

GEORGIA STATE BOARD OF PHARMACY

BOARD MEETING

November 09, 2011

Professional Licensing Boards

237 Coliseum Drive

Macon, GA 31217

Members Present:

Judy Gardner

Pat McPherson

Fred Barber

Ronnie Wallace

Tony Moye

Members Absent:

Steve Wilson, Chairperson

Bill Prather, Vice Chairperson

Al McConnell

Staff Present:

Eric Lacefield, Executive Director

Janet Wray, Board Attorney

Rick Allen, GDNA

Melanie Bradley, Board Support Specialist

Visitors:

Jim Bartling, Mercer

Coleen Schoch, King & Spalding

Scott Biddulph, Target

Ruth Thompson, TCSG

Hal Henderson, Omnicare

Jason Cheyney, GAPA

Rod Presnell, Medco

Jeff Mesaros, Medco

Judy Gardner established that a quorum was present and called the meeting to order at 10:00 a.m.

*Judy Gardner made a motion, Ronnie Wallace 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, and Tony Moye.*

Appointments – Executive Session

1. Severin T Ritter appeared before the Board to appeal the denial of his pharmacist reinstatement application. A motion was made by Tony Moye to overturn the Board's previous decision and to approve his application reinstatement of pharmacy license under a public Consent Order with 5 years probation. Pat McPherson seconded the motion and the Board voted unanimously in favor of the motion.
2. Michael A Powell appeared before the Board to appeal the denial of his pharmacist reinstatement application. A motion was made by Ronnie Wallace to affirm the Board's previous decision to deny and to require notarized signatures on the letters of support that were presented. Fred Barber seconded the motion and the Board voted unanimously in favor of the motion.
3. C.A.J. and her advocate appeared before the Board to discuss reinstatement of her pharmacy license. Fred Barber made a motion to reinstate her license under a private consent order with 5 years probation. Tony Moye seconded the motion and the Board voted unanimously in favor of the motion.
4. Rehan Ihsan submitted a letter to postpone his scheduled appointed. The Board viewed as informational.

Applications/Licensures

1. A.B.K. – Pharmacy Technician - Board recommended approval for registration.
2. A.B.A. – Pharmacy Technician - Board recommended approval for registration.
3. A.P. – Pharmacy Technician - Board recommended to deny registration.
4. A.M.F. – Pharmacy Technician - Board recommended approval for registration.
5. A.Y.S. – Pharmacy Technician - Board recommended to deny registration.
6. D.K.B. – Pharmacy Technician – Board recommended to schedule for an appearance.
7. L.A.A. – Pharmacy Technician – Board recommended to deny registration.
8. S.D. – Pharmacy Technician – Board recommended approval for registration.
9. T.S.S. – Pharmacy Technician – Board recommended to deny registration.
10. A.T.E. - Board recommended approval his application for pharmacy intern license.
11. B.A.Y. – Board recommended approval her application for pharmacy intern license.
12. J.W.P. - Board recommended approval his application for pharmacy intern license.
13. K.A. - Board recommended to accept intern hours submitted by the Oregon Board of Pharmacy.
14. A.A.A. – Board viewed the North Carolina Board of Pharmacy's Letter of Concern as informational.
15. D.E.B. – Board recommended approval her pharmacist reinstatement application.
16. F.G.W. – Board recommended approval his pharmacist reinstatement application.
17. G.T.L. – Board recommended to deny his pharmacist reinstatement application.
18. H.C.P. – Board recommended approval his nuclear pharmacist application pending a new page 2.
19. J.P. – Board recommended a new pharmacist application but not new fees for application.
20. K.B.T. – Board recommended to deny her request for early termination of probation on her pharmacist license.
21. M.C.P. – Board recommended approval her request to lift the pharmacist in charge restriction from her pharmacist license.

22. M.D.E. – Board recommended approval her pharmacist reinstatement application.
23. P.M.B. – Board recommended approval her pharmacist reinstatement application.
24. R.M.B. – Board recommended approval his pharmacist transfer application.
25. V.P. – Board recommended approval his pharmacist transfer application.
26. S.J.F. – Board recommended an investigative interview for applicant.
27. S.P. – Board recommended to schedule for an appearance.
28. A.A.M. – Pharmacy Technician - Board recommended approval for registration once proof of completion of probation is submitted.
29. C.M.D. – Pharmacy Technician - Board recommended to deny registration.
30. N.I.B.H.I. – Board recommended submission of complete application with SAMSHA and DCH approvals.
31. R.B.I. – Board recommended to reapply with correct application; not a limited chemical wholesaler distributor reinstatement application.
32. P.R.D. – Board viewed the response to the letter of concern as informational.
33. C.M.D. – Pharmacy Technician - Board recommended approval for registration.
34. T.W.B. – Pharmacy Technician – Board recommended reversal of previous decision and approval for registration.

