

**GEORGIA STATE BOARD OF PHARMACY**

**BOARD MEETING**

December 14, 2011

Professional Licensing Boards

237 Coliseum Drive

Macon, GA 31217

**Members Present:**

Bill Prather, Chairperson

Judy Gardner, Vice Chairperson

Pat McPherson

Fred Barber

Ronnie Wallace

Tony Moye

Al McConnell

Laird Miller

**Staff Present:**

Eric Lacefield, Executive Director

Wylencia Monroe, Board Attorney

Rick Allen, GDNA

Melanie Bradley, Board Support Specialist

**Visitors:**

Jim Bartling, Mercer

Scott Biddulph, Target

Andy Freeman, GPhA

Bill Prather established that a quorum was present and called the meeting to order at 9:56 a.m.

The new board member, E. Laird Miller, was sworn in by Professional Licensing Board Director, Lisa Durden.

*Judy Gardner made a motion, Tony Moye seconded, and the Board voted unanimously to enter into **EXECUTIVE SESSION** in accordance with O.C.G.A. §§43-1-19(h) 2 and 43-1-2(k) to review applications, deliberate on disciplinary matters, and to receive information on investigative reports. Voting in favor of the motion were those present who included Board members Pat McPherson, Fred Barber, Al McConnell, Laird Miller and Ronnie Wallace.*

**Appointments – Executive Session**

1. Duane K. Black appeared before the Board to appeal the denial of his Pharmacy Technician registration application. A motion was made by Judy Gardner to uphold the Board's previous decision to deny; Ronnie Wallace seconded the motion and the Board voted unanimously in favor of the motion.

2. B.L.F. and his advocate appeared before the Board to discuss his pharmacy intern application. A motion was made by Tony Moye to issue under a Public Consent Order; Judy Gardner seconded the motion and Lair Miller, Al McConnell, and Pat McPherson voted in favor of the motion. Fred Barber and Ronnie Wallace opposed the motion. Motion passes.
3. I.E.D. appeared before the Board to discuss his pharmacy intern application. Fred Barber made a motion to issue under a Private Consent Order with stipulations. Pat McPherson seconded the motion and the Board voted unanimously in favor of the motion.
4. C.L.J and her advocate appeared before the Board to discuss the reinstatement of her pharmacy license. Tony Moye made a motion to issue under a Private Consent Order with stipulations. Fred Barber seconded and the Board voted unanimously in favor of the motion.
5. M. Shane Miller appeared before the Board to appeal the denial of his pharmacist reciprocity application. Fred Barber made a motion to reverse the Board's previous decision and to approve the reciprocity application. Ronnie Wallace seconded the motion and Laird Miller and Pat McPherson voted in favor of the motion. Judy Gardner, Al McConnell, and Tony Moye opposed the motion. Motion passes.
6. Austin P. Conner appeared before the Board to appeal the denial of his pharmacy reinstatement application. Judy Gardner made a motion to uphold the Board's previous decision to deny; Al McConnell seconded the motion and the Board voted unanimously in favor of the motion.

#### **Applications/Licensures**

1. A.J.B. – Pharmacy Technician - Board recommended to deny registration and reapply once probation is terminated.
2. A.L.D. – Pharmacy Technician - Board recommended approval for registration.
3. C.L.J. – Pharmacy Technician - Board recommended approval for registration.
4. C.L.H. – Pharmacy Technician - Board recommended approval for registration.
5. D.M.G. – Pharmacy Technician - Board recommended approval for registration.
6. D.R.M. – Pharmacy Technician - Board recommended to deny registration.
7. D.R.L. – Pharmacy Technician - Board recommended approval for registration.
8. I.M. – Pharmacy Technician - Board recommended to deny registration.
9. K.N.S. – Pharmacy Technician - Board recommended approval for registration.
10. K.D.J. – Pharmacy Technician - Board recommended to deny registration and reapply once probation is terminated.
11. L.H.K. – Pharmacy Technician - Board recommended approval for registration.
12. L.C. – Pharmacy Technician - Board recommended approval for registration.
13. L.E.H. – Pharmacy Technician - Board recommended to deny registration and reapply once probation is terminated.
14. M.R. – Pharmacy Technician - Board recommended approval for registration.
15. M.D. – Pharmacy Technician - Board recommended to deny registration.

