from Stephanie Galindez and Dawn Head

The Board considered a request for a waiver from Ms. Stephanie Galindez to use the term "Apothecary" in her business name, The Home Apothecary. The Board also considered a request from Ms. Dawn Head to use the term "Apothecary" in her business name, Apothecary Solutions. Lisa Harris made a motion to deny both requests because each business name may be misleading or confusing to the public. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Nigel P. Pedersen, Emory University

The Board considered this request for waiver of the reinstatement fee. Michael Brinson made a motion to deny the request. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Larry L. McGee, UF Health Florida Recovery Center

The Board considered this request for UF Health Florida Recovery Center to be an approved treatment facility. Mike Faulk made a motion to approve the request. Carrie Ashbee seconded and the Board voted unanimously in favor of the motion.

Correspondence from Meryl Nolan, Venable

The Board considered this correspondence regarding whether or not a 3PL located in Georgia requires a Georgia license if the 3PL deals in medical devices. Ms. Emm stated that she, Mr. Changus and Director Troughton have been discussing medical devices and whether a license is required. She stated O.C.G.A. § 26-4-110(a) states that a license is required if the facility is distributing a device that meets the requirements of O.C.G.A. § 26-4-59. Ms. Emm stated this question is similar, but in regards to a 3PL. Mr. Changus 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."

Ms. Emm stated the practice of pharmacy has its own definition. Mr. Changus added that there are conflicts in the statute. Discussion was held regarding what devices are utilized in the practice of pharmacy. Mr. Changus stated any device with a drug component falls into this category. He stated that he thinks there are medical devices that would not contain a drug, but do not necessarily involve the practice of pharmacy. They may, however, involve the practice of medicine. Mr. Changus stated that he and board staff have been going back and forth with this a good bit. President Prather asked Mr. Changus for suggestions. Mr. Changus responded that if the company is located in Georgia, a license would be required if they deal in devices in the practice of pharmacy.

President Prather asked Ms. Claudia Lewis, Venable LLP, for her input. Ms. Lewis, who was present at the meeting, stated the company she represents is a 3PL provider that will be receiving medical devices. She stated that for right now they will be receiving phlebotomy devices. She added that there is no drug component and they would not consider themselves a distributor. Ms. Lewis stated they are a freight forwarder. She stated she understands the issue of which products are involved in the practice of pharmacy. Mr. Changus suggested to Ms. Lewis that if the company is working with devices that are involved in the practice of pharmacy, it would be best to get a license. Ms. Lewis responded by stating that they are essentially like a Federal Express or UPS facility. She stated they are just getting the devices to where they need to be. Vice-President Harris asked if the facility always knows what is in the boxes. Ms. Lewis responded yes, and that there is a chain of custody. Mr. Changus stated that if there is any contemplation, the safest route would be to get licensed.

Correspondence from Dr. Lois Lassister

The Board considered this correspondence regarding language proposed by New York relating to the compounding, dispensing and sale of pharmaceuticals. The Board directed staff to respond to Dr. Lassister by forwarding her a copy of the proposed amendments to Rule 480-11-.02 Compounding Drug Preparations it will be considering later that morning.

Correspondence from John Sisto, Express Scripts

The Board viewed this correspondence for informational purposes only.

Correspondence from Dr. John Horne

The Board considered this correspondence regarding antimicrobial stewardship. In his inquiry, Dr. Horne asks if his pharmacist needs to be licensed in Georgia to help a hospital in Georgia with its antimicrobial

stewardship program. The Board directed staff to respond to Dr. Horne by stating it does not have any purview over this matter.

Correspondence from Angela Cassano, Pharmfusion Consulting, LLC
The Board considered this correspondence regarding medication administration and centralized fill. The Board directed staff to respond to Ms. Cassano by forwarding her a copy of the proposed amendments to Chapter 480-10A Central Filling Regulations it will be considering later that morning.

Georgia Drugs and Narcotics Agency – Michael Karnbach
Deputy Director Karnbach reported that GDNA has conducted 1357 inspections and received 245 complaints for FY2019.

Deputy Director Karnbach reported that there is a news article on WSB regarding a pharmacy that had filled forged prescriptions. President Prather stated that he asked Deputy Director Karnbach to mention this matter just in case any of the board members had any questions. There were none.