Attorney General’s Report:

Senior Assistant Attorney General, Janet B. Wray presented a status report including 35 open cases and 7 closed cases. The following consent orders were presented for acceptance:

- Keith Cowart, Jr.; Pharmacist – Public Consent Order for Reinstatement
- R.S.E.; Pharmacist - Private Consent Order for Reinstatement
- Eric C. Gray; Pharmacist- Public Consent Order for Reinstatement
- C.L.H.; Pharmacist - Private Consent Order for Reinstatement
- Catherine P. Kain- Public Consent Order
- Walgreen’s #5899- Public Consent Order
- Jessica N. Summers; Pharmacy Technician- Public Consent Order for Reinstatement
- T.T.; Pharmacy Intern- Private Consent Order

Cognizant Report – Judy Gardner, Presiding Officer

GDNA Case #T11-45 – The Cognizant Member recommended immediate revocation of his pharmacy technician registration.

GDNA Case #A11-48 - The Cognizant Member recommended to accept the signed private interim consent order of assessment.

GDNA Case #T11-49 – The Cognizant Member recommended immediate revocation of his pharmacy technician registration.

GDNA Case #B-29972 – The Cognizant Member recommended closing the case - no violation.

GDNA Case #T-29776 – The Cognizant Member recommended immediate revocation of his pharmacy technician registration.

GDNA Case #A-30018 – The Cognizant Member recommended closing the case – no violation.

GDNA Case #B-30092 – The Cognizant Member recommended closing the case – no violation.

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; Judy Gardner seconded the motion. Voting in favor of the motion were Bill Prather, Tony Moyer, and Al McConnell.

OPEN SESSION

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

The Board voted to accept the following signed Board orders:

Keith Cowart, Jr.; Pharmacist – Public Consent Order for Reinstatement
R.S.E.; Pharmacist - Private Consent Order for Reinstatement
Eric C. Gray; Pharmacist- Public Consent Order for Reinstatement
C.L.H.; Pharmacist - Private Consent Order for Reinstatement
Catherine P. Kain- Public Consent Order
Walgreen's #5899- Public Consent Order
Jessica N. Summers; Pharmacy Technician- Public Consent Order for Reinstatement
T.T.; Pharmacy Intern- Private Consent Order

Tony Moyer made a motion to approve the minutes as amended from the October 12, 2011 Board meeting; Ronnie Wallace seconded the motion. The Board voted to approve the minutes.

Executive Director Eric Lacefield presented a list of licenses and registrations (454) that were issued from October 1-31, 2011. Ronnie Wallace made a motion to ratify the list of licenses and registrations; Tony Moyer seconded the motion. The Board voted to ratify the licenses and registrations issued.

The Board held elections for the 2012 Board Officers. Tony Moyer made a motion to nominate Judy Gardner for Vice Chairperson and Cognizant Member; Ronnie Wallace seconded, and the Board voted unanimously in favor of the motion. Judy Gardner made a motion to nominate Bill Prather for Chairperson; Ronnie Wallace seconded, and the Board voted unanimously in favor of the motion. The 2012 Board Officers are as follows:

Bill Prather, Chairperson
Judy Garner, Vice Chairperson/Cognizant Member

Executive Director Eric Lacefield presented a list of security prescription paper providers; three new provider and one software solution company. Ronnie Wallace made a motion to ratify the list of security prescription providers and to post list; Tony Moyer seconded the motion. The Board voted to ratify the list of security prescription providers and to post list.

Tony Moyer made a motion to amend the Board Rx Security Paper Policy to include the language of the law; Pat McPherson seconded the motion. The Board voted unanimously in favor of the motion.

Ronnie Wallace made a motion to adopt the previously adopted Specialty Pharmacy Accreditation Recognition as Board Policy #11. Tony Moyer seconded, and the Board unanimously in favor of the motion. Board Policy #11 reads as follows:

Board Policy #11

In the October 12, 2011 Board Meeting, the Georgia State Board of Pharmacy voted to adopt the following as Board Policy.

