

GEORGIA STATE BOARD OF PHARMACY

BOARD MEETING

April 11, 2012

Professional Licensing Boards

237 Coliseum Drive

Macon, GA 31217

Members Present:

Bill Prather, Chairperson
Judy Gardner, Vice Chairperson
Fred Barber
Ronnie Wallace
Tony Moye
Laird Miller

Members Not Present:

Al McConnell
Pat McPherson

Staff Present:

Eric Lacefield, Executive Director
Janet B. Wray, Board Attorney
Rick Allen, GDNA
Carol White, Board Support Specialist

Visitors:

Scott Biddulph, Target
Trey Freeman, Kroger
Jimmy England, Walgreens
Olufowoke Bgadebo
Pete Maurets
Helen Sloat, Kaiser
Cletus Foma, Prx Pharmacy
Sarah Ralston, GHCA
David Graves, Graves Pharmacy
Jim Bartling
Blake Brookerd
John Herbert

Jimmy Taylor
D. Ray Goskin, Jr, J.D.
Joe Morgan, MD
Moehah D'Morai
Hal Henderson, Omnicare
Brad Borum, Kaiser
Jason Broce, GHCA
Jim Bracewell, GH Pharmacy Association
Mike King, Publix
Lonnie Brown

Bill Prather established that a quorum was present and called the meeting to order at 10:11 a.m.

*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 Fred Barber, Laird Miller, and Ronnie Wallace.

Appointments – Executive Session

1. J.T. and his advocate appeared before the Board to discuss the reinstatement of his Pharmacist license. Tony Moyer made a motion to approve license. Fred Barber seconded the motion and the Board voted unanimously in favor of the motion. The Board asked J.T. to speak with the students at South University and South University needs to notify the board once J.T. has addressed the students.
2. M.B. and his advocated appeared before the Board to discuss reinstatement of his Pharmacist license. Laird Miller made a motion approve with restrictions. Ronnie Wallace seconded the motion and the board motion failed. The Board states M.B. could request an appointment with the board in six months and advised M.B. to carefully following the conditions of his consent order
3. L.D.B. appeared before the Board to discuss reinstatement. Laird Miller made a motion to approve reinstatement of license. Judy Gardner seconded the motion and motion carried
4. Moenah D’Morai appeared before the board to discuss appealing denial of Pharmacy Technician Registration Application. Fred Barber made a motion to deny and uphold their previous decision. Tony Moyer seconded the motion and the motion carried.
5. P.J.M **and** his advocate appeared before the board to discuss reinstatement . The Board recommended for you to review the requirements in the Board’s policies for reinstatement and begin working towards meeting the requirements listed. The Board would reconsider your request again after six months.
6. Cletus A. Forma and his Attorney , John Hurbert , appeared before the Board to discuss the application for licensure. Fred Barber made a motion to deny. Ronnie Wallace seconded the motion and it carried unanimously.

Applications/Licensures

1. C.A.R. – Pharmacy Technician - Board recommended approval for registration.
2. D.D.M. – Pharmacy Technician- Board recommended approval for registration.
3. K.F.S. – Pharmacy Technician – Board recommended denial of registration and reapply once probation is terminated.
4. L.A.A.-Pharmacy Technician – Board recommended approval for registration.
5. T.L.R. – Pharmacy Technician – Board recommended denial of registration and reapply once probation is terminated.
6. S.A.M. – Pharmacy Technician-LOE and Court Docs – Board recommended approval for registration.
7. E.A.H. – Pharmacy Intern- request to accept hours – Board recommended approval to accept hours.
8. X.I. – Pharmacy Intern – Board recommended approval.
9. P.B. – Pharmacy Intern Test request- The Board recommended applicant request a Board Waiver for Board Rule 480-2-.04.

