GEORGIA BOARD OF PHARMACY

Board Meeting 2 Peachtree St, N.W. 36th Floor Atlanta, GA 30303 November 9, 2016 9:00 a.m.

The following Board members were present:

Mike Faulk, President

Chris Jones, Vice-President

Vicki Arnold

Jim Bracewell

Lisa Harris

Laird Miller

Bill Prather

Bob Warnock

Staff present:

Tanja Battle, Executive Director

Dennis Troughton, Deputy Director, GDNA

Janet Wray, Senior Assistant Attorney General

Max Changus, Assistant Attorney General

Anil Foreman, Legal Officer

Brandi Howell, Business Operations Specialist

Visitors:

Frances Cullen

Emma Gant

Doug Jones

Jim Bartling

William Truelove

Ken Wilson

Lauren Willis

Paul Carpenter, SJCHS

Brian Robinson, Walgreens

Rondell Jaggers, GSHP

Ryan Loke, McKesson

Tamatha Cobb-Hunter

Leigh Carpenter, HoG

Jamie Diagostino, ElderCare Pharmacy

Young Chang, Walgreens

Drew Umberger, Cardinal Health

Mike King, Publix

Kimberly Ramseur, MAG

Stephen Snow

Robert Stannard

Michael Azzolin

Charlotte Kaye, Georgia Link/CVS

Stephen Georgeson, GACDS

Cameron Brown, Walmart

Greg Reybold, GPhA

Helen Sloat, Kaiser Permanente/Hemophilia of GA

Diane Sanders, Kaiser Permanente

President Faulk established that a quorum was present and called the meeting to order at 9:01 a.m.

Chris Jones made a motion and Jim Bracewell 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

Appearance

• E.R.G.

Attorney General's Report - Janet Wray

Ms. Wray presented the following consent orders:

- L.L.W.
- O.F.O.
- C.W.

Appearances

- D.W.J.
- W.T.T.

Applications

- C.L.M.
- C.F.H.
- J.P.L.
- L.J.B.
- K.E.H.
- S.F.
- S.A.S.B.
- C.E.W.
- A.R.S.
- L.D.M.
- S.L.L.
- S.A.T.

Appearances

- L.M.W.
- C.H.I. and C.H.P.

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

Open Session

President Faulk called the public hearing to order at 12:00 p.m.

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

Public comments from Robert Stannard, Bendin Sumrall & Ladner, LLC, were received. Mr. Stannard stated that the proposed amendments to this rule include that "All controlled substances and/or dangerous drugs shall be kept in the prescription department..." He asked if this rule only applies to retail

pharmacies and/or does it also apply to institutional healthcare pharmacies. Ms. Wray responded that this rule applies to retail pharmacies and that hospital pharmacies are addressed in a different chapter.

Written responses were received from Leigh Knotts, NACDS, and Robert Stannard, Bendin Sumrall & Ladner, LLC.

Rule 480-10-.20 Required Notifications to the Board

Public comments from Robert Stannard, Bendin Sumrall & Ladner, LLC, were received. Mr. Stannard stated that the amendment to this rule includes a definition of "significant amount" related to reporting amount. He added that in section (2)(e) of the amendment the "significant amount" description was not included, but it has been incorporated into the proposed amendments of other rules. He asked if this is a de minimus requirement for reporting or does this deal with controlled substances or all drugs.

Mr. Stannard continued by stating that his next question concerns section (3)(a)(2) regarding manufacturer's stocking units. He stated that a stock unit may be a vial or a case of vials. He asked does 20% loss of a 10ml vial trigger an immediate reporting requirement. He stated there have been some questions as to how to interpret the rule.

Mr. Stannard discussed language in the rule regarding "the theft of significant amount of any controlled substance or any dangerous drug". He stated that "significant amount" is not clear and asked what qualifies as a dangerous drug.

Lastly, Mr. Stannard commented that there appears to be an inconsistency in the proposed amendments to this rule regarding "immediate notification". He stated 480-10-.20(1)(b) requires notification to the Board of a theft or loss within 24 hours; however, section 480-10-20(3)(a)(1) requires notification within 72 hours.

He closed by stating that significant amount, immediate reporting, and immediate notification are the three (3) areas of concern. President Faulk responded by stating that the Board has had fair amount of discussion regarding significant amount; however, he stated that is a topic that will require further discussion. He continued by stating that in regards to "dangerous drugs", the rule does state "potential for abuse or theft". He stated that failing that, dangerous drugs would not be included in this.

