GEORGIA BOARD OF PHARMACY Board Meeting 2 Peachtree Street, NW, 36th Floor Atlanta, GA 30303 May 14, 2014 9:00 a.m.

The following Board members were present:

Al McConnell, Chairperson Laird Miller, Vice-Chairperson Jim Bracewell Mike Faulk Chris Jones Tony Moye Bill Prather Bob Warnock

Staff present:

Tanja Battle, Executive Director Rick Allen, GDNA Janet Wray, Senior Assistant Attorney General Brandi Howell, Business Operations Specialist

Visitors:

Patricia Yeatts, MAG Victor Johnson, Living Well Pharmacy Michelle Scurry, Living Well Pharmacy Regina Robins, CVS Gregory Lewis, Winn-Dixie Gary Millican, PPW Jim Bartling Chris Madigan **Pasquale Pietrefesa** Judy Gardner Hal Henderson Melvin Smith, CVS Nirmal Patel, Wal-Mart Jimmy England, Walgreens Scott Biddulph, Target Duane Richardson, Mercer Anthony Bragho, Walgreens Samantha Levine, Walgreens Brad Borum, Kaiser Stephanie Kozol, Holland & Knight Al Carter, Walgreens Michael Simko, Walgreens

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

Bill Prather made a motion and Chris Jones 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 Al McConnell, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Tony Moye, Bill Prather and Bob Warnock.

Executive Session

Appearances

• M.L.S.

- R.R.
- G.K.L.
- G.W.M.
- C.T.M.
- P.L.P.

Miscellaneous

Judy Gardner and Eric Lacefield discussed the upcoming examination in June.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Open Session

Approval of Minutes

Jim Bracewell made a motion to approve the Public Session minutes for the April 16, 2014 meeting. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Chris Jones made a motion to approve the Executive Session minutes for the April 16, 2014 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. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – Melissa E. Folsom

Laird Miller made a motion to deny the rule waiver petition. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – Roosevelt Warm Springs Rehabilitation and Specialty Hospitals, Inc.

Bob Warnock made a motion to grant a rule variance. Tony Moye seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Sergeant's PetCare Products, Inc.

Tony Moye made a motion to grant the rule waiver petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Walgreens

Jim Bracewell made a motion to grant the rule waiver petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen reported that Tramadol is now a schedule IV.

Correspondence from Stacie K. Neroni

The Board considered this correspondence from Ms. Neroni regarding a veterinarian who would like to compound and dispense medications to his/her patients. The Board directed staff to refer Ms. Neroni back to O.C.G.A. § 26-4-130 and state that the practitioner dispensing law and rules must be followed.

Correspondence from Bryan D. Huffman, Office of the Minnesota Attorney General

The Board considered this correspondence from Mr. Huffman regarding automated drug distribution systems. The Board directed staff to refer Mr. Huffman to the appropriate code section regarding this matter.

<u>Attorney General's Report – Janet Wray</u>

No report.

Executive Director's Report – Tanja Battle

No report.

Miscellaneous

<u>Rule 480-3-.03 Continuing Pharmacy Education:</u> Jim Bracewell made a motion to post Rule 480-3-.03 Continuing Pharmacy Education. Chris Jones seconded and the Board voted unanimously in favor of the motion.

480-3-.03 Continuing Pharmacy Education.

(1) The Georgia State Board of Pharmacy has the statutory responsibility and authority for the requirement of continuing education as prerequisite for a license renewal.

(2) The purpose of continuing education for pharmacists is to maintain and enhance the professional competency of pharmacists licensed to practice in Georgia for the protection of the health, safety and welfare of the people of the State of Georgia.

(3) As a requirement for the biennial renewal of his/her license, a pharmacist must complete not less than thirty (30) hours of approved continuing education.

(4) One hour of C.E. is defined as 0.1 C.E.U. Each pharmacist in the State of Georgia must obtain 30 hours of continuing education or 3.0 C.E.U.'s per biennium for license renewal.

(a) Certificates documenting that 30 hours of approved continuing education or 3.0 C.E.U.'s must be completed and dated within the biennium.