Specialty Pharmacy Accreditation Recognition

Pursuant to the authority delegated to the Board in O.C.G.A. § 26-4-28(a)(21), and acting as the sole governmental or other authority with the authority to (1) approve or recognize accreditation programs for specialty pharmacy practice, and (2) determine the acceptability of entities which may accredit pharmacies or certify pharmacists in a specialty of pharmacy practice in the State of Georgia, the Board approves and recognizes the URAC Specialty Pharmacy Accreditation Standards, Version 2.0, July 2010 ("URAC Accreditation") as an accreditation program for specialty pharmacy practice.

This policy does not require pharmacists or pharmacies to obtain URAC Accreditation as a prerequisite to specialty or advance pharmacy practice.

The Board held a public hearing regarding the proposed amendments to Board Rules, Chapter 480-19, Exempt Schedule V Over-the-Counter (OTC) Controlled Substances, Rule 480-19-.01 Excepted Sales of Schedule V Controlled Substances, Rule 480-19-.02 Exempt Schedule V Controlled Substances, proposed Rule 480-19-.03 Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine, Proposed Rule 480-19-.04 Record keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine, and Proposed Rule 480-19-.05 Exceptions to Exempt Schedule C-V Controlled Substance Drug Products Containing Pseudoephedrine Sales.

Following the comments and a letter from National Association of Chain Drug Stores, Tony Moyer made a motion to adopt the proposed amendments to Board Rules, Chapter 480-19, Exempt Schedule V Over-the-Counter (OTC) Controlled Substances, Rule 480-19-.01 Excepted Sales of Schedule V Controlled Substances, Rule 480-19-.02 Exempt Schedule V Controlled Substances, proposed Rule 480-19-.03 Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine, Proposed Rule 480-19-.04 Record keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine, and Proposed Rule 480-19-.05 Exceptions to Exempt Schedule C-V Controlled Substance Drug Products Containing Pseudoephedrine Sales; Pat McPherson seconded the motion, and the Board voted unanimously in favor to adopt the amended rules as follows:

480-19-.01 EXCEPTED SALES OF SCHEDULE V CONTROLLED SUBSTANCES.

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

Chapter 480-19 Exempt Schedule V Over-the-Counter (OTC) Controlled Substances, Amended.

- 480-19-.01 Excepted Sales of Non-Pseudoephedrine Schedule V Controlled Substances.
- 480-19-.02 Exempt Non-Pseudoephedrine Schedule V Controlled Substances.
- 480-19-.03 Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine
- 480-19-.04 Record keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine
- 480-19-.05 Exceptions to Exempt Schedule C-V Controlled Substance Drug Products Containing Pseudoephedrine Sales

480-19-.01 Excepted Sales of Non-Pseudoephedrine Schedule V Controlled Substances.
 No person shall obtain or attempt to obtain, sell, dispense or otherwise dispose of any non-pseudoephedrine substance included in Schedule V of the Georgia Controlled Substances Act, except as herein provided, and as in compliance with all other applicable laws, rules and regulations; ~~including Georgia Code Chapter 79A-8.~~ All terms used in this section shall have the same meaning as in ~~Georgia Code Chapter 79A-8~~ O.C.G.A. T. 16, Ch. 14 and T. 26, Ch. 4, as amended.

(a) A physician or medical practitioner may dispense Schedule V substances for legitimate medical purposes in the normal course of his/her professional practice. ~~A physician or medical practitioner may administer Schedule V substances in their offices but cannot charge for the dispensed drug.~~

(b) A licensed pharmacist, or intern acting under the immediate and direct supervision of a licensed pharmacist, may sell, dispense or otherwise dispose of without prescription not more than 4 oz. or 32 dosage units of an exempted non-pseudoephedrine Schedule V controlled substance within any 48 hour period of time, but only:

1. After applying reasonable means or effort to determine that such is to be used for legitimate medical purposes; and
2. After the purchaser has written his/her signature, date of birth, address, city, state and zip code upon a register which records and reflects the date of such transaction, the name, kind, quantity and intended use of such Schedule V substance sold, dispensed, or otherwise disposed of, and such records shall be maintained as required by Schedule V records.

(c) No person shall obtain or attempt to obtain, in any 48-hour period of time, more than 4 oz. or 32 dosage units of a Schedule V controlled substance.

Authority O.C.G.A. §§. 16-13-29.2, 26-4-27, 26-4-28.

480-19-.02 EXEMPT SCHEDULE V CONTROLLED SUBSTANCES.

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

480-19-.02 Exempt Non-Pseudoephedrine Schedule V Controlled Substances.

