GEORGIA BOARD OF PHARMACY

Board Meeting

Philadelphia College of Osteopathic Medicine (PCOM)

625 Old Peachtree Rd, NW August 2, 2017

9:00 a.m.

The following Board members were present:

Chris Jones, President

Bob Warnock, Vice-President

Vicki Arnold Jim Bracewell Mike Faulk Lisa Harris

Laird Miller (departed @ 2:00 p.m.)

Bill Prather

Staff present:

Tanja Battle, Executive Director

Rick Allen, Director, GDNA

Janet Wray, Senior Assistant Attorney General Max Changus, Assistant Attorney General

Brandi Howell, Business Support Analyst I

Visitors:

Linndsay Burckhalter, Publix

Joey Sturgeon, Silvergate Robert Stannard, Imprimis Jennifer Bellis, Imprimis Brad Binghan, Imprimis Keri Conley, GHA

TJ Kaplan, JLM Greg Reybold, GPhA

Young Chang, Walgreens Bob Coleman, GPhA

Jeenu Philip, Walgreens

Jeff Cox Jenny Kenyon Douglas Brush

Mel Goldstein

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.

Appearance

Appearance from Bob Coleman, Georgia Pharmacy Association. Mr. Coleman introduced himself to the Board and stated that he is looking forward to working its members.

Approval of Minutes

Bob Warnock made a motion to approve the Public Session minutes from the July 12, 2017 meeting. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Laird Miller made a motion to approve the Executive Session minutes from the July 12, 2017 meeting. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Jim Bracewell made a motion to ratify the list of licenses issued. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Adama Pharmac, LLC

Bob Warnock made a motion to grant the rule waiver petition. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Ironshore Pharmaceuticals, Inc.

Lisa Harris made a motion to grant the rule waiver petition. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Onyx Pharmaceuticals, Inc.

Laird Miller made a motion to grant the rule waiver petition. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Correspondence from Chip Robison

The Board considered this correspondence from Mr. Robison, who is wanting to begin a collaborative pharmacy program with physicians for medication counseling and is requesting to know where he can get accredited as a patient medication reviewer for pharmacogenetics results. Bob Warnock made a motion to direct staff to respond to Mr. Robison by referring him to O.C.G.A. Sections §§ 26-4-50 and 43-34-24 for more information regarding this matter. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Greg Lang, Good Samaritan Health Center of Gwinnett

The Board considered this correspondence regarding O.C.G.A. § 43-34-23 Delegation of authority to nurse or physician assistant. Jim Bracewell made a motion to direct staff to respond to Dr. Lang and suggest he contact the Georgia Composite Medical Board regarding this matter since it pertains to the Georgia Medical Practice Act. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jeannie Pierson

The Board considered this correspondence asking what is the educational requirement to mix intravenous fluids without actually administering the fluids? Mike Faulk made a motion to direct staff to respond by requesting additional information about the clinical research setting from Ms. Pierson. Additionally, the Board would like to know what the purpose of the mixing of the mixing is. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Robert Stannard, Bendin Sumrall & Ladner, LLC

The Board considered this correspondence from Mr. Stannard, who was present at the meeting. Mr. Stannard explained that his correspondence is concerning Non-Resident 503B Outsourcing Facilities. He introduced Brad Bingam, Imprimis, NJOF. Mr. Stannard explained that there is conflicting information between the Board's licensure requirements and licensing requirements under Federal law. He stated that the FDA has made clear that a facility cannot be both a 503A and 503B as there are separate governing rules. He stated there have been a lot of issues with 503B facilities. He stated state boards govern and regulate 503A facilities. In Georgia, for a non-resident to get appropriate licensure to distribute as a 503B, they have to get a non-resident permit. He added that in order for the facility to have a manufacturing permit, the 503B facility that is out of state get a manufacturing permit, but also have a Georgia pharmacy permit, combing 503A/503B. He further stated that he is requesting a waiver and exemption so the facility he is representing can distribute and dispense and can proceed and do that without having to get a 503A. Ms. Wray explained that the client should submit a rule waiver and

provide verification of 503B licensure with the waiver for the manufacturing permit because the outsourcing facility is recognized in law as one of the categories of manufacturing pharmacy licenses. Ms. Wray responded by stating the rule waiver is only on the home state license Mr. Stannard responded by stating he understands a waiver will need to be submitted; however, the rule currently reads the facility has to have home state and 503B to obtain licensure. Mr. Miller responded that Georgia needs to come up with a 503B. Ms. Wray responded that it would be just a category of the manufacturing pharmacy license. Lisa Harris made a motion to respond to Mr. Stannard that the facility would need to submit a rule waiver petition to the Board. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Beth Gorse

The Board considered this correspondence regarding venipuncture. Bill Prather made a motion to direct staff to respond to Ms. Gorse by stating that the Board does not view venipuncture as an activity that requires licensure under the Pharmacy Practice Act. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

<u>Correspondence from Dr. Donald Fordham, Speaker of the Congress of Delegates for the GA</u> Academy of Family Physicians

The Board viewed this correspondence for informational purposes only.