Mr. Stannard asked if practitioners would need to report any loss of a dangerous drug as opposed to a certain amount. Mr. Jones responded by stating that this pertains to controls and the Board has discussed moving dangerous drugs out of this rule. He continued by stating that the idea was to identify drugs that people are stealing or seeing disappear and add it on to an inventory list. He continued by stating that the Board does have authority to make any drug a dangerous drug.

Mr. Stannard asked about "significant amount" and what is going into reporting requirements. Mr. Jones stated that significant amount is kind of like a red flag for a pharmacist. Mr. Stannard responded by stating that there may be a little bit of a conflict in the law and asked if a practitioner runs the risk violating the Georgia statute in order to comply with proposed board rule. Ms. Wray responded by stating that O.C.G.A. § 26-4-112 states that the board shall be notified immediately upon the occurrence of any of the following: (1) Permanent closing of a licensed pharmacy; (2) Change of ownership, management, or location of a licensed pharmacy; (3) Change of the pharmacist in charge of a licensed pharmacy; (4) Any theft or loss of drugs or devices of a licensed pharmacy; (5) Any known conviction of any employee of a licensed pharmacy of any state or federal drug laws; (6) Disasters, accidents, theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law; (7) Occurrence at a licensed pharmacy of a significant adverse drug reaction as defined by rules of the board; or (8) Any and all other matters and occurrences at a licensed pharmacy as the board may require by rule. She continued

by stating that what is happening is the pharmacies are not reporting any theft or losses in some instances. The Board is trying to clarify what constitutes the need to report here. She continued by stating that if it was reported to DEA or police, that it has to be reported. If there is a discrepancy of this amount, that is a loss. The Board called that a significant loss. She stated that perhaps the Board needs to say a "loss is a discrepancy of *this* amount". Mr. Stannard responded by stating in section (2)(e) any loss needs to be reported. He stated that he understood what Ms. Wray was stating, but for practitioners that are trying to progressively report, understanding whether it is a significant amount is a huge deal. Ms. Wray stated that the Board is trying to use terminology that pharmacists use instead of what attorneys use. She continued by stating to be mindful that section (8) of O.C.G.A. § 26-4-112 states "any and all other matters and occurrences at a licensed pharmacy as the board may require by rule". After further discussion, Ms. Wray stated that the Board will need to go back and work on this rule more and consider the comments that are being made. Mr. Stannard asked the Board about the inconsistency regarding "immediate notification". He asked if it was to be reported in 24 hours or 72 hours. President Faulk stated that it needs to be 72 hours. Once there is discovery, a pharmacist should make the call as soon as he or she can within 72 hours.

Written responses were received from Leigh Knotts, NACDS, Greg Reybold, GPhA, and Robert Stannard, Bendin Sumrall & Ladner, LLC.

Rule 480-13-.05 Physical Requirements. Amended.

No comments or written responses were received.

Bob Warnock made a motion to adopt Rule 480-13-.05 Physical Requirements. Amended. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Rule 480-13-.06 Drug Distribution and Control

Public comments from Rondell Jaggers, GSHP, were received. He stated he wanted to follow up on some comments made regarding hospital regulations as it seems there will be some further deliberations from the Board regarding the matter. He added that they just want to help their membership understand the Board's intent. President Faulk commented that was a good point and the Board did have more work to do on the subject.

Written responses were received from Greg Reybold, GPhA.

Rule 480-13-.11 Required Notifications to the Board

Public comments were received from Robert Stannard, Bendin Sumrall & Ladner, LLC. Mr. Stannard commented that he wanted to make the Board aware that there were some typographical errors related to Rule 480-13-.06.

Written responses were received from Greg Reybold, GPhA, Robert Stannard, Bendin Sumrall & Ladner, LLC, and Jodi Dick.

