GEORGIA BOARD OF PHARMACY

Board Meeting Mercer University College of Pharmacy 3001 Mercer University Dr. Atlanta, GA 30341 March 7, 2018

9:00 a.m.

The following Board members were present:

Chris Jones, President Bill Prather, Vice-President Vicki Arnold Jim Bracewell Mike Faulk Lisa Harris Laird Miller **Bob Warnock**

Staff present:

Tanja Battle, Executive Director Dennis Troughton, Director, GDNA Ronnie Higgins, Deputy Director, GDNA Max Changus, Assistant Attorney General Kimberly Emm, Attorney Brandi Howell, Business Support Analyst I

Visitors:

Rena Estep, Walgreen Co. LeighAnne Jacobson, Publix Lea Bonner, Mercer University Stephen Georgeson, GRA Jeenu Phillip, Walgreens John Rocchio, CVS Health Beth Jarrett, Walmart Justin Spinks, Walmart John Olsen, Encompass, Rx Kim Reese, Encompass Rx Jessica Kilcoyne, Velano Vascular

Becca Hallum, GHA

Amanda Roberson, Eldercare Pharmacy

Kimberly Ramseur, Medical Association of GA

Jim Bartling, Bartling & Associates

Open Session

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

President Jones welcomed the visitors and Dean Brian Crabtree. Dean Crabtree welcomed the Board to the Mercer campus. Dean Crabtree stated that he has asked Lea Bonner, Assistant Dean, to be present at most of the board meetings so if there are any questions related to students or curriculum, they would like to provide that information. He stated that Mercer University would like to be a resource for the Board. He thanked the Board for its mission and stated that if the school can be of support in any way to let him know.

Appearance

Appearance by Kim Reese and John Olsen, Encompass Rx, LLC, PHRE009830: Ms. Reese spoke to the Board regarding the facility's denied rule waiver petition. Mr. Olsen stated that the concern is it would be a substantial hardship to obtain written patient authorizations to deliver medications to the physician's office or the hospital and obtaining written authorization would cause an undue delay in the dispensing of

medications. President Jones asked what would be the alternative. Mr. Olsen responded the alternative is to obtain and document verbal consent from patients to deliver their medications to their physician's office or hospital and they will confirm such requests with the prescribing physician. Discussion was held regarding signing of a release form by the patient. Mike Faulk made a motion to uphold the denial. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Approval of Minutes

Bill Prather made a motion to approve the Public Session minutes from the February 7, 2018 meeting. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Jim Bracewell made a motion to approve the Executive Session minutes from the February 7, 2018 meeting. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Bill Prather 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 Variance or Waiver

Jim Bracewell made a motion to grant a rule waiver petition from La Jolla Pharmaceutical Company. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to grant a rule waiver petition from MedMark Treatment Centers Columbus North. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion to deny rule variance petitions from Genoa a QoL Healthcare Company LLC, PHRE010079, Genoa a QoL Healthcare Company LLC, PHRE010081, Genoa a QoL Healthcare Company LLC, PHRE010169, Genoa a QoL Healthcare Company LLC, PHRE010194, Genoa a QoL Healthcare Company LLC, PHRE010078, Genoa Healthcare Company LLC, PHRE010078, Genoa Healthcare LLC, PHH007941, Genoa Healthcare LLC, PHRE009729, Genoa Healthcare LLC, PHRE010136, and Genoa Healthcare LLC, PHRE010297. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Dimitra Travlos, ACPE

The Board considered this request from ACPE asking the Board to consider recognition of IPCE credits. Representatives of ACPE met with the Board in February and submitted additional information as requested. Jim Bracewell made a motion to approve the request. Bill Prather seconded and the Board voted in favor of the motion. Laird Miller opposed.