Attorney General's Report – Max Changus
Mr. Changus stated there is a bunch of legislation moving through right now. Mr. Changus stated that he was asked to comment internally on the Pharmacy Anti-Steering Bill. He commented that there were changes from the original version and that a substitute did pass out of the House Committee.

Executive Director's Report – Tanja Battle
Continuing Education Report: Report presented. Mike Faulk made a motion to ratify the below continuing education programs approved since the previous meeting. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
03/13/2019	.5	Kaiser Permanente Georgia	Infection by Talaromcyces Marneffei: A Clinical Case	2019-0007

Correspondence from Cami Allen, PharmD On Demand, Liberty Regional Medical Center, PHH003603: The Board considered this correspondence regarding a rule waiver petition denied by the Board at its February 2019 meeting. Vicki Arnold made a motion to approve the rule waiver petition. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Correspondence from Luis J. Lanz, Quarles & Brady: The Board considered this correspondence regarding the practice of pharmacy. In his inquiry, Mr. Lanz asks if the state deems prior authorization tasks to be the practice of pharmacy, and thereby require a pharmacy license. The Board directed staff to respond by stating it declines to issue such a broad statement; however, it will evaluate specific scenarios. Before the Board can respond to his inquiry, it is requesting he provide additional information. Specifically, who are the parties involved, who will be making contact with whom, how will authorizations be transmitted, who will be communicating regarding changes, etc. Additionally, the Board requested he provide a detailed, fact specific account of what the client is seeking to accomplish and how they wish to accomplish it.

Legal Services – Kimberly Emm
No report.

Miscellaneous

Mike Faulk made a motion to post Chapter 480-10A Central Filling Regulations. Michael Brinson seconded and the Board voted unanimously in favor of the motion.

Chapter 480-10A Central Filling Regulations

Rule 480-10A-.01 Definitions

For purposes of these Rules and Regulations, the following definitions apply:
(1) "Board" shall mean the Georgia Board of Pharmacy
(2) "Originating Pharmacy" shall mean the licensed retail pharmacy from which a prescription is physically received and dispensed to the patient or patient's caregiver which is outsourcing prescription filling services. This pharmacy shall be the dispensing pharmacy.
(3) "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.

Rule 480-10A-.02 Licensing and Contracting

(1) All pharmacies providing central filling services to retail pharmacies in Georgia must be appropriately licensed in Georgia.
(2) A central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of an originating pharmacy only if the parties have a contractual relationship permitting such activity or share a common owner.
(a) The contract or agreement shall outline the services to be provided and the responsibilities and accountabilities of each pharmacy, in relation to such services, in compliance with federal and state laws, rules and regulations.
(b) 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.
(3) The originating and central fill pharmacy shall be jointly responsible for all prescriptions filled utilizing central fill services.

Rule 480-10A-.04 Policies and Procedures

(1) 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 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; and
(iii) Compliance with all federal and state laws, rules, and regulations pertaining to the central filling of prescriptions.

Rule 480-10A-.05 Transmission and Labeling

(1) The transmission and labeling of controlled substance prescriptions processed utilizing central fill services must comply with all federal and state laws, rules, and regulations.

(2) The originating pharmacy must comply with the minimum required information for the patient record system and all requirements of a prescription drug order as outlined in the Georgia law and Board rules prior to sending a prescription to the central fill pharmacy.

(3) All prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile.

(4) All transmission records must include the following:

(a) "CENTRAL FILL" written on the face of a prescription if it is a hard copy prescription,

(b) 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,

(c) Number of refills already dispensed and number of refills remaining (if applicable),

(d) The name of the originating pharmacy pharmacist transmitting the prescription, and

(e) The date of transmittal.

(5) All receipt of transmission records must include all information included in subsection 4 and 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.

(6) The label affixed to the container of a dangerous drug or other non-controlled substance filled by a central fill pharmacy must contain the following:

(a) Date of fill or refill,

(b) The originating pharmacy name, address, and telephone number,

(c) The central fill pharmacy's unique identifier,

(d) The serial number of the prescription,

(e) The name of the patient,

(f) The name of the prescribing practitioner,

(g) Name of supervising physician if applicable,

(h) Expiration date of the dispensed drug, and

(i) The directions for use and cautionary statements, if any, contained in such prescription or required by law.