Before the sale of any non-pseudoephedrine Schedule V Controlled Substance without a prescription, a licensed pharmacist should first determine whether or not the product to be sold is packaged in a container with not more than 4 ounces or 32 dosage units of the drug, and whether the label provided by the product manufacturer contains a Federal Caution or Warning. If such Legend or Warning or Rx Only indication is present on the manufacturer's label, this product cannot be sold without a prescription.

Authority O.C.G.A. §§ 16-13-22, 16-13-34, 26-4-27, 26-4-28.

480-19-.03 OVER-THE-COUNTER (OTC) SALES OF EXEMPT SCHEDULE V CONTROLLED SUBSTANCE DRUG PRODUCTS CONTAINING PSEUDOEPHEDRINE

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.
480-19-.03 Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine

(a) No person shall obtain or attempt to obtain, sell, dispense or otherwise distribute any exempt Schedule V controlled substance drug product containing pseudoephedrine as listed under O.C.G.A. 16-13-29(5), except as herein provided, and as in compliance with all other applicable state or federal laws, rules and regulations. All terms used in this section shall have the same meaning as in O.C.G.A. T.16, Ch. 13 and T. 26, Ch. 4.

1) All exempt Schedule V controlled substance pseudoephedrine containing drug products must be stored in a pharmacy's prescription department.

2) All pharmacy personnel who engage in the sale or distribution of exempt Schedule V controlled substance containing drug products must complete the DEA's self-certification training as required by the Combat Methamphetamine Epidemic Act of 2005, 21 U.S.C. 830.

(b) A registered pharmacist or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may sell, dispense or otherwise dispose of without prescription not more than 3.6 grams every 24 hours, or a maximum of 9 grams every 30 days, to each customer of a pseudoephedrine containing drug product, but only:

1) After applying reasonable means or effort to determine that such is to be used for legitimate medical purposes, following the proper record keeping procedures, and ensuring the required information has been properly recorded in a logbook which contains either a written or electronic list of sales.

2) For hand-written logbooks used to record patient information before the sale of an exempt Schedule V pseudoephedrine containing drug product can take place:

(A) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist, must approve all such sales or transactions. Approval means verifying the patient's identification and ensuring the patient has a valid reason for obtaining the pseudoephedrine. After approval, the registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may direct designated pharmacy personnel, to complete any sales transactions to a patient by writing in the logbook at a minimum the name of the pseudoephedrine containing drug product, strength, and quantity sold along with the name of the patient, their date of birth, address, zip code, date and time of sale; The pharmacy may require additional patient information for the logbook as long as the required information is obtained.

(B) The patient must sign the logbook to acknowledge the sale and receipt of the pseudoephedrine containing drug product.

(C) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may personally, or may direct designated pharmacy to, ask the patient to produce a photo identification issued by a state or the federal government to use in verifying that the patient's name on the photo identification matches the name the patient wrote

in the logbook; No exempt Schedule V pseudoephedrine containing drug product can be sold to a patient unless they present appropriate identification

(D) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist must or may direct designated pharmacy personnel to verify that the date and time of the sale and other information that has been entered in the logbook is correct by use of the patient's photo identification, and initial the logbook verifying the information for the sale as being correct.

3) For electronic logbooks used to record patient information for the sale of an exempt Schedule V pseudoephedrine containing drug product:

(A) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist, must approve all such sales or transactions. Approval means verifying the patient's identification and ensuring the patient has a valid reason for obtaining the pseudoephedrine. After approval, the registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may direct designated pharmacy personnel, to complete any sales transactions to a patient by entering, at a minimum, the name of the pseudoephedrine containing drug product, strength, and quantity sold; the patient's name, date of birth, address, and zip code, or entering this information may be accomplished through a point of sales system and bar code reader. The pharmacy may require additional patient information for the logbook as long as the required information is obtained.

(B) The computer for the electronic logbook can automatically enter the date and time of the sale,

(C) The patient's signature on the logbook must be captured using an electronic signature system of a type similar to or one used for credit card purchases

(D) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may personally, or may direct designated pharmacy personnel to, must ask the patient to produce a photo identification issued by a state or the federal government to use in verifying that the patient's name on the photo identification matches the name the patient wrote in the logbook; No exempt Schedule V pseudoephedrine containing drug product can be sold to a patient unless they present appropriate photo identification

(E) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist must, or may direct designated pharmacy personnel to, enter their name or pharmacist, pharmacy intern license number, or pharmacy personnel's identification in the logbook to indicate the information for the sale is correct.