Correspondence from Serra J. Schlanger, Hyman, Phelps & McNamara PC

The Board considered this correspondence requesting guidance regarding pharmacy statutes and regulations. The Board recommended staff respond to Ms. Schlanger's questions as follows:

- Can a company licensed as a drug manufacturer in Georgia also own and operate a retail mail order pharmacy located in Georgia? *If it complies with the requirements of the law*.
- If so, could the pharmacy be located in the same facility as the manufacturer's offices? *If it complies with the requirements of the law.*
- Are there any requirements about what products a pharmacy has in stock? For example, can a pharmacy carry and dispense only a limited number of products? Can a pharmacy carry and

dispense products from only one manufacturer (e.g., the one that owns and operates the pharmacy)? *There are no requirements as to what the pharmacy is required to stock.*

Correspondence from Megan Bunch, Maxor National Pharmacy Services, LLC

The Board considered this correspondence asking how will removing a sterile clean room affect a home healthcare retail pharmacy license. Vicki Arnold made a motion to direct staff to respond to Ms. Bunch by stating that if they are removing the sterile compounding area, they can no longer provide sterile compounding. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

<u>Correspondence from Amy Adams, Investigational Drug Service University of Virginia Health System</u>

The Board considered this correspondence regarding sending drugs to other sites for a proposed multicenter investigator-initiated study. Bill Prather made a motion to direct staff to respond by stating that a wholesale permit would need to be obtained prior to conducting the study. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Robert Brennan regarding WellStar Kennestone Hospital

The Board considered this correspondence regarding a proposed relocation. The Board recommended inviting Mr. Brennan for an appearance with the Board to further discuss this matter.

Georgia Drugs and Narcotics Agency - Dennis Troughton

Director Troughton reported that 1,218 inspections have been conducted this year to date. He stated GDNA has begun conducting visits to animal shelters that euthanize animals as was discussed at the January meeting to get an idea of how the drugs used in the procedure are handled. He stated there are a variety of methods they are seeing including paper records in the facilities, electronic records, and sites where the veterinarian who performs the procedures brings the drugs with him/her and takes the drugs when he/she leaves. This is being done with an educational overtone and the agents will make suggestions on security and the importance on maintaining accurate usage records. He stated they provide them with the Board approved form for record keeping. He added that the Georgia Board of Pharmacy and the Georgia Board of Agriculture are aware of the visits and when GDNA enters these facilities.

Director Troughton stated a chain pharmacy has asked the question if Rule 480-36.-07(2) removes the requirement for the written consent if the pharmacies have common ownership. Director Troughton stated he has shared this question with Mr. Changus for his input. Mr. Changus stated the way that is written suggests you do not have to obtain written consent from the primary dispensing pharmacy when there is common ownership.

Mr. Miller discussed central fill and his concern that a patient might not know what is going on. Mr. Changus stated section (b) of Rule 480-36-.07 reads in part "Such notification may be provided through a one-time written consent from the patient or the patient's authorized representative and through use of a sign in the pharmacy which states: "Remote Order Processing Utilized Here." Such sign must be clear and legible with letters at least three (3) inches in size, and the sign shall be free from obstruction and visible to patients at the time the prescription is presented to the pharmacy." President Jones stated that the sign, in his opinion, should be enough. Mr. Miller responded by stating that he is big believer on erring on the side of caution when it comes to protecting the public. He stated the patient should give informed consent. Mr. Prather added that the Board is talking about central adjudication and not central fill. Discussion was held. Mr. Changus stated the way the rule reads is the primary dispensing pharmacy is required to give notice to patients if they are utilizing Remote Order Processing. The rule also uses the word "may" related to providing written consent and the use of a sign.

President Jones asked Director Troughton what GDNA sees as it relates to Remote Order Entry. Director Troughton responded by stating almost nothing. Deputy Director Higgins stated they ran into a chain that was doing it and they were trying to interpret this rule. He asked how they should enforce the rule in the field. Mr. Changus asked if there was notice or signs? Deputy Director Higgins stated no. Mr. Changus responded by stating that was a violation. Deputy Director Higgins stated that signed consent is the big question. Mr. Changus stated that it is not necessarily a violation of the rule if the pharmacy is under the same ownership. A representative from Eldercare Pharmacy stated that she was interested in this topic as well. She stated that they are a long-term care, closed door pharmacy and a sign does not make sense in their environment. She said they have a signed contract with a long-term Care facility. In the administration packet, the patient may choose Eldercare. She asked how do they segregate from those who sign it and those who do not. She stated that if the Board is considering revising the rule, the signage does not always apply because the patient does not always see it. President Jones responded by stating that she may be able to obtain a waiver from the sign because they are a closed-door pharmacy.