Rule 480-10A-.06 Information Systems, Record Keeping, and PDMP Compliance

(1) 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 process and dispense the prescription.

(2) The originating pharmacy shall be responsible for maintaining compliance with the Prescription Drug Monitoring Program for all qualifying prescriptions pursuant to O.C.G.A. § 16-13-59 including those filled utilizing central fill services.

(3) The record keeping of prescriptions processed utilizing central fill services must comply with all federal and state laws, rules, and regulations.

(4) The originating pharmacy must have a pharmacist, pharmacy intern, pharmacy extern, or pharmacy technician sign for the receipt of all prescriptions received from the central fill pharmacy.

(a) Such receipts must be maintained as a part of the prescription record. Receipts shall include the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the originating pharmacy employee accepting delivery.

(b) The pharmacist on duty at the originating pharmacy must verify the receipt of all controlled substances.

(5) The originating pharmacy 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 information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the originating pharmacy's prescriptions.

Rule 480-10A-.07 Patient Counseling
(1) It shall be the responsibility of the pharmacist on duty at the originating pharmacy to perform patient counseling of all prescriptions.
(2) The central fill pharmacy shall not perform patient counseling on behalf of the originating pharmacy.

Rule 480-10A-.08 Notification to Patients
(1) An originating pharmacy that utilizes central 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.
(b) Notification may be provided through the use of a sign located in the originating pharmacy which is clearly visible to and readable by the public.

In the same motion, the Board voted to post Rule 480-11-.02 Compounding Drug Preparations.

Rule 480-11-.02. Compounded Drug Preparations
(1) Compounded drug preparations -Pharmacist/Patient/Prescriber Relationship.
(a) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations that are not commercially available in the marketplace or commercially available in the place as outlined by the restrictions under 12(b). Dispensing of pharmaceutical products shall be consistent with the provisions of O.C.G.A. T. 16, Ch. 13 and T. 26, Ch. 4 relating to the issuance of prescriptions and the dispensing of drugs.
(b) Pharmacists shall receive, store, or use pharmaceuticals that have been manufactured or repackaged in a FDA-registered facility. Pharmacists shall also receive, store, or use pharmaceuticals in compounding preparations that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.
(c) Pharmacists may compound pharmaceuticals prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such preparations compounded at the pharmacy. Preparations compounded in anticipation of a valid prescription drug order shall be properly labeled to include the name of the compounded pharmaceutical, date of compounding, and beyond-use date. ~~The distribution of compounded preparations, for office use by a practitioner, shall not exceed 5% of production of compounded preparation in a calendar year by that pharmacy. Amounts produced greater than 5% shall be considered manufacturing and will require separate licensure as a manufacturer. Pharmacists must maintain a separate compounding log for each compounded preparation that includes the quantity and amount of each pharmaceutical that is compounded. Pharmacists shall label all compounded preparations that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. T. 16, Ch. 13 and O.C.G.A. T. 26, Chs. 3 and 4, and Board rules and regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.~~
(d) The distribution of compounded preparations for office use by a practitioner, excluding veterinarians, is prohibited. The distribution of compounded preparations, for office administration or emergency dispensing, to a veterinarian shall not exceed 5% of production of compounded preparation in a calendar year by that pharmacy. Amounts produced greater than 5% shall be considered manufacturing and will require separate licensure as a manufacturer.
(1.) "Emergency Dispensing" shall mean no more than a 96 hour supply dispensed for an urgent condition to an animal patient by a licensed veterinarian with a valid veterinarian-client-patient relationship when timely access to a compounding pharmacy is not available.
(e) Pharmacists must maintain a separate compounding log for each compounded preparation that includes the quantity and amount of each pharmaceutical that is compounded. Pharmacists shall label all

compounded preparations that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. T. 16, Ch. 13 and O.C.G.A. T. 26, Chs. 3 and 4, and Board rules and regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

(~~d~~f) All compounded preparations labeled in accordance with Board rules and regulations regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of O.C.G.A. T. 16, Ch. 13, and T. 26, Chs. 3 and 4.

(2) Compounded drug preparations - Pharmacist for Distribution to Veterinarian ~~Practitioner~~

(a) Only a pharmacy licensed or registered by the Board may distribute compounded preparations to veterinarians ~~practitioners~~ licensed in this state for administration or emergency dispensing to their patients in the course of their professional practice, either personally or by an authorized person under their direct and immediate supervision.

