GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 5th Floor
Atlanta, GA 30303
April 17, 2019
9:00 a.m.

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

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

Visitors:
Greg Reybold, GPhA
Anthony Grzib, Wedgewood Pharmacy
Jimmy Perren, Relay Health
Diane Sanders, Kaiser Permanente
Megan Hathaway, Pharmerica
Peter Cullen, ProCare Rx
Stacy Burke, Publix
Lea Winkles, Mercer University
Leigh Carpenter, Hemophilia of Georgia
Christy Norman, Emory Healthcare
Michael Hanichen, Emory Healthcare
Stephanie Kirkland, Eldercare
Amanda Roberson, Eldercare
Michael McDonald, Clean Harbors Aragonite
Alana Powell, CVS Health
Susan Walls, Independent
Travis J. Clark, CAPS-Norcross
Beth Jarrett, Walmart
Laura Ko, Shepherd Apothecary
Cecil Cordle, CVS Health
Vince Obsitnik, GVMA
Stephen Snow, Bendin Sumrall & Ladner
Dr. John Kennedy
Devin Kreel, MAG
Yu Jin Kang, CAPS
Jameisha Shavers
James Bartling
Travis J. Clark, CAPS-Norcross
Luc Boulet, GSPPS & GOS
Beth Richardson

Shea Ross-Smith, Kaiser Permanente
Becca Hallum, GHA
Bryan Fiveash, GVMA
Helen Sloat, Kaiser Permanente / Hemophilia of GA
Jeff Burnette

President Prather established that a quorum was present and called the meeting to order at 9:19 a.m.

Public Hearing

President Prather called the Public Hearing to order at 9:19 a.m.

Chapter 480-10A Central Filling Regulations
No comments were received.

Written responses were received from Stephen Georgeson, GRA, Greg Reybold, GPhA, and John Rocchio, CVS Health.

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

Rule 480-13-.05 Physical Requirements.Amended
No comments or written responses were received.

Michael Brinson made a motion to adopt Rule 480-13-.05 Physical Requirements.Amended. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Rule 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician.
No comments or written responses were received.

Lisa Harris made a motion to adopt Rule 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician. Michael Brinson seconded and the Board voted unanimously in favor of the motion.

Rule 480-11-.02 Compounded Drug Preparations
Public comments were received from Greg Reybold, GPhA. Mr. Reybold stated that he appreciated the opportunity to offer oral and written comments to the Board. He stated the Association has worked hard on this matter with the Board. He commented that animal patient access to medication is important and the Association supports this; however, Mr. Reybold stated that there were implications with this rule. He stated that with regard to veterinary dispensing, it is important that it be limited to emergency situations and in conversations GPhA has had with the Georgia Veterinary Medical Association (GVMA), GPhA suggested a 72-hour supply, but the rule states 96.

Mr. Reybold discussed prohibition on distribution of compounded preparations for office use. He stated the proposed changes take steps that enhance animal patient access to medications and care while at the same time depriving human patients of the same. He added that the proposed changes appear to be significantly more restrictive than federal law and even the FDA's interpretation of federal law. Director Troughton commented that animal use compounding is exempt from 503a and 503b. He added that this is only focused on the vet. He stated that if they are exempt, this should be safe. Mr. Reybold agreed, but stated that 503a and 503b do not speak to that. He added that this proposed rule does not contemplate that,

but goes beyond the ability of other pharmacies from providing to other practitioners. He commented that, at a minimum, the rule could use some closer scrutiny. Discussion was held. Mr. Reybold stated that in his mind there are two issues: animal compounding, which everyone is supportive of, but this rule, animal patients and veterinarians aside, it prohibits from providing to other practitioners. Director Troughton commented that the Board does have the option to waive the rule. Mr. Reybold responded that there are implications there. President Prather thanked Mr. Reybold for his comments. President Prather commented that at this time the Board will deal with the seen and not the unforeseen.

President Prather thanked the GVMA for their patience with the Board. President Prather asked if there were any additional comments.