Rule 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician

Public comments were received from Robert Stannard, Bendin Sumrall & Ladner. Mr. Stannard commented that item (a)(15) bars registered pharmacy technicians from accepting or verifying controlled substance deliveries to a pharmacy. He stated that prohibiting a pharmacy technician from accepting or verifying controlled substance deliveries may inadvertently result in the loss of an important internal control, particularly for smaller pharmacies. President Faulk responded by stating that the problems the Board has seen have been where technicians have ordered and checked in the drugs. He stated that the theft is amazing. He added that the Board is trying to have some accountability of the pharmacist and not

everything the Board is doing is going to be embraced. He added that it is an inconvenience, but it is necessary to have the technicians out of the equation as there are too many thefts taking place. He stated that the Board appreciates his comments, but he is not sure how flexible the Board will be. Mr. Stannard responded that all kinds of separate functions have been divided up so the opportunity for diversion is not there. He stated he would be happy to submit some examples for the Board's consideration. He stated the real target may be the technicians, and if there is no objection, he will send a follow up letter that explains further. Ms. Wray responded to Mr. Stannard by stating that he is talking about the division of labor. She stated that the rule just states they cannot accept controlled substance deliveries. Mr. Stannard commented that the pharmacist has to order the drugs. Mr. Jones responded by stating nowhere in the proposed rule does it say the pharmacist has to order drugs. He stated the diversion is occurring with the delivery driver and the technician. Discussion was held about further defining the steps of signing for the delivery and verification. Ms. Wray added that the Board can further define the steps by policy as it would be impossible to put that kind of detail in a rule. She stated that the intent of the rule is the technician cannot accept and verify controlled substances.

Written responses were received from Leigh Knotts, NACDS, and Robert Stannard, Bendin Sumrall & Ladner, LLC.

Rule 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances or Dangerous Drugs
Public comments were received from Robert Stannard, Bendin Sumrall & Ladner, LLC. Mr. Stannard commented that there appears to be several typographical errors.

Written responses were received from Leigh Knotts, NACDS, Greg Reybold, GPhA, and Robert Stannard, Bendin Sumrall & Ladner, LLC.

Rule 480-18-.06 Drug Distribution and Control

No public comments were received. A written response was received from Greg Reybold, GPhA.

Rule 480-2-.06 Temporary Licenses

No public comments or written responses were received.

Bill Prather made a motion to adopt Rule 480-2-.06 Temporary Licenses. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Rule 480-33-.06 Drug Distribution and Control

No public comments were received. A written response was received from Greg Reybold, GPhA.

Rule 480-48-.02 Conditions for Use of Delivery by Mail

Public comments from John Rocchio, CVS, were received. Mr. Rocchio commented that there is concern that the amended language is inconsistent with both the intent and plain reading of House Bill 886, Georgia Statute 26-4-60(a)(11)(A)(vi) and (a)(11)(B)(iii) and expert testimony. He stated there is no USP approved method. It is more of a USP reviewed storage of that drug. He stated that within the rule this may include temperature tags and temperature sticks, but does not include insulated packaging. President Faulk commented that the Board wants very much to be in compliance with the statute. He stated the person receiving the package should have some idea that what they have received has not been compromised. Mr. Rocchio responded by stating that they would absolutely take the product back if it was compromised. Mr. Warnock asked if there is any indication in the packaging if it should be "cold" or not. Mr. Rocchio stated that information is provided to the patient in advance. Ms. Harris stated that she thinks one issue is certain pharmacies goes to great lengths to test the packages, but there are others that ship that do not go to those lengths. Discussion was held regarding prepackaging. Mr. Rocchio was asked for suggestions with language that the Board could consider. Ms. Wray stated that the Board is

concerned that the rule states the shipper provide adequate notice. She stated it would be helpful to know what language should be included in the package. Mr. Miller commented by suggesting adding language saying deliver by "x amount" of days. He added that the Board's concern is for the patient and not the company. He said the label should be clearly marked as to when the package left the facility. Mr. Rocchio stated he would provide the suggested language to the Board.

A written response was received from John Rocchio, CVS.

Rule 480-8-.06 Drug Distribution and Control

No public comments were received. A written response was received from Greg Reybold, GPhA.

The hearing was adjourned at 1:21 p.m.

Open Session

President Faulk welcomed the visitors.

Approval of Minutes

Laird Miller made a motion to approve the Public and Executive Session minutes for the October 19, 2016 meeting. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Ratifications

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

Petition for Rule Variance/Waiver - Oconee Regional Medical Center, PHH004139

Vicki Arnold made a motion to deny the rule variance/waiver petition. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance - Piedmont Mountainside Hospital-Ellijay

Vicki Arnold made a motion to table the rule variance petition pending an inspection from GDNA. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Sharps Compliance Inc.