(b) A ~~practitioner~~ veterinarian shall make a request to the pharmacy for a compounded preparation in the same manner as ordering products from a wholesale pharmaceutical distributor or manufacturer and not by using a prescription drug order.

(c) A pharmacy receiving an order from a ~~practitioner~~ veterinarian for a compounded preparation shall maintain such order with its compounding records as required in Rule 480-11-.08 and other rules and regulations of the Board.

(d) Pharmacists shall label all compounded preparations distributed to ~~practitioner~~ veterinarian for administration or emergency dispensing to their patients with the following:

1. "By purchase order, Not by prescription",
2. "For Office Use Administration or Emergency Dispensing by a Veterinarian Only - Not for resale",
3. The name of the active ingredients and strengths contained in the compounded preparation,
4. The lot number or identification of the compounded preparation,
5. The pharmacy's name, address and telephone number,
6. The initials of the pharmacist verifying the finished compounded preparation and the date verified,
7. The quantity, amount, size, or weight of the compounded preparation in the container,
8. An appropriate beyond-use (expiration) date of the compounded preparation as determined by the pharmacist in compliance with Board rule and USP-NF standards for pharmacy compounding, and
9. Appropriate ancillary instructions such as storage instructions or cautionary statements, and where appropriate, hazardous drug warning labels.

(e) Pharmacists shall enter into a written agreement with a ~~practitioner~~ veterinarian for the ~~practitioner's~~ veterinarian's use and emergency dispensing of the compounded preparation before providing any compounded preparation to the ~~practitioner~~ veterinarian. The written agreement shall provide the following information:

1. The name and address of the ~~practitioner~~ veterinarian, license number and contact information.
2. An agreement by the ~~practitioner~~ veterinarian that the compounded preparation may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except for a case in which emergency dispensing is required.
3. An agreement by the ~~practitioner~~ veterinarian to include on the patient's chart, or medication administration record the lot number and beyond-use date of the compounded preparation administered or dispensed to the patient.
4. The procedures for a patient to report an adverse reaction or to submit a complaint about a compounded preparation.
5. The procedure to be used when the pharmacy has to recall a batch of compounded preparation.

(f) When pharmacists are compounding ~~sterile~~ preparations to be provided to ~~practitioners~~ veterinarians for use in patient care or when pharmacists are altering or repackaging such products for ~~practitioners~~ veterinarians to use in patient care in the ~~practitioner's~~ veterinarian's office, the ~~sterile~~ compounding shall be conducted as allowed by applicable federal law and Board rules and shall be in compliance with USP-NF standards for ~~sterile~~ compounding.

~~(g) Sterile compounded preparations may be dispensed to practitioners in quantities no more than 100 individual dosage containers and must have a beyond-use date no more than one week.~~
(~~h~~g) Pharmacist<u>s</u> may not compound Schedule II, III, IV or V controlled substances, as defined in Article 2 of Chapter 13 of Title 16 without a patient specific prescription drug order.
~~(i) Prior to any pharmacy engaging in the practice of compounding preparations for use in the practitioner's office, the pharmacy must notify the Georgia Drugs and Narcotic Agency ("GDNA") of its practice, and must maintain on file the written acknowledgement of receipt of the notice from GDNA.~~
(~~j~~i) Nothing in this paragraph shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners employed by an institution or its affiliated entities; provided, however, pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to the other rules and regulations of the Board governing the compounding of pharmaceuticals.
(3) Pharmacists must maintain documentation of proof that the beyond-use date on compounded pharmaceuticals is valid.
(4) Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final verification check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.
(5) Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.
(6) Pharmacists may use prescription bulk substances in compounding when such bulk substances:
(a) Comply with the standards of an applicable USP-NF monograph, if such monograph exists, including the testing requirements, and the Board rules on pharmaceutical compounding; or are substances that are components of pharmaceuticals approved by the FDA for use in the United States; or otherwise approved by the FDA;
(b) Are manufactured by an establishment that is registered by the FDA; and
(c) Are distributed by a wholesale distributor licensed by the Board and registered by the FDA to distribute bulk substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.
(7) Pharmacists shall maintain records of all compounded pharmaceutical products. Pharmacist shall maintain a complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail when such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.
(a) This record-keeping requirement does not apply when FDA-approved and labeled sterile injectable drug products, produced by registered pharmaceutical manufacturers, are reconstituted under conditions as allowed by USP 797, and each such sterile drug product must be administered within 24 hours of being reconstituted.
(8) Pharmacists engaged in the compounding of pharmaceuticals shall operate in conformance with Georgia laws and regulations. Non-sterile compounded preparations shall be subject to USP 795. All sterile compounded preparations shall be subject to USP 797.
(9) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.
(10) Special precaution preparations. If drug preparations with special precautions for contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.
(11) Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved.