10. N.D.T.– Pharmacy Intern Hours request – Board recommended approval of Pharmacy Intern Hours request.
12. J.C.E.– Pharmacist Reciprocity and Discp docs – Board recommended to allow reciprocity.
13. F.M.E. – Pharmacist Reciprocity – Board recommended denying Pharmacy application.
- 14.- C.H.M. – Pharmacist, Request to Lift Supervised Practice-Board recommended to approve the lifting of supervised practice from the consent order.
15. M.L.O. – Pharmacist, MPJE update-The Board recommended referring to the Attorney General's office to reinstatement under Policy 3A.
- 16.C.N.D. – Pharmacist, Request to amend Private Consent Order-Board recommended sending to the Attorney General's office to amend his Public Consent Order to reflect he first Offender treatment.
17. J.B.K.– Pharmacist OMPE Results-Board recommended issuing license.
18. Xttrium Laboratories Inc. – PHWH & PHMA Consent Order from Rhode Island- Pharmacy self-reporting, Board considered information only, no Board action required.
19. LifeScience Logistics LLC- PHWH Reinstatement – Board recommended to issue.
20. B.M. – Pharmacy Intern- Board recommended approval for registration.
21. The Medicine Shop – Response to LOC- Board considered information only, no Board action required.
- 22.Carmichael Drugs – Response to LOC- Board considered information only, no Board action required.
23. G.R.J. – Pharmacist request of hours re Private Consent Order-Board recommended approval of applicant's request as long as in one calendar week, from Sunday – Saturday, Applicant does not work more than 40 hours.
24. A.H. – Pharmacist, Request for an appearance. Board recommended to approve scheduling for next available appointment.
25. S.P. – Request to amend Public Consent Order to a Private Consent Order –The Board approved change from a Public Consent order to a Private Consent Order.

Attorney General's Report:

Janet Wray presented a status report including 37 open cases and 6 closed cases. The following consent orders were presented for acceptance:

- Tiffany Allen – Registered Pharmacy Technician – Voluntary Surrender
- Judith Morales – Registered Pharmacy Technician – Voluntary Surrender
- F.H.B. – Pharmacist – Private Consent Order
- J.R.D. – Pharmacist Private Interim Consent Order
- J.B.M. – Private Consent Order

Cognizant Report – Judy Gardner

GDNA Case #A-30281– Board recommendation to issue Intern License.

GDNA Case #A-30130 - The Cognizant Member recommended accepting the signed Private Interim Consent Order.

GDNA Case #T 12-18 – The Cognizant Member recommended sending a Letter of Concern.

GDNA Case #A 12-19 - The Cognizant Member recommended an OMPE.

GDNA Case #T-30216 - The Cognizant Member recommended accepting the signed voluntary surrender order.

GDNA Case #T-30256 - The Cognizant Member recommended accepting the signed voluntary surrender order.

GDNA Case #A-30187– The Cognizant Member recommended a Public Reprimand with a \$50,000.00 for the Pharmacy. The Cognizant member recommended the Pharmacist in Charge receive a Public Consent Order with 2 years of probation. The Cognizant Member recommended a strong Letter of Concern to each Pharmacist.

GDNA Case#A-30203 - The Cognizant Member recommended a public Reprimand with a \$50,000.00 fine . The Cognizant member recommended the Pharmacist in Charge receive a Public Consent Order with 2 years of probation. The Cognizant member recommended a strong Letter of Concern to each Pharmacist.

GDNA Case #-30204 – The Cognizant Member recommended scheduling an Investigative Interview.

GDNA Case #B-30274 – The Cognizant Member recommended a Private Consent Order with a \$2000.00 fine for the Pharmacist in Charge.

GDNA Case #B-30208 – The Cognizant Member recommended closing out due to no violation.

GDNA Case #B-30210- The Cognizant Member recommended closing out due to no violation.

GDNA Case #B-30211- The Cognizant Member recommended Letter of Concern.

GDNA Case # B-30212- The Cognizant Member recommended closing out due to no violation.

GDNA Case # B-30217 – The Cognizant Member recommended closing out.

GDNA Case # B-30233 – The Cognizant member recommended closing out due to no violation.

GDNA Case #A-30227- The Cognizant member recommended a Letter of Concern.