(4) The quantities of different strength pseudoephedrine containing drug products that equals 3.6 grams is:

Tablets/capsules - Number of tablets/capsules that equal 3.6 grams

Ingredients	Number of tablets = 3.6 grams
30 mg Pseudoephedrine HCl	146 Tablets
60 mg Pseudoephedrine HCl	73 Tablets

120 mg Pseudoephedrine HCl	36 Tablets
30 mg Pseudoephedrine Sulfate	155 Tablets
60 mg Pseudoephedrine Sulfate	77 Tablets
120 mg Pseudoephedrine Sulfate	38 Tablets
240 mg Pseudoephedrine Sulfate	19 Tablets

Liquids -Number of milliliters that equal 3.6 grams

Ingredients	Number of milliliters (ml) = 3.6 grams
6.25 mg Ephedrine HCl/ 5 ml Liquid	3515 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	468 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	2929 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	1464 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	366 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	366 ml

(c) No registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist can knowingly sell more than 9 grams of pseudoephedrine to a patient in a 30 day period of time.

(1) The quantities of different strength pseudoephedrine containing drug products that equals 9 grams is:

Tablets/capsules - Number of tablets/capsules that equal 9 grams

Ingredients	Number of tablets = 9 grams
30 mg Pseudoephedrine HCl	366 Tablets
60 mg Pseudoephedrine HCl	183 Tablets
120 mg Pseudoephedrine HCl	91 Tablets
30 mg Pseudoephedrine Sulfate	389 Tablets
60 mg Pseudoephedrine Sulfate	194 Tablets

120 mg Pseudoephedrine Sulfate	97 Tablets
240 mg Pseudoephedrine Sulfate	48 Tablets

Liquids -Number of milliliters in 9 grams

Ingredients	Number of milliliters (ml) = 9 grams
6.25 mg Ephedrine HCl / 5 ml Liquid	8788 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	1171 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	7323 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	3661 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	915 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	915 ml

(d) All logbooks must be retained for a minimum period of 2 years from the date of the last recorded sale.

(e) Logbooks must be kept in a secure location in the pharmacy and information contained in a logbook can be shared:

(A) To comply with state or federal laws and rules;

(B) For a product recall

(C) With local, state, and federal law enforcement officers, to allow logbook information to be inspected, copied.

(f) Nothing in this rule would prohibit pharmacies, or 3rd party information technology company acting on behalf of a pharmacy, to report or transmit sales data for exempt Schedule V controlled substance drug products containing pseudoephedrine to the state operated central registry, also known as the Georgia Methamphetamine Information System (GMIS). Without approval from GDNA, such data cannot be reported to any other central record keeping system. These sales may be reported to the registry either electronically, by means of transmitting a faxed copy of a handwritten logbook, or by sending copies of handwritten logbooks to the GDNA designated collection location for the registry via the U.S. mail or other similar means.

(g) Nothing in this rule requires a pharmacy to maintain a logbook that is separate and apart from the logbook required under the U.S. Combat Methamphetamine Epidemic Act of 2005, 21 U.S.C 830 and 844, other than drug products containing pseudoephedrine must be stored in the prescription department area of a pharmacy and the sales are made by a registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist.

Authority O.C.G.A. §§ 16-13-22, 16-13-29, 16-13-29.2, 16-13-34, 26-4-27, 26-4-28.

480-19-.04 RECORD KEEPING FOR OVER-THE-COUNTER (OTC) SALES OF EXEMPT SCHEDULE V CONTROLLED SUBSTANCE DRUG PRODUCTS CONTAINING PSEUDOEPHEDRINE

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

480-19-.04 Record keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine

(a) A record created this rule must be maintained in the pharmacy at which the transaction occurred, except that records may be kept either at a single, central location for the pharmacy or by a third party information technology company on behalf of the pharmacy only if the pharmacy has notified the GDNA of its intention to do so and received GDNA approval.

(1) Written notification must be submitted by registered or certified mail, return receipt requested, to the Director, Georgia Drugs and Narcotics Agency, 40 Pryor Street, SW, Suite 2000, Atlanta, Georgia 30303.

(2) This notification must include telephone and address contact information as well as a telephone number and email address for a point of contact person who is responsible for providing requested record for either the pharmacy's central record keeping location or any third party information technology company.

(3) The Director of the Georgia Drugs and Narcotics Agency shall issue written approval of any central record keeping location or third party information technology company prior to records being maintained in such a manner.