16. N.M.H. – Pharmacy Technician - Board recommended approval for registration.
17. P.L.H. – Pharmacy Technician - Board recommended approval for registration.
18. S.A.H. – Pharmacy Technician - Board recommended approval for registration.
19. S.B.T. – Pharmacy Technician - Board recommended approval for registration.
20. B.C.V. – Board recommended approval her application for pharmacy intern license.
21. D.J.P. – Board recommended to deny his pharmacist application.
22. J.R.M. – Board recommended approval her pharmacist application.
23. J.L.M. – Board recommended approval her pharmacist reinstatement application under Public Consent Order and \$12,000 fine.
24. K.R.M. – Board recommended she submit a copy of the protocol for the Drug Therapy Modification and have the supervision physician sign off on protocol.
25. L.S.L.LLC – Board recommended approval the pharmacy wholesale reinstatement application under Consent Order and \$30,000 fine.
26. T.P.O.S. – Board recommended the opioid treatment clinic provide official documentation on the sale of the business and change of ownership.
27. D.C. – Board viewed the response to the letter of concern as informational.
28. Y.A.K. – Board requested staff send letter requesting she submit letter from current supervisor as required within 3 business days or Board will confirm denial.
29. M.I. – Board viewed the disciplinary reporting as informational.
30. C.E.H. – Board recommended approval his pharmacist application.
31. S.P.I. – Board viewed the disciplinary reporting as informational.

**Attorney General’s Report:**

Wylencia Monroe presented the attorney general’s status report. The following consent orders were presented for acceptance:

- J.H. - Pharmacist – Private Interim Consent Order
- L.M.D. - Private Interim Consent Order
- D.W.W. - Pharmacist- Private Interim Consent Order for Assessment
- C.A.H.J. – Pharmacist - Private Consent Order for Reinstatement
- Severin Ritter – Pharmacist- Public Consent Order for Reinstatement

**Cognizant Report – Judy Gardner, Presiding Officer**

**GDNA Case #T11-37** – The Cognizant Member recommended to accept the signed interim consent order.

**GDNA Case #A11-47** - The Cognizant Member recommended to accept the signed interim consent order.

**GDNA Case #A11-51** – The Cognizant Member recommended an order of mental physical evaluation.

**GDNA Case #A11-52** – The Cognizant Member recommended to accept the signed interim consent order.

**GDNA Case #A-39973** – The Cognizant Member recommended a \$5,000 fine and 5 years probation for the opioid treatment clinic pharmacy.

**GDNA Case #A-30077** – The Cognizant Member recommended a \$60,000 fine and 5 years probation to the wholesaler pharmacy.

**GDNA Case #A-29966** – The Cognizant Member recommended a \$60,000 fine and 5 years probation to the wholesaler pharmacy.

**GDNA Case #A-29987** – The Cognizant Member recommended to issue a letter of concern to the registered technician regarding practicing outside the scope of technician practice; pharmacist must attend misfill school, pharmacist must submit written plan for correcting the problem, and \$500 fine.

**GDNA Case #A-30063** – The Cognizant Member recommended to schedule an investigative interview for all five pharmacists involved.

**GDNA Case #A-20134** – The Cognizant Member recommended to schedule an investigative interview.

**GDNA Case #A-29627** – The Cognizant Member recommended to issue a letter of concern to the pharmacist regarding a registered technician practicing outside the scope of technician practice and issue a letter of concern to the registered technician regarding practicing outside the scope of technician practice.

At the conclusion of **EXECUTIVE SESSION**, Tony Moye made a motion to enter into **Open Session** to vote on the matters discussed in Executive Session and to conduct other Board business; Al McConnell seconded the motion. Voting in favor of the motion were Judy Gardner, Pat McPherson, Fred Barber, Laird Miller and Ronnie Wallace.

#### **OPEN SESSION**

Tony Moye made a motion to approve the recommendations made in Executive Session; Judy Gardner seconded the motion. Voting in favor of the motion were Al McConnell, Pat McPherson, Fred Barber, Laird Miller and Ronnie Wallace.