Public comments were received from Stephen Snow, Bendin Sumrall & Ladner. Mr. Snow stated that as far as the "seen/unforeseen", 503a and503b is a "foreseen." He commented that the vets' language is attached to the compounding rule and stated it is a flat prohibition. He stated that under Georgia rule, if adopted as is, no 503b will be able to provide to any practitioner. Mr. Snow stated there needs to be a carve out for practitioners in the rule. He added that he thinks this is a very "here and now" issue.

Ms. Emm stated that she is hearing the comments being received about 503b. She stated the rule was drafted regarding 503a. She added that the rule can be amended to enter a subsection stating it does not pertain to 503bs. President Prather asked if that would require the Board to repost the rule. Mr. Changus responded that it would. Director Troughton stated that from a timing standpoint, there are no 503bs in Georgia and if it were passed as it is now, they would not have to comply with this rule. He stated that he knows the veterinarians would like to see some action on the rule now. He asked if the Board could adopt the rule today and go back and amend it.

Mr. Snow commented that 503b facilities do have to be licensed and comply with Georgia rules. Director Troughton responded that they do only if they are non-resident pharmacy. Mr. Snow stated that it will be a problem long-term if not corrected now. Ms. Emm stated she added proposed language to subsection (d) that reads, "This subsection shall not effect 503b outsourcing facilities ability to provide non-patient specific compounded preparations for office use by a practitioner". Mr. Changus stated maybe what a decent route would be is for the Board to vote to adopt, then immediately go ahead and the Board can vote to post the rule change discussed by Ms. Emm. Mr. Changus stated that the Board has identified that the point brought up is worthy of addressing and it is dealing with the fact that it wants to move this matter along for the veterinarians, although Mr. Snow has brought up this issue. Mr. Changus added that if the Board votes to adopt and if there is a better suggestion, it would have a second amendment to the current rule. This would allow the Board to move the issue that was brought before it initially, but also address the other issue mentioned to the Board today.

Public comments were received from Dr. John Kennedy. Dr. Kennedy expressed his concern for the students graduating. He stated that in reading the rule, he is not sure what the Board is trying to fix with office use. Dr. Kennedy explained to the Board what his facility does. He stated that they currently do not do office use. Discussion was held. Ms. Harris commented that this rule would not stop patient-specific compounding. Dr. Kennedy stated he was talking about the 5% federal law. Ms. Harris stated that would not come into play. President Prather thanked Dr. Kennedy for his comments.

President Prather stated that the Board will proceed with adopting this rule at this time. Michael Brinson made a motion to adopt Rule 480-11-.02 Compounded Drug Preparations. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

Written comments were received from Dr. Mike Zager and Dr. Vince Obsitnik, Georgia Veterinary Medical Association, Dunn DVM, Dr. Hannah Fearing, Dr. Cara McNamee, Dr. Patricia Lane, Dr. Mark

Mosher, Dr. Craig Padgett, Barry J. Seigel on behalf of Wedgewood Pharmacy, Greg Reybold, GPhA, Dr. Lois Lassiter, Scott Brunner, International Academy of Compounding Pharmacists, and Dr. Amanda Hall.

The hearing adjourned at 9:54 a.m.

Open Session

Approval of Minutes

Lisa Harris made a motion to approve the Public and Executive Session minutes from the March 6, 2019 meeting and the Public and Executive Session minutes from the March 27, 2019 Emergency Conference Call. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

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

Petitions for Rule Waiver or Variance

Michael Brinson made a motion to approve the rule variance petition from Bright Star Healthcare Group, LLC. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Michael Brinson made a motion to deny the rule variance petition from MEI Services, PHRE009919. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

Michael Brinson made a motion to grant the rule variance petition from Optim Medical Center-Screven, PHH003751. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Michael Brinson made a motion to grant the rule variance petition from Summit Cancer Care, PHRE009051. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