Director Troughton discussed the appearance in February by Dr. Pitou Devgon with Velano Vascular regarding the device they have to make blood draws through a peripheral catheter safer and easier. Director Troughton stated this has raised some questions that GDNA needs assistance with. They are requesting that saline flushes be made a "medical device" so they can be used by phlebotomist in hospital without any nursing involvement. Ms. Arnold stated the Board limited it to 10 ml's. Director Troughton stated the Georgia Composite Medical Board said they will not weigh in on this matter. President Jones stated right now it is still the way it was and if the Board does not have any comment or feedback, it could go ahead and add it on permanently.

Lastly, Director Troughton reported that Deputy Director Higgins will receive the John Atkinson service award. He stated it will be presented to Deputy Director Higgins at the NABP annual meeting.

Attorney General's Report - Max Changus

No report.

Executive Director's Report - Tanja Battle

Continuing Education Report: Report presented. Jim Bracewell made a motion to ratify the below named continuing education program approved since the previous meeting. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Date of	Hours	Sponsoring Group	Program Title	CE Code
Program				
03/08/2018	0.5	Kaiser Permanente	Clinical Case: Malignant	2018-0002
			Ascites	

Jim Bracewell made a motion to ratify the denial of the continuing education program titled "Basic Homeopathic Principles". Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Medication Errors Course: Ms. Battle reported that the Board office has been contacted by individuals unable to take the medication errors course offered by Oregon State University. She requested the Board explore the availability of having multiple course options.

Miscellaneous

Central Fill: The Board discussed Washington State Department of Health's requirements for central filling of prescriptions. President Jones requested Ms. Emm draft a rule based on the information discussed and present it to the Board at a future meeting.

Certified Paramedics giving vaccinations in a pharmacy: President Jones asked if this was something the pharmacist could delegate. Mr. Prather stated the question is if the pharmacist can use the paramedic in the pharmacy to do injections. Director Troughton stated that, based on information received from the Department of Public Health, the paramedic could administer the injection based on an order from the physician. Ms. Battle asked Mr. Warnock and Ms. Harris about her understanding through their meeting regarding Stockpile Strategic Planning that paramedics could not administer injections. Ms. Harris and Mr. Warnock both responded by stating the paramedics could not dispense drugs. Ms. Battle asked if this inquiry needs to go to who licenses paramedics and EMTs? Mr. Changus added that was one of his suggestions as paramedics are not in the chain of command of a pharmacist.

Rule 480-35-.03 Continuing Education: Mike Faulk made a motion to post Rule 480-35-.03 Continuing Education. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Rule 480-35-.03. Continuing Education

In order to renew a certification under this chapter, the continuing education must:

- (1) Be from a provider approved by the Board pursuant to Rule 480-3-.03 or a provider approved by ACPE.
- (2) Have been taken and credit received for the continuing education during the 12 months preceding the application for renewal.
- (3) Have been from a live program at least 1.0 contact hour (0.1 CEU) in length.
- (4) Have been on the topic of the therapy area in which the Pharmacist seeks to make drug therapy modifications.

A motion was made by Jim Bracewell, seconded by Lisa Harris, 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 proposed 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.

Mike Faulk made a motion and Lisa Harris 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, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Appearances

- T.K.C.
- M.D.K.
- Y.H.

Georgia Drugs and Narcotics Agency – Dennis Troughton

- J.L.J.
- J.C.H.

- GDNA case #A32281
- GDNA case #T-32251
- C.D.C.

Application

• N.L.C.