Chris Jones made a motion to approve the rule waiver petition. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Radius Health, Inc.

Bob Warnock made a motion to approve the rule waiver petition. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Correspondence from Greg Shuford, Trinity Hospital of Augusta

The Board considered this correspondence regarding whether or not it is permissible for the hospital inpatient pharmacy to purchase medications (all non-controlled) for the Wound Care Department of the hospital. The Board directed staff to schedule Mr. Shuford for an appearance to further discuss this matter.

Correspondence from Jessica M. Burns, Walmart

The Board discussed this correspondence regarding a remodel of its pharmacy. Bill Prather made a motion to table this matter pending an inspection from GDNA. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Correspondence from Nick Masino

The Board considered this correspondence regarding outsourcing facilities. The Board directed staff to respond by stating the non-resident outsourcing facility will need to obtain a non-resident pharmacy permit and a manufacturer pharmacy permit before it can ship into Georgia.

Correspondence from Cynthia Rhodes

At its October 2016 meeting, the Board considered correspondence from Ms. Rhodes requesting clarification on license regulations for drug manufacturers. At that time, the Board voted to table the correspondence and request additional information from Ms. Rhodes. Ms. Rhodes supplied the additional information that the Board requested. After review of this information, the Board directed staff to respond by stating each entity would need to be licensed in the state of Georgia, based on the information provided.

Correspondence from Elizabeth Russell, NABP

The Board considered this correspondence inquiring if the Board would be planning to send a member to the interactive board member forum November 30th-December 1st. The Board directed staff to respond by stating that a board member would not be able to attend at this time.

Correspondence from Todd Moody

The Board considered this correspondence regarding licensure requirements for oxygen concentrators. Bill Prather made a motion to table this correspondence pending research to be conducted by Mr. Miller regarding the matter. Lisa Harris seconded and the Board voted in favor of the motion.

Georgia Drugs and Narcotics Agency - Rick Allen

No report.

Attorney General's Report – Janet Wray

No report.

Executive Director's Report – Tanja Battle

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

Sponsoring Group	Program Title
The Medical Center Navicent Health	Central vs. Peripheral Lines

Renewals: Ms. Battle reported 4300 pharmacists have renewed to date. She requested everyone please spread the word regarding licensure renewal. A final reminder notice will be sent out.

Newsletter: Ms. Battle stated that the Board has previously talked about a way to disseminate information to licensees. She reported that she is currently working with internal Department of Community Health staff regarding the matter and may have a solution soon.

Miscellaneous

Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed. President Faulk stated that at the last meeting, the Board had some discussion regarding this rule. He stated that the Board is very passionate about what it does and added that everyone is interested in getting this rule right. He stated that the Board appreciates the effort on everyone's part. Mr. Jones stated that after the last meeting he contacted the GDNA agents and requested they make suggestions as to amendments to the rule. He stated he also met with Deputy Director Troughton and another agent yesterday. He stated they discussed

additional changes based on suggestions provided. Laird Miller made a motion to post Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

A motion was made by Chris Jones, seconded by Bill Prather, 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.

Chris Jones made a motion and Jim Bracewell 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

Correspondences/Requests

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

- Z.P.I.
- S.D.W.
- R.P.S.
- L.W.S.
- F.C.M.

Cognizant's Report - Chris Jones

- GDNA Case # T-31993
- GDNA Case # T-31959
- GDNA Case # B-31781
- GDNA Case # B-31803
- GDNA Case # B-31940
- GDNA Case # B-31953
- GDNA Case # B-31954
- GDNA Case # B-31900
- GDNA Case # B-31981
- GDNA Case # B-31980

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

Open Session

Jim Bracewell made a motion for the Board to take the following actions:

Appearance

• E.R.G. Denied Pharmacist Reciprocity Overturn denial and approve to sit for the exam

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

L.L.W. Private Consent Order accepted
 Olayinka F. Olaniyi Public Consent Order accepted
 C.W. Private Consent Order accepted

Appearances

D.W.J. Request to lift PIC restriction Request approved
 W.T.T. Request to discuss reinstatement Request approved