Discussion was held regarding the rule waiver petition submitted by Budd Terrace Pharmacy. Director Troughton stated that GDNA has inspected the facility. He stated that Rule 480-13-.05(1) states, "The hospital pharmacy space requirements should be a minimum of 10 square feet per hospital bed". Director Troughton added that he did not see any reason to deny the request. Mr. Henderson asked why the facility was applying for a hospital license and then trying to petition the Board for exceptions. Director Troughton responded that they want to use floor stock in the facility, which is not permitted with a retail license. Mr. Henderson stated that if this rule waiver is granted, it may open the flood gates for other people that want to do the same thing. Director Troughton responded that if the facility meets the requirements for a hospital permit, then he sees no reason to deny the request. Mr. Henderson responded that he was thinking of any possible implications down the road. Michael Brinson made a motion to grant the rule variance request. Lisa Harris seconded and the Board voted in favor of the motion, with the exception of Hal Henderson who opposed.

Discussion was held. Michael Hanichen, Budd Terrace Pharmacy, was present at the meeting and spoke to the Board regarding how operations of the facility and the reason for the request. He stated that Budd Terrace Pharmacy is a Long-Term Care Pharmacy that has two patient populations. He stated in 2014, due to drug waste, they switched to Omnicell, but using Omnicell did not fit under the retail license and they had to apply for a hospital permit. He stated when they do have an IV need, they use the immediate use, premix, or outsource. He stated as far as the square footage goes, they do not have any more space to increase their footprint. He stated they work under Emory and are part of their contract. Mr. Henderson reiterated that he fears the Board would be opening a flood gate and stated the major purpose of doing this is for the facility to reduce cost. Christy Norman, Emory Healthcare, was also present and spoke to the

Board. She stated this also enhances patient care and using the Omnicell only provides the drugs needed at the time and reduces waste of blister packs. Mr. Henderson stated that OmniCell is a type of RAMS, but it is a floor stock. He stated they are not labeling the dose out of the machine. He added that has never been done in nursing homes before. Director Troughton stated that he was not speaking on their behalf, but if it is a RAMS, it comes out patient-specific and labeled properly. He added that was why they applied for the hospital permit. He stated, as a retail pharmacy, you would have to be a RAMS, for a hospital they can use Pyxis. Mr. Henderson stated he understands what they are trying to accomplish, but feels it requires some further investigation and thought. President Prather asked Mr. Henderson what type of investigation as GDNA has already inspected the facility. Mr. Henderson responded that it is a conceptual thing he is concerned with. Mr. Snow commented that he understands Mr. Henderson's concerns, but as Director Troughton pointed out, the facility has gone through the process of applying for the hospital license and applied for a petition for the variance of two items. He stated that is why we have this waiver/variance process. He added that the requirement in the rule does not fit this entity. Mr. Snow stated the number of beds does not work per square footage. He stated this facility is trying to do the right thing and satisfy all the requirements. He added that it seems like an appropriate situation for which to allow a variance. Mr. Henderson commented that he has an issue with it. Mr. Snow asked if there is any additional information that can be provided to the Board. Mr. Hanichen stated that since they have had Omnicell, it has been must simpler to track diversion. Mr. Henderson stated he does not want to go too far out of line here. He stated he is very familiar with the facility. He stated that is not what the issue is for him. He stated the issue is doing floor stock in a skilled nursing home and getting around it with hospital license. Mr. Changus discussed what the appropriate use of a rule waiver is. He stated that here is a limited situation involving space and the flow hood. Mr. Henderson asked Mr. Changus if the Board has approved the hospital license. Mr. Changus responded that discussion can go forward in Executive Session as it involves an application. He stated that if there is no objection to the request for a variance regarding these two issues, then advance that ball since that is not the Board's concern. The previous motion died. Michael Brinson made a motion to grant the rule variance petition. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

Michael Brinson made a motion to grant the rule waiver petition from Effingham Health System, PHH007975. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Correspondence from Chester Sosebee, UGA Veterinary Teaching Hospital

The Board considered this correspondence regarding an invitation to the Board to tour the University of Georgia Veterinary Teaching Hospital. Mr. Brinson stated he will attend the tour and will contact Dr. Sosebee to arrange such.