(5) A pharmacist licensed before or during the first six (6) months of the biennium (January to June), shall be required to obtain 30 hours of C.E. A pharmacist licensed during the following twelve (12) months (June to July) shall be required to obtain 15 hours of C.E. A pharmacist licensed during the last six (6) months of the biennium shall be exempt from continuing education for that biennium only.

(6) In the event of an audit and a pharmacist fails to submit certificates, which document his/her required continuing education credits, the Board will not process his/her request to renew the license until the continuing education requirements are provided to the Board.

(a) The pharmacist may not carry over continuing education credits from one licensing period to the next.

(b) Nothing is meant to prohibit representatives from the Georgia Drugs and Narcotics

Agency (GDNA) from assisting, auditing, or verifying a pharmacist's continuing education certificates as needed.

(c) Each licensed pharmacist shall maintain these certificates of attendance at continuing education meetings for a period of two (2) years from the date of the preceding renewal period.

(7) The staff of the Professional Licensing Boards <u>Georgia Board of Pharmacy</u> may audit, or otherwise select randomly, the continuing education of a percentage of licensees as determined by the Board.

(8) The Board shall accept all continuing education approved by other Boards of

Pharmacy provided those Boards reciprocate this courtesy with Georgia.

(9) Approval of providers and sponsors shall be as follows:

(a) All providers and sponsors of continuing education must be approved by the Board.

(b) American Council on Pharmaceutical Education (A.C.P.E.) approved providers shall submit documentation to the Board of such approval every two (2) years and have blanket approval.

(c) All other providers shall request approval of programs as a provider on the program approval form each time a program is presented. Nothing in these rules are meant to prohibit the Board and/or GDNA from establishing a program or programs which can be granted special program approval(s) by the Board, and which may be utilized on more than one occasion or whenever such program or programs are presented by the Board or GDNA during a biennium.

(10) The following criteria for quality shall be used for the approval of providers:

(a) There shall be an administrative authority charged with the responsibility of maintaining the criteria for quality in continuing education programming for each provider.

(b) The administration shall be stable and an established procedure shall exist that insures an orderly transfer of responsibilities in the event there is a change in administration.

(c) Providers shall present a program or activity based on the needs of the target audience or the timeliness of the topic.

(d) Program objectives and rationale shall be stated.

(e) Providers shall give adequate, advanced promotional information, material about target audience, goals and objectives, program content, faculty credentials and fees.

(f) Each approved provider of continuing education in the State of Georgia shall provide

a means of registration of the participants at each program and a record of attendance shall be maintained for a period of five (5) years. The provider shall also furnish to each participant, adequate documentation of his successful completion of the program.

(g) There shall be a method of program evaluation established and a statement of the evaluation process planned shall accompany each application. (The Board may supply sample forms.)

(11) Providers shall furnish each participant with adequate documentation of this or her participation in the program. Information shall include:

(a) Name and license number in each state of participant;

(b) Name of provider;

(c) Name of program;

(d) Hours/C.E.U. completed;

(e) Date of completion;

(f) Authorized signature.

(12) The provider shall develop policies and procedures for the management of grievances. (This does not have to be submitted to the Board.)

(13) The facility shall be appropriate and adequately equipped to support the delivery of the program.

(14) Approval of programs shall be as follows:

(a) Acceptable forms of continuing education shall be as follows:

1. Institutes, seminars;

2. Lectures, conferences, workshops;

3. Correspondence and electronically delivered courses that are A.C.P.E. approved.

(b) The following are not acceptable as continuing educations programs: welcoming remarks, business sessions, unstructured demonstrations, degree programs, or medical continuing education programs which are not A.C.P.E. or Georgia Board approved.

(15) All continuing education providers seeking approval of the continuing education program by the Georgia Board shall submit a program approval form for each program presented. These forms should be submitted sixty (60) days in advance. The Board may exempt programs from this advance time requirement period as set forth by Board policy.