(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet or an appropriate barrier isolator. Other preparations should not be compounded in this cabinet.
(b) Personnel compounding cytotoxic drugs shall wear protective apparel as outlined in the National Institute of Occupation Hazards (NIOSH.) in addition to appropriate compounding attire as described in USP 797.
(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations.
(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.
(e) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.
(f) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and delivered in a manner to minimize the risk of accidental rupture of the primary container.
(g) Disposal of cytotoxic and/or hazardous wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of cytotoxic and/or infectious waste in a manner so as not to endanger the public health.
(12) Pharmacists shall not engage in the following:
(a) The compounding for human use of a pharmaceutical product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe.
(b) The compounding of any pharmaceutical products that are essentially copies of commercially available pharmaceutical products. However, this prohibition shall not include:
1. The compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,
2. The compounding of a commercially available manufactured pharmaceutical during times when the product is not available from the manufacturer or wholesale distributor,
3. The compounding of a commercially manufactured pharmaceutical that appears on the drug shortages list, or
4. The mixing of two or more commercially available products of which the end product is a commercially available product.
(13) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. Section 26-4-130 shall comply with all the provisions of this rule and other applicable Board laws, rules and regulations.

A motion was made by Mike Faulk, seconded by Lisa Harris, and the Board voted that the formulation and adoption of these proposed rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the rule amendment 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 proposed 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.

Lisa Harris 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 Vicki Arnold, Carrie Ashbee, Michael Brinson, Mike Faulk, Lisa Harris, and William Prather.

Executive Session

Georgia Drugs and Narcotics Agency – Michael Karnbach

- M.F.W.

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- J.T.S.
- T.M.T.
- M.D.I.

Mr. Changus discussed the following cases:

- K.L.L.
- G.M.B.
- J.N.C.
- C.D.
- S.B.A.
- V.J.P./P.A.S.C.H.C.

Executive Director's Report – Tanja Battle

- Presented letter for dissemination regarding complaint received.

Legal Services – Kimberly Emm

- D.4.L.I.
- G.P.

Appearances

- G.R.J.
- P.E.H.

Cognizant's Report – Lisa Harris

- GDNA Case # T32798
- GDNA Case # B32723
- GDNA Case # B32768
- GDNA Case # B32774
- GDNA Case # B32779
- GDNA Case # A32711
- GDNA Case # B32748
- GDNA Case # B32706
- GDNA Case # T32780
- GDNA Case # B32761
- GDNA Case # B32720
- GDNA Case # B32759
- GDNA Case # A32824
- GDNA Case # A32785
- GDNA Case # A32600
- PHAR190157
- PHAR190174

Applications

- G.G.
- M.S.H.
- C.M.C.
- E.J.C.
- A.A.L.
- J.A.W.
- M.J.
- A.G.D.
- C.S.E.
- C.J.P.
- E.C.M.
- P.A.R.
- T.A.P.
- C.A.S.
- Z.C.
- D.N.B.
- A.S.M.
- L.S.L.
- W.M.L.
- A.
- P.M.P.

Correspondences/Requests

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

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

Open Session

Lisa Harris made a motion for the Board to take the following actions:

Georgia Drugs and Narcotics Agency – Michael Karnbach

- M.F.W. Refer to the Department of Law

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- Joshua T. Sturdivant Public Consent Order accepted
- T.M.T. Private Consent Order accepted
- M.D.I. Public Consent Order to be accepted and signed with express permission upon receipt of the original

Mr. Changus discussed the following cases:

- K.L.L. Close case
- G.M.B. Counterproposal accepted
- J.N.C. Update provided
- C.D. Modified previous disposition
- S.B.A. Close case
- V.J.P./P.A.S.C.H.C. Close with a letter of concern

Executive Director's Report – Tanja Battle

- The Board approved the letter drafted in response to complaint received.