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

OPEN SESSION

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

The Board voted to accept the following signed Board orders:

Tiffany Allen – Registered Pharmacy Technician – Voluntary Surrender
Judith Morales – Registered Pharmacy Technician – Voluntary Surrender
F.H.B. – Pharmacist – Private Consent Order

J.R.D. – Pharmacist Private Interim Consent Order
J.B.M. – Private Consent Order

Approval of Board Minutes. Ronnie Wallace made a motion to approve the minutes from the March 14, 2011 Board meeting; Fred Barber seconded the motion and the Board voted to approve the minutes.

Executive Director Eric Lacefield presented a list of licenses and registrations (425) that were issued from March 1-31, 2012. Ronnie Wallace made a motion to ratify the list of licenses and registrations; Laird Miller seconded the motion. The Board voted to ratify the licenses and registrations issued.

Maria S. Martinez submitted a Rule Waiver request of the requirement that a Pharmacy Technician must have a high school diploma or GED. Ronnie Wallace made a motion to approve the Rule Waiver request with the terms and condition that she can go to work but she must get her GED within 2 years. Tony Moye seconded the motion.

The Board held a public hearing regarding the Board Rule, Chapter 480-37, Remote Automated Medication Systems in the State of Georgia.

Following the comments regarding the Board Rule, Chapter 480-37, Remote Automated Medication Systems in the State of Georgia, the Board can't vote on the rule until April 25, 2012 due to the Board rule not being posted in 30 days before the board meeting

**SYNOPSIS OF PROPOSED CHANGES TO THE RULES OF THE
GEORGIA STATE BOARD OF PHARMACY,
CHAPTER 480-37, REMOTE AUTOMATED MEDICATION SYSTEMS
IN THE STATE OF GEORGIA.**

Purpose: The purpose of this rule amendment is to provide the requirements for licensure and operation of remote automated medication systems in this state.

Main Features: The main feature is to allow for the use of remote automated medication systems in skilled nursing facilities or hospice, and to provide minimum regulations for their use.

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

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 by a registered pharmacist 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, registered pharmacy technicians or registered nurse 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 or a licensed practical 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 registered pharmacist. When the RAMS employs bar code technology to prevent filling errors, it may also be restocked by a registered nurse.

(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 by a registered pharmacist no less than once every 30 days. All controlled substances drugs in a RAMS must inventoried no less than once every 7 days by a registered pharmacist or registered nurse. 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/outdated return transactions shall be documented by the RAMS.

(2) Board of Pharmacy inspections 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.

Sally Leonard requested the Board to lift the Probation from her Consent Order. Tony Moye made a motion to approve the request; Fred Barber seconded the motion and the Board voted to approve the lifting of probation from her consent order.

Executive Director’s Open Session – Mr. Eric Lacefield

- Mr. Lacefield presented the Board with a Policy for Administratively Processing Licenses. Ronnie Wallace made a motion to approve; Judy Gardner seconded the motion and motion carried.

Miscellaneous

Ms. Gardner discussed with the Board the concerns of renewals for licensure. Ms. Gardner stated according to Georgia Law the license expires on the date established by the Division Director. Executive Director Lacefield stated he can refer this to Division Director, Lisa Durden, and she will come down and talk to the board regarding this issue.

Judy Garner made a motion for Tony Moye to be the delegate at the National Association Board of Pharmacy. Laird Miller seconded the motion and the motion carried. Judy Gardner will notify the NABP that Tony Moye will be the Board’s representative. Director Lacefield stated the Board’s membership fees have been paid.

The Board changed the time of their next board meeting, May 9, 2012, from 10:00 a.m. to 9:30 a.m.

No more business was discussed and the meeting adjourned at 4:22 p.m.

The next Pharmacy Board meeting will be on Wednesday, May 9, 2012 at 9:30 a.m. at the Office of the Professional Licensing Boards, 237 Coliseum Drive, Macon, Georgia 31217.

Bill Prather, President
The Georgia State Board of Pharmacy

Date

Eric Lacefield, Executive Director
The Georgia State Board of Pharmacy

Date