Correspondence from Linda Stevens, Pipeline Rx

The Board considered this correspondence. Ms. Stevens stated that she understands Remote Order Entry and Review pharmacy facilities are not required to obtain licensure in Georgia at this time; however, she stated the company would like to open a facility in Georgia and asked what type of licensure would be needed for such. Lisa Harris made a motion to direct staff to respond by stating that the Board suggests Pipeline Rx apply for a retail pharmacy license. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency - Rick Allen

No report.

Attorney General's Report - Max Changus

No report.

Executive Director's Report - Tanja Battle

Correspondence from Mike Long, Elements Behavioral Health. Ms. Battle stated that this facility has submitted information regarding its treatment programs for the Board's consideration. She added that the Board recently adopted the criteria for the addiction programs. The Board suggested tabling this matter until the September meeting to allow time for the Board to review the program, along with the addiction program criteria.

Report presented. Laird Miller made a motion to ratify the below continuing education programs approved since the previous meeting. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Date of	Hours	Sponsoring Group	Program Title	Contact Person	CE Code	Date
Program						Notified
8/11/2017	6	Georgia Society for Parenteral	GASPEN Summer Meeting PN Bootcamp	Yolanda Whitty	2017-0008	Approved 7/14/17
7/27/2017	0.5	Kaiser Permanente	Clinical Pharmacy Information Series	Urvi Vora Choksi	2017-0009	Approved 7/21/17

Miscellaneous

Animal Shelters and Euthanasia Drugs: The Board discussed correspondence regarding O.C.G.A § 4-11-5.1. Euthanasia of dogs and cats by animal shelters or facilities operated for collection of stray, neglected, abandoned, or unwanted animals. Director Allen stated this matter would fall under the Georgia Board of Veterinary Medicine. Ms. Battle responded by stating that the above mentioned code section was provided. Ms. Wray added that although he provided that code section, he only sent a portion of it. Discussion was held. Ms. Wray stated that according to the rule provided, 40-13-13-.08, the Board must also approved the form used for euthanasia records. She added that the law allows the Board to limit the quantity of possession of sodium pentobarbital and other drugs. President Jones requested Mr. Miller, who was recently appointed to the Georgia Veterinary Medical Association Task Force, ask what is appropriate and report back to the Board. It was also suggested that the Board send a letter to the Veterinary Medical Association Task Force for their opinion on what they think is appropriate. Bill Prather made a motion to direct staff to send this correspondence to the Georgia Veterinary Medical Association Task Force. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

The Board discussed Chapter 480-7C Institutional Pharmacy Permits and recommended tabling this rule until the Board's September meeting.

The Board discussed Chapter 480-36 Retail Pharmacy Requirements for Remote Prescription Drug Order Processing. President Jones appointed Ms. Harris and Mr. Prather to work on suggested language and bring back to the Board at a future meeting.

Vicki Arnold made a motion and Bob Warnock seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2), §43-1-2(k) and § 50-14-3(b)(2) to deliberate and receive information on applications, investigative reports, the Assistant Attorney General's report, and discuss personnel matters. Voting in favor of the motion were those present who included Vicki Arnold, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller and Bob Warnock.

Executive Session

Appearances

- J.F.C.
- J.J.S.

Applications

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

Georgia Drugs and Narcotics Agency - Rick Allen

Director Allen reported on investigative matters.

Miscellaneous

The Board discussed staffing matters.

Cognizant's Report - Bob Warnock

- GDNA Case # A-17-09
- GDNA Case # A-32114
- GDNA Case # A-32136
- GDNA Case # B-32169
- GDNA Case # B-32207
- GDNA Case # B-32197
- GDNA Case # B-32180
- GDNA Case # B-32213
- GDNA Case # B-32167

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- A.R.
- C.V.S.P.
- J.W.T.

Ms. Wray discussed the following cases:

- A.H.P.
- B.S.I.S.
- A.H.
- G.M.B.

Applications

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

- N.A.
- N.A.
- N.A.
- N.A.
- N.A.
- N.A.
- N.A.
- P.P.

Executive Director's Report – Tanja Battle

• H.S.

Correspondences/Requests

- E.P.
- L.P.
- O.M.D.I.
- A.A.L.
- R.A.S.
- M.S.P.
- C.J.B.
- K.L.H.
- J.D.H.
- J.R.H.
- O.M.C.S.

Miscellaneous

The Board discussed staffing matters.