Cognizant's Report - Bill Prather

- GDNA Case # T-32446
- GDNA Case # B-32336
- GDNA Case # B-32383
- GDNA Case # B-32388
- GDNA Case # B-32389
- GDNA Case # B-32400
- GDNA Case # B-32401
- GDNA Case # A-32419
- GDNA Case # B-32422
- GDNA Case # A-32288
- GDNA Case # A-32433
- GDNA Case # B-32402
- GDNA Case # A-32424
- GDNA Case # A-32434
- GDNA Case # B-32435
- GDNA Case # A-32444
- GDNA Case # T-32443

Attorney General's Report - Max Changus

Mr. Changus presented the following consent orders for acceptance:

- C.M.L.
- M.R.U.
- T.S.S.
- S.P.
- M.D.C.
- K.
- B.P.
- M.T.
- M.C.C.G.
- C.V.S.P.
- C.V.S.P.
- D.M.S.
- J.W.S.
- B.Z.

Mr. Changus discussed the following cases:

- C.P.
- W.P.
- B.R.I.S.
- B.R.
- N.L.P.

- A.S.D.
- P.P.S.

Executive Director's Report - Tanja Battle

- A.D.M.
- A.J.H.

Legal Services – Kimberly Emm

• Requested and received legal advice regarding changes in ownership/changes in location

Applications

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

Correspondences/Requests

- A.P.N.Y.
- G.R.
- A.P.S.P.
- M.V.P.S.
- C.
- M.C.P.S.
- V.N.H.
- A.A.L.
- J.V.A.
- S.S.P.
- C.A.P.
- J.T.S.
- K.A.S.
- S.I.
- M.C.C.G.
- V.R.J.

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

Open Session

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

Appearances

T.K.C. Request to discuss reinstatement Refer to the Department of Law
 M.D.K. Denied pharmacist reinstatement Overturn denial and refer to the

Department of Law

• Y.H. Denied 7th attempt at MPJE Overturn denial and approve request

Georgia Drugs and Narcotics Agency - Dennis Troughton

J.L.J. Table pending receipt of additional information
 J.C.H. Table pending receipt of additional information

GDNA case #A32281 Schedule for Investigative Interview
 GDNA case #T-32251 Schedule for Investigative Interview

• C.D.C. Table pending receipt of additional information

Application

• N.L.C. Pharmacist Reciprocity Approved to sit for the exam

Cognizant's Report - Bill Prather

• GDNA Case # T-32446 Accept Voluntary Surrender

GDNA Case # B-32336
GDNA Case # B-32383
GDNA Case # B-32388
GDNA Case # B-32389
GDNA Case # B-32389
Close with no action Misfill Policy #2
Misfill Policy #1

• GDNA Case # B-32400 Close case and refer to the Georgia Composite Medical Board

• GDNA Case # B-32401 Close with no action

• GDNA Case # A-32419 Refer to the Department of Law

GDNA Case # B-32422 Schedule for Investigative Interview
 GDNA Case # A-32288 Schedule for Investigative Interview

• GDNA Case # A-32433 Refer to the Department of Law

• GDNA Case # B-32402 Misfill Policy #1

• GDNA Case # A-32424 Schedule for Investigative Interview

• GDNA Case # A-32434 Refer to the Department of Law

• GDNA Case # B-32435 Close case with no action

• GDNA Case # A-32444 Accept Private Interim Consent Order

• GDNA Case # T-32443 Revoke Technician Registration

<u>Attorney General's Report – Max Changus</u>

Mr. Changus presented the following consent orders for acceptance:

Private Consent Order accepted
M.R.U.
Private Consent Order accepted
T.S.S.
Private Consent Order accepted
S.P.
Private Consent Order accepted
M.D.C.
Private Consent Order accepted
Private Consent Order accepted
Private Consent Order accepted
Public Consent Order accepted

B.P. Private Consent Order accepted

M.T. Private Consent Order accepted

M.C.C.G.
 CVS Pharmacy #5725
 CVS Pharmacy #2544
 D.M.S.
 Private Consent Order accepted
 Public Consent Order accepted
 Private Consent Order accepted

• J.W.S. Private Consent Order accepted, but will not be effective until

individual submits application for reinstatement and fee.