A motion was made by Laird Miller, seconded by Jim Bracewell, and the Board voted that the formulation and adoption of this amendment does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board 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§ 50-13-9 16

4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this rule will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

The Board briefly discussed Rule 480-48-.01 Definitions, Rule 480-48-.02 Conditions for Use of Delivery by Mail, and Rule 480-6-.02 Nonresident Pharmacy Permit. The Board stated that it would hold a conference call prior to the Board meeting in Athens on June 17th to vote to post these rules. This will allow for the scheduling of a public hearing at the July meeting during which comments may be received.

<u>Rule 480-27-.02 Prescription Drug Order Requirements:</u> Discussion was held regarding this rule. Mr. Allen stated that the way the rule is written all electronically generated drug orders presented to a patient by a practitioner, regardless of whether or not the patient is a CMS patient, must be printed on security paper, and must contain either an electronically reproduced visual image signature of the practitioner with the wording that indicates the signature was electronically generated or the original signature of the practitioner.

Mr. Moye stated that he would like to address the issue of rescheduling Zohydro from a schedule II to a schedule I as other states are doing. Mr. Miller made a motion to send a letter to the Georgia Board of Dentistry and the Georgia Composite Medical Board requesting their support in rescheduling Zohydro.

<u>Tamper Resistant Paper for Computer Generated Prescriptions</u>: The Board discussed correspondence received from Keith Chambers. The Board directed staff to respond to Mr. Chambers by referring him to Rule 480-27-.02 for more information.

<u>Pharmacist In Charge Inquiry:</u> Ms. Battle stated that she received an inquiry about a PIC that is in the National Guard and has to be away temporarily for 13 days. Because there is nothing that addresses time parameters for a PIC being away, the question is regarding whether or not notice or a change in the PIC is necessary. The Board responded that it would not require such.

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 Al McConnell, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Tony Moye, Bill Prather and Bob Warnock.

Executive Session

Attorney General's Report - Janet Wray

Ms. Wray presented the following consent orders for acceptance:

- P.G.
- D.H. and H.B.P.
- A.W.I.
- M.C.B.
- D.W.W.
- R.E.J.

Ms. Wray presented the following Inactive Status application for consideration:

• G.L.

Ms. Wray discussed the following cases:

- L.P.
- P.B.

Georgia Drugs and Narcotics Agency – Rick Allen

Discussed draft rule of 480-27-.01 regarding printed and electronic daily drug orders.

Mr. Allen discussed a document on sterile compounding.

<u>Cognizant's Report – Laird Miller</u>

- GDNA Case #T-31105
- GDNA Case #T-31104
- GDNA Case #B-31090
- GDNA Case #T-31086
- GDNA Case #A14-13
- GDNA Case #B-31084
- GDNA Case #A-30920
- GDNA Case #B-31082
- GDNA Case #B-31083
- GDNA Case#-A31039
- GDNA Case #B-30937
- GDNA Case #B-31060
- GDNA Case #A-31095
- GDNA Case #A-31007
- GDNA Case #A-31055
- GDNA Case #A-31056
- GDNA Case #A-30510-98

Applications

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

Correspondences/Requests

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

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Open Session

Chris Jones made a motion to approve all recommendations based on deliberations in Executive Session as follows:

Appearances

- M.L.S. No action
- R.R. Overturn denial and approve with private consent order
- G.K.L. Overturn denial and approve registration
- G.W.M. Approve pending receipt of additional information
- C.T.M. Table pending receipt of additional information
- P.L.P. Approve pending receipt of additional information

Miscellaneous

Judy Gardner and Eric Lacefield discussed the upcoming examination in June. No action taken.

<u> Attorney General's Report – Janet Wray</u>

Ms. Wray presented the following consent orders for acceptance:

- Peter Gyimah Public Consent Order accepted
- D.H. and H.B.P. Private Consent Order accepted
- A.W.I. Private Consent Order accepted
- M.C.B. Private Consent Order accepted
- D.W.W. Private Consent Order accepted
- Robert E. Jennings Public Consent Order accepted

Ms. Wray presented the following Inactive Status application for consideration:

• G.L. Application accepted

Ms. Wray discussed the following cases:

- L.P. Close case with no action
- P.B. Close case with no action

Georgia Drugs and Narcotics Agency - Rick Allen

Discussed draft rule of 480-27-.01 regarding printed and electronic daily drug orders. No action taken.