Legal Services – Kimberly Emm

- D.4.L.I. Open Records Request Approved request
- G.P. Open Records Request Approved request

Appearances

- G.R.J. Request to reinstate license Refer to the Department of Law
- P.E.H. Request to reinstate license Refer to the Department of Law

Cognizant's Report – Lisa Harris

- GDNA Case # T32798 Accept Voluntary Surrender
- GDNA Case # B32723 Close with no action
- GDNA Case # B32768 Close with a letter of concern
- GDNA Case # B32774 Close with no action
- GDNA Case # B32779 Misfill Policy #1
- GDNA Case # A32711 Close with no action
- GDNA Case # B32748 Close with a letter of concern
- GDNA Case # B32706 Close with a letter of concern
- GDNA Case # T32780 Revoke Technician Registration
- GDNA Case # B32761 Close with no action
- GDNA Case # B32720 Close with no action
- GDNA Case # B32759 Close with no action
- GDNA Case # A32824 Accept Private Interim Consent Order for Assessment

• GDNA Case # A32785	Accept Private Interim Consent Order
• GDNA Case # A32600	Refer to the Department of Law
• PHAR190157	Respond to complainant by stating if he/she is concerned about his/her medication, the individual needs to contact the pharmacist regarding such.
• PHAR190174	The Board viewed this correspondence for informational purposes only.

Applications

• Gustavo Garcia, Jr.	Pharmacy Technician	Approved for registration
• Matthew S. Hunsinger	Pharmacy Technician	Approved for registration
• Christopher M. Cutler	Pharmacy Technician	Approved for registration
• Emma J. Cole	Pharmacy Technician	Approved for registration
• Aliyah A. Lozada	Pharmacy Technician	Approved for registration
• Joel A. Williams	Pharmacist Intern	Approved application
• Marium Javed	Pharmacist Intern	Approved application
• A.G.D.	Pharmacist Reciprocity	Approved to sit for the exam
• C.S.E.	Pharmacist Reciprocity	Approved to sit for the exam
• Christina J. Pleas	Pharmacist Reinstatement	Approved application
• E.C.M.	Pharmacist Reinstatement	Refer to the Department of Law
• Patrick A. Russo	Pharmacist Reinstatement	Approved application
• Timothy A. Poole	Pharmacist Reinstatement	Approved application
• C.A.S.	Temporary Pharmacist	Denied application
• Z.C.	Temporary Pharmacist	Denied application
• Daniel N. Brush	Nuclear Pharmacist	Approved application
• A.S.M.	Request for Inactive Status	Denied request
• L.S.L.	Pharmacist Exam	Approved to sit for the exam
• Weng M. Lam	Pharmacist Reinstatement	Approved application
• A.	Durable Medical Equipment	Denied application
• P.M.P.	Durable Medical Equipment	Denied application

Correspondences/Requests

• P.H.I.	Notice of Discipline	No action
• D.C.A.P.	Notice of Discipline	No action
• W.V.P.	Notice of Discipline	No action
• B.P.	Notice of Discipline	No action
• B.P.	Notice of Discipline	No action
• A.D.V.I.	Notice of Discipline	No action
• D.P.S.	Notice of Discipline	No action
• D.P.S.	Notice of Discipline	No action
• H.S.T.P.	Notice of Discipline	No action
• M.Q.P.	Notice of Discipline	No action
• P.C.P.C.	Notice of Discipline	No action
• H.W.	Notice of Discipline	No action
• R.I.	Remote order entry	Approved
• R.W.C.	Correspondence	Table pending receipt of additional information
• C.A.Z.	Request for early release from	Approved request

	probation	
• L.C.C.	Request to terminate probation	Approved request
• J.M.C.	Request for early release from probation	Denied request
• C.A.T.	Correspondence	The Board viewed this correspondence for informational purposes only.
• E.H.B.	Request for 4th attempt at NAPLEX with accommodations	Denied request
• J.B.	Appearance request	Approved request
• A.M.M.	Fee dispute	Denied request
• C.I.	Request to be allowed to keep license number after changing locations	Denied request
• C.C.	Correspondence	The Board viewed this correspondence for informational purposes only.

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

There being no further business to discuss, the meeting was adjourned at 2:37 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, April 17, 2019 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