B.Z. Amended Consent Order for Reinstatement accepted

Mr. Changus discussed the following cases:

• C.P. Counterproposal accepted

• W.P. Update provided

• B.R.I.S. Counterproposal accepted

B.R. Update providedN.L.P. Update provided

• A.S.D. Counterproposal denied; initial disposition amended

• P.P.S. Update provided

Executive Director's Report - Tanja Battle

A.D.M. Open Records Request Approved request
 A.J.H. Correspondence No action taken

Legal Services – Kimberly Emm

• Requested and received legal advice regarding changes in ownership/changes in location

Applications

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•	Melanie L. Clark	Pharmacy Technician	Approved for registration
•	Dionshay L. Fallen	Pharmacy Technician	Approved for registration
•	Amanda L. Parson	Pharmacy Technician	Approved for registration
•	Jesse A. Barrita	Pharmacy Technician	Approved for registration
•	Ruth Vasquez	Pharmacy Technician	Approved for registration
•	Tomya D. Laughlin	Pharmacy Technician	Approved for registration
•	Sheena Ivey	Pharmacy Technician	Approved for registration
•	Makayla S. Richards	Pharmacy Technician	Approved for registration
•	Alia R. Snyder	Pharmacy Technician	Approved for registration
•	Samuel K. Poole III	Pharmacy Technician	Approved renewal
•	Samuel O. Ogunyemi	Pharmacist Intern	Approved application
•	Candace M. Nichols	Pharmacist Cert of DTM	Approved application
•	Helen T. Bryant	Pharmacist Cert of DTM	Approved application
•	Kacie L. Waters	Pharmacist Cert of DTM	Approved application
•	Thy M. Trinh	Pharmacist Cert of DTM	Approved application
•	G.D.D.I.	Wholesaler Pharmacy	Table pending receipt of additional information

Correspondences/Requests

•	A.P.N.Y.	Notice of Discipline	No action taken
•	G.R.	Notice of Discipline	No action taken
•	A.P.S.P.	Notice of Discipline	No action taken
•	M.V.P.S.	Notice of Discipline	No action taken
•	C.	Notice of Discipline	No action taken

•	M.C.P.S.	Notice of Discipline	No action taken
•	V.N.H.	Request to take NAPLEX a 4 th time	Denied request and application
•	A.A.L.	Request to take MPJE a 7 th time	Denied request
•	J.V.A.	Request to take MPJE a 4 th time	Approved request
•	S.S.P.	Correspondence	Refer to the Department of
			Law
•	C.A.P.	Correspondence	Offer Voluntary Surrender
•	J.T.S.	Appearance request	Denied request
•	K.A.S.	Request to terminate consent order	Approved request
•	S.I.	Request to extend application	Approved request
•	M.C.C.G.	Remote Order Entry	Approved
•	V.R.J.	Correspondence regarding the	Denial upheld
		Board's denial of her request to take	
		the NAPLEX a 4 th time	

Jim Bracewell seconded and the Board voted in favor of the motion, with the exception of Chris Jones, who abstained from the vote regarding GDNA Case #A-32419.

Correspondence from Kelly Stuart

The Board considered this correspondence asking if the it considered training patients who are starting subcutaneous immunoglobin infusions via syringe pump as part of routine pharmacist counseling and does Georgia allow for starting IV's as part of a clinical pharmacist's collaborative scope of administration. The Board directed staff to respond by stating that it would not be routine pharmacist counseling unless the pharmacist involved with the counseling is also involved with the dispensing of the drug and providing of the pump. Lastly, the Board does not allow for starting IV's as part of a clinical pharmacist's collaborative scope of administration.

There being no further business to discuss, the meeting was adjourned at 3:57 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, April 18, 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