Applications

•	Chelsea L. McGill	Pharmacy Technician	Approve for registration
•	C.F.H.	Temporary Pharmacist	Denied application
•	J.P.L.	Pharmacist Reciprocity	Approved to sit for the exam
•	L.J.B.	Pharmacist Reciprocity	Overturn denial and approve to sit for
			the exam
•	Kristin E. Harfoot	Pharmacist Intern	Approved application
•	Sabena Furman	Pharmacist Intern	Approved application
•	Sayyid A.S.Bahaduri	Pharmacist Intern	Approved application
•	C.E.W.	Pharmacist Intern	Approved pending receipt of

			additional information
•	Addison R. Sanders	Pharmacist Intern	Approved application
•	L.D.M.	Pharmacist Intern	Denied application
•	Sara L. Ly	Pharmacist Certification of DTM	Approved application
•	Stephanie A. Thrall	Pharmacist Certification of DTM	Approved application
	-		
_	<u>rances</u>		
•	L.M.W.	Request to discuss reinstatement	Request approved
•	C.H.I. and C.H.P.	Previous inspection	No action taken
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	spondences/Requests	D	D : 1
•	C.R.H.	Remote Order Entry	Denied Table 1
•	F.P.H.	Remote Order Entry	Table pending receipt of additional information
•	C.M.C.	Remote Order Entry	Table pending receipt of additional information
•	C.M.C.	Remote Order Entry	Table pending receipt of additional information
•	C.N.H.	Remote Order Entry	Table pending receipt of additional information
•	D.H.	Remote Order Entry	Table pending receipt of additional information
•	E.M.C.	Remote Order Entry	Table pending receipt of additional information
•	R.R.M.C.	Remote Order Entry	Table pending receipt of additional information
•	S.C.H.P.	Remote Order Entry	Denied
•	C.H.T.C.	Remote Order Entry	Denied
•	J.P.W.	Appearance request	Table pending receipt of additional information
•	J.R.H.	Correspondence	The Board viewed this correspondence for informational purposes only
•	P.D.D.	Appealing the Board's decision to deny request to retake the NAPLEX	Directed staff to inform applicant that she qualifies for reciprocity
•	M.B.H.	Appealing Board's decision to deny request for a 4 th attempt to take NAPLEX	Denial upheld
•	O.O.A.	Request for waiver of the 91-day wait period to retake NAPLEX	Request approved
•	T.I.N.	Request to take MPJE a 4 th time	Request approved
•	C.C.R.	Request to lift supervised	Request approved
		practice restriction	
•	C.J.A.	Request to retake NAPLEX in 30 days	Request denied
•	F.B.H.P.	Notice of adverse drug reaction	The Board viewed this correspondence for informational purposes only
•	A.H.	Notice of discipline	No action taken

•	M.	Notice of discipline	Refer to the Attorney General's office to add to existing file
•	S.P.	Notice of discipline	No action taken
•	A.H.	Notice of discipline	No action taken
•	M.P.I.	Notice of discipline	No action taken
•	W.I.	Notice of discipline	Letter of concern
•	Z.P.I.	Notice of discipline	No action taken
•	S.D.W.	Request to take MPJE a 4 th time	Request approved
•	R.P.S.	Notice of discipline	No action taken
•	L.W.S.	Request regarding reinstatement	Directed staff to inform the individual that she must apply for reinstatement. \$200 may be applied towards the reinstatement fee.
•	F.C.M.	Request to terminate probation	Request approved

Cognizant's Report - Chris Jones

• GDNA Case # T-31993	Accept Voluntary Surrender
• GDNA Case # T-31959	Accept Voluntary Surrender
• GDNA Case # B-31781	Refer to the Attorney General's office for discipline
• GDNA Case # B-31803	Refer to the Attorney General's office for discipline
• GDNA Case # B-31940	Close case with no action
• GDNA Case # B-31953	For RPh #1, refer to the Attorney General's office for discipline.
	For RPh #2, letter of concern.
 GDNA Case # B-31954 	Misfill Policy #1
• GDNA Case # B-31900	Close case with no action
• GDNA Case # B-31981	Refer to the Attorney General's office for discipline
• GDNA Case # B-31980	Table pending receipt of additional information

Laird Miller seconded and the Board voted in favor of the motion, with the exception of Bob Warnock, who recused himself from the vote regarding GDNA Case #B31781.

There being no further business to discuss, the meeting was adjourned at 3:33 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, December 14, 2016 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Operations Specialist Minutes edited by Tanja D. Battle, Executive Director