Mr. Allen discussed a document on sterile compounding. Mr. Allen indicated that they are following USP 797. He further indicated that sterile mixing is the same thing as sterile compounding.

Cognizant's Report – Laird Miller

- GDNA Case #T-31105 Accept Voluntary Surrender
- GDNA Case #T-31104 Revoke technician registration
- GDNA Case #B-31090 Revoke technician registration
- GDNA Case #T-31086 Accept Voluntary Surrender
- GDNA Case #A14-13 Accept Private Interim Consent Order
- GDNA Case #B-31084 Refer to the Attorney General's office for discipline
- GDNA Case #A-30920 Refer to the Attorney General's office for discipline
- GDNA Case #B-31082 Close with no action
- GDNA Case #B-31083 Close with no action
- GDNA Case#-A31039 Refer to the Attorney General's office for discipline
- GDNA Case #B-30937 Close with no action
- GDNA Case #B-31060 Close with no action
- GDNA Case #A-31095 Refer to the Attorney General's office for discipline
- GDNA Case #A-31007 Table pending receipt of additional information
- GDNA Case #A-31055 Refer to the Attorney General's office for discipline
- GDNA Case #A-31056 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-98 Refer to the Attorney General's office for discipline

Applications

•	K.T.R.	Pharmacy Technician	Denial overturned and approved registration
•	Kathryn A. Wheeler	Pharmacy Technician	Approved registration
•	R.R.M.	Pharmacy Technician	Denied registration
•	I.S.B.	Pharmacy Technician	Denied registration
•	P.L.H.	Pharmacy Technician	Denied registration
•	S.T.S.	Pharmacy Technician	Table pending receipt of additional
			information
•	C.A.P.	Pharmacy Technician	Denied registration
•	A.C.S.	Pharmacy Technician	Denied registration
٠	Kimberly L. Scott	Pharmacy Technician	Approved registration
•	C.A.G.	Pharmacist	Approved
•	G.A.Z.	Pharmacist	Table pending receipt of additional
			information
•	N.A.P.	Pharmacist Reciprocity	Approved
•	J.A.M.	Pharmacist Intern	Hours denied
•	S.E.C.	Pharmacist Intern	Hours approved
•	T.J.B.	Pharmacist Intern	Hours approved
•	E.W.	Wholesaler Pharmacy	Approved application
•	E.R.	Wholesaler Pharmacy	Approved application

•	C.P.L. S.K.S.	Wholesaler Pharmacy Researcher Pharmacy	Refer to the Attorney General's office for discipline Table pending receipt of additional information		
Correspondences/Requests					
•	J.F.C.	Appearance request	Approved request		
•	T.E.L.	Correspondence	Denied request		
•	P.M.B.	Appearance request	Approved request		
•	A.H.S.	Remote Order Entry	Approved		
•	B.M.C.	Request for fee waiver	Denied request		
•	M.B.G.	Request to lift PIC restriction	Denied request		
•	A.N.S.	Requesting breakdown of	Approved request		
		NAPLEX scores			
•	U.P.S.S.C.S.	Notice of discipline	For informational purposes only		
•	D.E.G.	Extension request	Request approved		
•	C.C.	Notice of discipline	No action taken		

N.S.P. Correspondence For informational purposes only
J.W. Correspondence Send response to individual stating he/she must petition the Board
A.S. Extension request Requested approved

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Bill Prather seconded and the Board voted in favor of the motion, with the exception of Mike Faulk, who recused himself from the vote regarding G.K.L.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, June 17, 2014, at 9:00 a.m. at the University of Georgia College of Pharmacy, South Pharmacy Building, 250 W. Green Street, Athens, GA 30602.

The Board meeting adjourned at 4:36 p.m.

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