Correspondence from Michelle Ames, PruittHealth

The Board considered this correspondence regarding the automated CUBIE system from the CUBEX company and the requirement in Board Rule 480-24-.04(7)(d) which states, "An emergency drug kit must be inventoried at least once a month by a pharmacist from the provider pharmacy and sign a card attached to the kit indicating the date it was inspected. The provider pharmacy must maintain an adequate record of such inspections." In her inquiry, Ms. Ames asks if a pharmacist inventorying each CUBIE on exchange that fell below a set par level would meet the intent of the rule. In response, the Board directed staff to respond by affirming this would meet the intent of the rule.

Correspondence from Adrienne Baker, GA NADDI

The Board viewed this correspondence for informational purposes only.

Miscellaneous
The Board considered the Barnes Healthcare Insulin Substitution Standing Order Protocol submitted. Lisa Harris made a motion to approve the protocol submission. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Dennis Troughton
Director Troughton introduced Special Agent Eric Durham to the Board.

Director Troughton updated the Board on House Bill 324.

Director Troughton reported that GDNA has conducted 1630 inspections and received 296 complaints for FY2019.

Attorney General's Report – Max Changus
No report.

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
04/11/2019	.5	Kaiser Permanente Georgia	Laughter isn't always the best medicine: A clinical case on pseudobulbar affect	2019-0008

Renewals: Ms. Battle reported that pharmacy technicians and facilities are currently renewing. She requested the Board and guests remind licensees about renewals as the expiration date is approaching.

Legal Services – Kimberly Emm
No report.

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

Executive Session

Appearance
- J.B.

Georgia Drugs and Narcotics Agency – Dennis Troughton
- J.C.
- R.C.
- C.H.I.
- G.P.
- V.

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- B.U.I.
- N.R.P.
- B.P.S.
- W.R.T.
- O.A.
- P.E.H.
- C.D.
- C.D.
- K.P.G.C.P.

Mr. Changus discussed the following cases:

- B.P./F.W.P.
- I.R.
- R.H.P.
- GDNA Case #A32766

Executive Director's Report – Tanja Battle

- A.M.M.

Legal Services – Kimberly Emm

- S.P.I.

Cognizant's Report – Lisa Harris

- GDNA Case # T32812
- GDNA Case # T32877
- GDNA Case # B32758
- GDNA Case # B32776
- GDNA Case # B32767
- GDNA Case # B32772
- GDNA Case # B32750
- GDNA Case # B32807
- GDNA Case # B32783
- GDNA Case # B32784
- GDNA Case # A32796
- GDNA Case # T32647
- GDNA Case # B32801
- GDNA Case # B32781
- GDNA Case # A32702
- GDNA Case # A29727
- GDNA Case # A29410
- GDNA Case # A29708
- GDNA Case # A29993
- GDNA Case # B32745
- GDNA Case # B32763
- GDNA Case # B32820
- GDNA Case # B32769
- GDNA Case # A32873

- GDNA Case # A32872
- GDNA Case # B32833
- GDNA Case # A32747
- GDNA Case # A32669
- GDNA Case # A32874

Applications

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

Correspondences/Requests

- A.P.S.P.

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

- J.N.C.

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

Open Session

Michael Brinson made a motion to repost Rule 480-11-.02 Compounded Drug Preparations. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

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 non-patient specific compounded preparations for office use by a practitioner, excluding veterinarians, is prohibited. This subsection shall not affect 503b outsourcing facilities ability to provide non-patient specific compounded preparations for office use by a practitioner. 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) Pharmacists 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 Hal Henderson, and the Board voted that the formulation and adoption of this rule amendment does 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 this rule amendment will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Hal Henderson made a motion for the Board to take the following actions:

Appearance

• J.B.	Request to reinstate license	Refer to the Department of Law

Georgia Drugs and Narcotics Agency – Dennis Troughton

• J.C.	Correspondence	No Action
• R.C.	Correspondence	No Action

• C.H.I.	Durable Medical Equipment	Approved application
• G.P.	Correspondence	Board directed GDNA to respond by stating the authorized collector box in the assisted living facility would be permissible.
• V.	Correspondence	Board directed GDNA to respond by stating a pyxis machine could not be utilized in the setting described.