The Board voted to accept the following signed Board orders:

- J.H. - Pharmacist – Private Interim Consent Order
- L.M.D. - Private Interim Consent Order
- D.W.W. - Pharmacist- Private Interim Consent Order for Assessment
- C.A.H.J. – Pharmacist - Private Consent Order for Reinstatement
- Severin Ritter – Pharmacist- Public Consent Order for Reinstatement

Tony Moye made a motion to approve the minutes as amended from the November 9, 2011 Board meeting; Judy Gardner seconded the motion and the Board voted to approve the minutes.

Executive Director Eric Lacefield presented a list of licenses and registrations (512) that were issued from November 1-30, 2011. Judy Gardner made a motion to ratify the list of licenses and registrations; Ronnie Wallace seconded the motion. The Board voted to ratify the licenses and registrations issued.

Executive Director Eric Lacefield presented a list of security prescription paper providers; including one software system company. Judy Gardner made a motion to ratify the list of security prescription providers and to post list; Fred Barber seconded the motion. The Board voted to ratify the list of security prescription providers and to post list.

Ronnie Wallace made a motion to amend the Board Memo Regarding Security Paper; Judy Gardner seconded and the Board voted unanimously to amend the Board Memo Regarding Security Paper and to post as follows:

**Georgia State Board of Pharmacy**

**Policy on Approval of Security Paper for Prescription Pads or Paper**

NOTE: Struck through text will be deleted. Underlined text will be added.

All vendors, which produce security paper used in the printing or creation of pads of prescriptions to be used in this state, and which security paper contains all of the following criteria will be deemed to be an approved vendor by the Georgia State Board of Pharmacy:

- (1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- (2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription form by the practitioner; and
- (3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

By meeting all of the criteria identified above, a vendor may market and sell security paper for use in the production of prescriptions and prescription pads in this state provided the vendor notifies the Board in writing and provides the Board a copy of the product. If the Board determines that the paper submitted does not meet the requirements listed above, the Board will notify the vendor in writing. The Board will maintain a list of approved vendors.

All approved security paper shall have the Board's seal of approval affixed to the paper. The Board's seal of approval, as shown below, will be ½ inch in diameter, with the text in the seal being Georgia font, with the Rx within the circle being a size of 9 pt, with the text "GEORGIA STATE BOARD OF PHARMACY" within the circle capitalized with a size of 4 pt, and the text "SEAL OF APPROVAL" underneath the Rx with a size of 3 pt and capitalized.

The seal as shown below is the official seal:



Where security paper is in the form of a prescription pad, each pad shall bear an identifying lot number, and each piece of paper in the pad shall be numbered sequentially beginning with the number one.

The security paper requirements shall not apply to:

- (1) Prescriptions that are transmitted to the pharmacy by telephone, facsimile, or electronic means; or
- (2) Prescriptions written for inpatients of a hospital, outpatients of a hospital, residents of a nursing home, inpatients or residents of a mental health facility, or individuals incarcerated in a local, state, or federal correctional facility when the health care practitioner authorized to write prescriptions writes the order

into the patient's medical or clinical record, the order is given directly to the pharmacy, and the patient never has the opportunity to handle the written order. In the event a prescription pad containing the Board seal, sequential numbering, and lot number is not available for the prescription or prescription paper containing the Board seal is not available for the prescription, and a medical health emergency exists, a prescription may be issued on paper meeting the requirements for approval for an amount of medication to cover not more than 30 days. The prescription must contain a statement that an emergency exists. All providers must have the board-approved security paper by ~~December 31, 2011~~ March 31, 2012. This exception for emergencies only applies to prescriptions written before ~~December 31, 2011~~ March 31, 2012.

Kimberly S. Hill submitted a waiver request of the requirement that a Pharmacy Technician must have a high school diploma or GED. Ronnie Wallace made a motion to grant the waiver requests, Pat McPherson seconded the motion and the Board voted to grant the waiver request because the applicant was working as a technician at the time that the law and rules were enacted.

Christopher Heard, Lisa Hodnett, and Wallace H. Lowder submitted letters requesting an appearance before the Board. Tony Moyer made a motion to grant the waiver requests for an appearance; Ronnie Wallace seconded the motion, and the Board voted to grant the requests for an appearance.

Jeff Dalton submitted a letter requesting an appearance before the Board. Ronnie Wallace made a motion to deny the request for an appearance; Al McConnell seconded the motion, and the Board voted to deny the request for an appearance.