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

Open Session

Bill Prather made a motion to take the following actions:

Appearances

J.F.C. Request to lift consent order
 J.J.S. Refer to the Department of Law
 Refer to the Department of Law

Applications

• A.V.P. Temporary Pharmacist Approved application

•	C.P.	Pharmacist Examination	Approved to sit for the exam
•	J.M.M.	Pharmacist Reciprocity	Approved to sit for the exam
•	T.M.H.	Pharmacist Reciprocity	Denied application
•	K.S.H.	Pharmacist Reciprocity	Approved to sit for the exam
•	J.D.C.	Pharmacist Renewal	Approved renewal
•	J.S.H.	Nuclear Pharmacist	Approved application
•	S.L.H.	Pharmacist Reinstatement	Denied application
•	M.J.R.	Pharmacist Reciprocity	Approved to sit for the exam
•	T.B.T.	Temporary Pharmacist	Approved application
•	W.G.L.	Pharmacist Reciprocity	Approved to sit for the exam
•	S.S.	Temporary Pharmacist	Approved application

<u>Georgia Drugs and Narcotics Agency – Rick Allen</u> Director Allen reported on investigative matters.

Miscellaneous

The Board discussed staffing matters. The Board voted to appoint Dennis Troughton as Interim Director of the Georgia Drugs and Narcotics Agency.

Cognizant's Report - Bob Warnock

•	GDNA Case # A-17-09	Refer to the Department of Law
•	GDNA Case # A-32114	Refer to the Department of Law
•	GDNA Case # A-32136	Refer to the Department of Law
•	GDNA Case # B-32169	Close with no action
•	GDNA Case # B-32207	Close with no action
•	GDNA Case # B-32197	Misfill Policy #1
•	GDNA Case # B-32180	Close case with letter of concern
•	GDNA Case # B-32213	Misfill Policy #1
•	GDNA Case # B-32167	Misfill Policy #1

Attorney General's Report - Janet Wray

Ms. Wray presented the following consent orders:

AlivaRy

Public Consent Order

•	AlıxaRx	Public Consent Order accepted
•	C.V.S.P.	Private Consent Order accepted
•	J.W.T.	Private Consent Order accepted contingent upon having a complete
		reinstatement application

Ms. Wray discussed the following cases:

•	A.H.P.	Rescind referral to the Department of Law and approve renewal of non-resident pharmacy
•	B.S.I.S.	Rescind referral to the Department of Law and proceed with investigation by GDNA
•	A.H.	Rescind referral to the Department of Law and approve renewal of non-resident pharmacy
•	G.M.B.	Proceed with interim suspension

Applications

•	Yemisrach Fekadu	Pharmacy Technician	Approved for registration
•	Dustin B. Shattuck	Pharmacy Technician	Approved for registration

•	Quadiyyah M. Winston Michell L. Abernathy Vonnetta R. Jackson Shatonya C. Kelley K.L.C.	Pharmacy Technician Pharmacy Technician Pharmacy Technician Pharmacy Technician Pharmacy Technician	Approved for registration Approved for registration Approved for registration Approved renewal Table renewal pending receipt of additional information
•	Courtney D. Ellis	Pharmacy Technician	Approved renewal
•	Jenipher T. Echevarria	Pharmacy Technician	Approved renewal
•	Jarred M. Sturm	Pharmacy Technician	Approved renewal
•	K.C.	Pharmacy Technician	Approved renewal with a letter stating the Board is not waiving its right to take disciplinary action should the final disposition of criminal case results in a conviction.
•	M.N.L.	Pharmacy Technician	Table renewal pending receipt of additional information
•	Riza Dianati	Pharmacist Intern	Approved application
•	Ernessa A. Samuel	Pharmacist Intern	Approved application
•	William A. Van Story	Pharmacist Intern	Approved application
•	Par Pharmaceuticals, Inc.	Wholesaler Pharmacy	Approved renewal
•	Par Sterile Products, LLC	Wholesaler Pharmacy	Approved renewal
•	F.P.H.I.	Wholesaler Pharmacy	Refer to the Department of Law
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	nexAir, LLC	Wholesaler Pharmacy	Approved renewal
•	N.A.	Wholesaler Pharmacy	Refer to the Department of Law
•	Promius Pharma, LLC	Wholesaler Pharmacy	Approved renewal

Executive Director's Report – Tanja Battle

• H.S. Denied Pharmacist Exam

The Board directed staff to respond to applicant by stating the Board reconsidered the request; however, as previously stated, the individual does not meet the minimum requirements for licensure at this time.

Correspondences/Requests

•	E.P.	Notice of Discipline	Refer to GDNA
•	L.P.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken

•	O.M.D.I.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken
•	O.M.D.I.	Notice of Discipline	No action taken
•	A.A.L.	Request to take MPJE a 6 th attempt	Approved request
•	R.A.S.	Appearance request	Approved request
•	M.S.P.	Request to terminate consent order	Approved request
•	C.J.B.	Request to lift PIC restriction	Approved request
•	K.L.H.	Request for reimbursement of late renewal fee	Approved request
•	J.D.H.	Remote Order Entry	Approved
•	J.R.H.	Request regarding supervision	Denied request
•	O.M.C.S.	Remote Order Entry	Table pending receipt of additional information

Miscellaneous

The Board discussed staffing matters. No action taken.

Mike Faulk seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 6:10 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, September 13, 2017 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