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- Baxalta US, Inc. Public Consent Order accepted
- N.R.P. Private Consent Order accepted
- Battens Prescription Shoppe Public Consent Order accepted
- W.R.T. Private Consent Order accepted
- Omnicare of Atlanta Public Consent Order accepted
- P.E.H. Private Consent Order accepted
- Central Drugs Public Consent Order accepted
- Central Drugs Public Consent Order accepted
- Kaiser Permanente Glenlake Public Consent Order accepted

Mr. Changus discussed the following cases:

- B.P./F.W.P. Amend referral to note clarification on fine
- I.R. Close case with no action
- R.H.P. The Board agreed to the proposal provided
- GDNA Case #A32766 No action

Executive Director's Report – Tanja Battle

• A.M.M.	Fee Dispute	Denied request

Legal Services – Kimberly Emm

• S.P.I.	Open Records Request	Approved request

The Board recommended authorizing approval for staff to administratively release application files to law enforcement agencies including, but not limited to the FBI, DEA, DOJ, GBI, etc. Staff can notify the Board as information.

Cognizant's Report – Lisa Harris

- GDNA Case # T32812 Accept Voluntary Surrender
- GDNA Case # T32877 Accept Voluntary Surrender
- GDNA Case # B32758 Table pending receipt of additional information
- GDNA Case # B32776 Close with letter of concern
- GDNA Case # B32767 Close with letter of concern
- GDNA Case # B32772 Close with no action
- GDNA Case # B32750 Close with no action
- GDNA Case # B32807 Close with no action
- GDNA Case # B32783 Close with no action
- GDNA Case # B32784 Close with no action
- GDNA Case # A32796 Refer to the Department of Law
- GDNA Case # T32647 Close with letter of concern

- GDNA Case # B32801 Misfill Policy #1
- GDNA Case # B32781 Close with no action
- GDNA Case # A32702 Investigative Interview
- GDNA Case # A29727 Offer Voluntary Surrender / Refer to the Department of Law for Revocation if the Voluntary Surrender is not received by 06/01/2019.
- GDNA Case # A29410 Close with no action
- GDNA Case # A29708 Offer Voluntary Surrender / Refer to the Department of Law for Revocation if the Voluntary Surrender is not received by 06/01/2019.
- GDNA Case # A29993 Offer Voluntary Surrender / Refer to the Department of Law for Revocation if the Voluntary Surrender is not received by 06/01/2019.
- GDNA Case # B32745 Close with no action
- GDNA Case # B32763 Close with no action
- GDNA Case # B32820 Close with no action
- GDNA Case # B32769 Close with letter of concern
- GDNA Case # A32873 Letter from the Board requesting the owner relinquish the permit. Discuss options if the individual chooses not to comply.
- GDNA Case # A32872 Refer to the Department of Law
- GDNA Case # B32833 Close with no action
- GDNA Case # A32747 Offer Private Interim Consent Order
- GDNA Case # A32669 Table pending receipt of additional information
- GDNA Case # A32874 Accept Voluntary Surrender

Applications

• Jada D. Ragin	Pharmacy Technician	Approved for registration
• Sanah S. Chaudhry	Pharmacy Technician	Approved for registration
• Alicia N. Dixon	Pharmacy Technician	Approved for registration
• Bindiya V. Pithwa	Pharmacy Technician	Approved for registration
• Ashley N. Jordan	Pharmacy Technician	Approved for registration
• Sheila R. Parker	Pharmacy Technician	Approved for registration
• Elisabeth I. Young	Pharmacy Technician	Approved for registration
• Jeffrey D. Harp	Pharmacy Technician	Approved for registration
• Marcus M. Jones, Jr.	Pharmacy Technician	Approved for registration
• Jamal R. Temple	Pharmacy Technician	Approved for registration
• Holly L. Bryson	Pharmacy Technician	Approved for registration
• Anne D. Worlds	Pharmacy Technician	Approved for renewal
• D.A.R.	Pharmacist Reinstatement	Denied application
• George D. Allmond	Pharmacist Reinstatement	Approved application
• Alissa M. Tran	Pharmacist Reinstatement	Approved application
• Amit K. Patel	Pharmacist Reinstatement	Approved application
• Craig W. Trobaugh	Pharmacist Reinstatement	Approved application
• Edgar W. Johnson III	Pharmacist Reinstatement	Approved application
• Ilsim J. Kim	Pharmacist Reinstatement	Approved application
• James W. Marrone	Pharmacist Reinstatement	Approved application
• Major M. White	Pharmacist Reinstatement	Approved application
• Stacy L. Brown	Pharmacist Reinstatement	Approved application
• T.H.P.	Pharmacist Reinstatement	Refer to the Department of Law
• Udeme S. Asuamah	Pharmacist Reinstatement	Approved application
• A.L.B.	Pharmacist Reciprocity	Approved to sit for the exam