Kristie E. Piasta sent an inquiry to the Board regarding allergy testing and treatment in Georgia. The Board advised that a fully licensed physician may provide antigens to a patient for self-administration at home; also antigen preparation is defined in Rule 480-28-.08 and that a medical assistant may assist in antigen preparation.

Pamela Surrent sent an inquiry regarding SB36 and proper and acceptable forms of identification. The Board advised that staff send a letter stating the requirements of the law which require government identification.

Partners Rx Management requested information on the practice of pharmacy as it relates to a pharmacist providing formulary, drug information, patient consultations, or drug history review. The Board advised that a Georgia licensed pharmacist must be the one to give on site consultations at an employee health fair regarding a formulary or drug benefit, field questions on medications, provide medication counseling, or a drug history review. The Board advised that there is no such "locum tenens" status or exception to being a licensed pharmacist in Georgia.

James L. Wilson requested the Board lift the pharmacist in charge restriction from his public consent order. Fred Barber made a motion to approve the request; Judy Gardner seconded the motion, and the Board voted to approve the request to lift the pharmacist in charge restriction from his public consent order.

The Board received an open records request from the Texas Board of Pharmacy. Judy Gardner made a motion to approve the open records request; Pat McPherson seconded the motion, and the Board voted to approve the open records request.

### **Miscellaneous**

The Board instructed staff to schedule no more than three pharmacists and three pharmacy technicians appearances per meeting.

Judy Gardner made a motion to post Rule 480.37; Pat McPherson seconded and the Board voted unanimously to post Rule 480.37:

### **Georgia State Board of Pharmacy Rule 480-37**

#### **480-37-.01 Definitions**

#### **480-37.02 Licensure**

#### **480-37-.03 General Requirements**

#### **480-37-.04 Inspections**

#### **480-37-.01 Definitions**

For purposes of this Chapter, the following words shall mean:

- (a) "Board" means the Georgia Board of Pharmacy
- (b) "GDNA" means the Georgia Drugs and Narcotics Agency.
- (c) "Remote automated medication system" or "RAMS" means an automated mechanical system in which medication is stored and retrieved for a specific patient pursuant to a practitioner's prescription medication order.

Authority: O.C.G.A. Sections 26-4-5 and 26-4-28.

#### **480-37.02 Licensure**

- (a) In order to install or operate a RAMS, a Georgia licensed pharmacy must make application for licensure to the Board on a form approved by the Board, and pay a fee. No person other than an approved licensed pharmacy may install or operate a RAMS. Each location having a RAMS must have a separate license from the Board. If more than one licensed pharmacy operates a RAMS at the same skilled nursing facility or hospice, each licensed pharmacy must maintain a registration at the skilled nursing facility or hospice. A Georgia licensed pharmacy that has paid a fee for one RAMS location will not be required to pay fees for the additional locations.
- (b) A Georgia licensed pharmacy may only use the RAMS at a skilled nursing facility or hospice licensed as such pursuant to O.C.G.A. T. 31, Ch. 7, that does not have an on-site licensed pharmacy.
- (c) The Pharmacist-in-Charge (PIC) for a licensed pharmacy shall be considered the PIC for each separate license to operate a RAMS at a skilled nursing facility or hospice.

(d) The RAMS must collect, control, and maintain all transaction information.

Authority: O.C.G.A. Sections 26-4-5, 26-4-28 and 26-4-110.

### **480-37.03 Minimum Requirements**

Minimum Requirements. A pharmacy may use a RAMS provided that:

- (a) The pharmacy has a policy and procedure manual at the skilled nursing facility or hospice that includes:
  - 1) The type or name of each RAMS including a serial number or other identifying nomenclature.
  - 2) A method to ensure security of a RAMS to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.
  - 3) A process of filling and stocking a RAMS with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.
  - 4) Documentation of inventory procedures including removal of any discontinued/out-dated medications.
  - 5) Compliance with a Continuous Quality Improvement Program.
  - 6) A method to ensure that patient confidentiality is maintained.
- (b) No more than a 30 day supply of each individual medication may be stocked in a RAMS at one time.
- (c) All drugs in a RAMS must inventoried no less than once every 30 days and documentation must be maintained of the inventories including the removal of any discontinued/out of date medications.
- (d) All the registered pharmacists, licensed pharmacy interns or registered pharmacy technicians involved in the process of stocking, entering information into RAMS, or inventorying the RAMS must be identified. No person shall be permitted to perform a function related to the machine that they are not authorized to do in the pharmacy. Specifically, where direct supervision is required in the pharmacy, such supervision must occur in duties related to the RAMS.
- (e) Patient confidentiality must be maintained.
- (f) The PIC, or a pharmacist designated by the PIC, must be able to revoke, add, or change access to RAMS at any time.
- (g) Only a Georgia registered nurses or a Georgia licensed practical nurse may be assigned access to and remove dangerous drugs from a RAMS.
- (h) Only a Georgia registered nurse may access and remove a controlled substances from a RAMS
- (i) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.
- (j) The system shall maintain a readily retrievable electronic record to identify all pharmacists,

pharmacy interns, or registered pharmacy technicians involved in the processing of the prescription order.

(k) A RAMS shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(l) The stocking or restocking of a dangerous drug or controlled substances shall only be completed by a Georgia pharmacist or a pharmacy intern/extern under the direct on-site supervision of a Georgia licensed pharmacist.

(m) A RAMS must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from a RAMS.

(o) All medication shall be packaged and labeled in compliance with Board rules and laws for patient specific labeled medication and/or unit of use medication.

(p) The licensed pharmacist responsible for filling, verifying, or loading the RAMS shall be responsible for their individual action.

(q) A prescription drug dispensed by the RAM pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

(r) A licensed pharmacist may remove discontinued and/or out-dated medications from the RAMS and return such medications to the licensed pharmacy for proper disposition. A registered or licensed practical nurse may remove discontinued and/or out-dated medications and place them in the designated secured return bin in a RAMS.

Authority: O.C.G.A. Sections 26-4-5, 26-4-28, 26-4-80, 26-4-82 and 26-4-110.

#### **480-37.03 Dispensing of Drugs.**

Drugs shall only be dispensed by the RAMS pursuant to prescription drug orders of practitioners authorized under the laws of this state to prescribe drugs.

Authority: O.C.G.A. Sections 16-13-41, 16-13-74, 26-4-5, and 26-4-28.

#### **480-37-.04 Inspections**

(1) The Pharmacist in Charge, personally or by licensed pharmacist designee, shall inspect all RAMS within his/her jurisdiction and responsibility and make appropriate written records of such inspections.

Such inspections, at a minimum, shall verify that:

a) All drugs in a RAMS must inventoried no less than once every 30 days. All controlled substances drugs in a RAMS must inventoried no less than once every 7 days. A system of accountability must exist for all drugs contained in a RAMS.

- (b) Drugs requiring special storage conditions are properly stored to insure their stability;
  - (c) No outdated drugs are stocked in a RAMS;
  - (d) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;
  - (e) Only medications may be stored in a RAMS and all medications stored in the RAMS must be on the RAMS inventory list.
  - (f) All necessary and required security and storage standards are met;
  - (g) A licensed pharmacist will empty the return bin at least every 30 days. Discontinued/out-dated return transactions shall be documented by the RAMS.
- (2) Board of Pharmacy shall be conducted by representatives of the GDNA. Such inspections shall include all aspects of the management and operation of all RAMS in this State to verify compliance with the Pharmacy Laws, the Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety, and welfare of patients of the skilled nursing facility and/or hospice are protected. A written report shall be filed with the GDNA, the licensed pharmacy, and skilled nursing facility or hospice. Any discrepancies or deficiencies noted shall be corrected and written notice filed with GDNA within 30 days after receipt of the inspection notice.

Authority: O.C.G.A. Sections 26-4-5, 26-4-28 and 26-4-29.

No more business was discussed and the meeting adjourned at 3:52 p.m.

The next Pharmacy Board meeting will be Wednesday, January 11, 2012 at 10:00 a.m. at the Office of the Professional Licensing Boards, 237 Coliseum Drive, Macon, Georgia 31217.

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 Bill Prather, President  
 The Georgia State Board of Pharmacy

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 Date

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 Eric Lacefield, Executive Director  
 The Georgia State Board of Pharmacy

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 Date