• Priyank S. Shah	Pharmacist Reciprocity	Approved application
• D.M.M.	Pharmacist Exam	Approved to sit for the exam
• K.D.R.	Pharmacist Exam	Approved to sit for the exam
• R.C.C.	Pharmacist Exam	Approved to sit for the exam
• Hyoung Choi	Pharmacist Renewal	Approved for renewal
• Young J. Jo	Pharmacist Reinstatement	Approved application
• Zachary M. Ruege	Pharmacist Certification of DTM	Approved application
• C.H.A.	Wholesaler Pharmacy	Table pending receipt of additional information
• O.C.I.	Durable Medical Equipment	Denied application
• A.S.O.C.	Clinic Pharmacy	Table pending receipt of additional information
• C.M.C.A.C.T.R.M.C.	Hospital Pharmacy	Table pending receipt of additional information
• T.R.M.C.	Hospital Pharmacy	Table pending receipt of additional information
• T.R.E.P.	Retail Pharmacy	Table pending receipt of additional information

Correspondences/Requests

• A.P.S.P.	Notice of Discipline	No action
• A.P.S.	Notice of Discipline	No action
• C.D.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• C.W.	Notice of Discipline	No action
• D.S.I.G.	Notice of Discipline	No action
• D.S.I.G.	Notice of Discipline	No action
• M.D.I.	Notice of Discipline	No action
• M.D.	Notice of Discipline	No action
• H.F.P.A.S.	Notice of Discipline	No action
• H.P.	Notice of Discipline	No action
• I.P.I.	Notice of Discipline	No action
• A.S.P.C.	Notice of Discipline	No action
• R.R.V.P.	Notice of Discipline	No action
• W.P.N.	Notice of Discipline	No action

• P.S.	Notice of Discipline	Table pending receipt of additional information
• P.S.	Notice of Discipline	Table pending receipt of additional information
• P.S.	Notice of Discipline	Table pending receipt of additional information
• P.S.	Notice of Discipline	Table pending receipt of additional information
• P.S.	Notice of Discipline	Table pending receipt of additional information
• P.S.	Notice of Discipline	Table pending receipt of additional information
• P.S	Notice of Discipline	Table pending receipt of additional information
• P.S.	Notice of Discipline	Table pending receipt of additional information
• U.G.H.I.	Remote order entry	Denied
• N.R.H.	Remote order entry	Denied
• C.A.T.	Correspondence	The Board viewed this correspondence for informational purposes only.
• M.C.B.	Request to terminate probation	Approved request
• D.W.W.	Request to terminate probation	Approved request
• T.N.H.	Request to terminate probation	Approved request
• K.W.S.	Request to lift supervised practice	Approved request
• R.W.C.	Correspondence	Schedule to meet with the Board
• R.D.H.	Correspondence	The Board viewed this correspondence for informational purposes only.
• D.L.	Request for extension of intern license	Approved request
• T.J.M.	Request for extension of application	Approved request
• K.G.P.	Request for 4th attempt at MPJE	Approved request
• J.F.C.	Request regarding employment	Approved request
• J.N.C.	Correspondence	Approved lifting of probation/Approved for renewal of pharmacist license

Lisa Harris seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 3:39 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, May 8, 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