(b) The records required to be kept under this rule must be readily retrievable and available for inspection and copying by GDNA or other law enforcement officers as requested as provided for under the provisions of 21 U.S.C. 880, and the U.S. Combat Methamphetamine Epidemic Act of 2005.

(1) A record developed and maintained to comply with federal law may be used to meet the requirements of this rule if the record includes the information specified by this rule.

(2) Readily retrievable shall mean records must be produced by the pharmacy or the pharmacy's third party information technology company in less than 6 hours for all electronically maintained records or 24 hours for any handwritten records.

(c) If a pharmacy fails to produce records or produce records in the required time is considered a violation of O.C.G.A. Sections 16-13-37, 16-13-39, and 16-13-42.

Authority O.C.G.A. §§. 16-13-22, 16-13-29, 16-13-29.2, 16-13-34, 16-13-35, 26-4-27, 26-4-28, 26-4-60.

480-19-.05 EXCEPTIONS TO EXEMPT SCHEDULE V CONTROLLED SUBSTANCE DRUG PRODUCTS CONTAINING PSEUDOEPHEDRINE SALES

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

480-19-.05 Exceptions to Exempt Schedule V Controlled Substance Drug Products Containing Pseudoephedrine Sales.

(a) Any drug product containing pseudoephedrine which comes in a container packaged by the its manufacturer with and its label contains a Federal Caution or Rx Only indication, this product is not an exempt narcotic under this rule and cannot be sold as an Exempt OTC Schedule V drug product and can only be dispensed by a pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist upon receipt of a prescription issued by a licensed practitioner.

(1) Such prescriptions should be filed and maintained in the manner set forth for Schedule III, IV or V controlled substance prescriptions.

(b) Any licensed practitioner who is authorized to dispense drugs by O.C.G.A. 26-4-130 may dispense drug products containing pseudoephedrine in accordance to state laws and board of pharmacy rule 480-28.

(1) Such prescriptions dispensed according to board of pharmacy rule 480-28 should be filed and maintained in the manner set forth for Schedule III, IV or V controlled substance prescriptions.

Authority O.C.G.A. §§ 16-13-22, 16-13-34, 26-4-27, 26-4-28, 26-4-130

The Board held a public hearing regarding the proposed amendments to Board Rules, Chapter 480-22, Rule 480-22-.12 Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or and Advanced Practice Registered Nurse (APRN) licensed to practice in the state of Georgia.

Following the comments, Ronnie Wallace made a motion to adopt the proposed amendments to Board Rules, Chapter 480-22, Rule 480-22-.12 Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or and Advanced Practice Registered Nurse (APRN) licensed to practice in the state of Georgia; Tony Moyer seconded the motion, and the Board voted unanimously in favor to adopt the amended rules as follows:

CHAPTER 480-22, RULE 480-22-.12 REQUIREMENTS OF PRESCRIPTION DRUG ORDERS AS ISSUED BY A PHYSICIAN'S ASSISTANT (PA) OR AN ADVANCED PRACTICE REGISTERED NURSE (APRN) LICENSED TO PRACTICE IN THE STATE OF GEORGIA.

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

480-22-.12 Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia.

(1) Under O.C.G.A. § 43-34-103(e.1), a physician's assistant (PA) licensed by the Georgia Composite Board of Medical Examiners is permitted to issue a prescription drug order or orders for any dangerous drugs, as defined in O.C.G.A. § 16-13-71 without the co-signature of a supervising physician pursuant to the authority delegated by the PA's supervising physician and contained in the PA's job description.

(a) A PA cannot issue a prescription for any C-II, III, IV, or V controlled substance without having such prescription co-signed by his or her supervising physician, unless such PA has his/her own DEA number.

(b) Delegation of such authority shall be contained in the job description required by O.C.G.A. § 43-34-103(e.1). The delegating physician shall remain responsible for the medical acts of the PA.

(2) Nothing in this Rule, Title 16, Chapter 13 or Title 43, Chapter 34, shall be construed to create a presumption of liability, either civil or criminal, on the part of a pharmacist who in good faith fills a prescription drug order presented by a patient pursuant to this Rule.

(a) A pharmacist shall presume that the prescription drug order was issued by a PA duly licensed and qualified under Title 43, Chapter 34 to prescribe pharmaceutical agents.

(b) A pharmacist shall presume that the drug prescribed by the PA is a drug approved by the supervising physician in the PA's job description, unless the pharmacist has actual or constructive knowledge to the contrary.

(3) The PA shall only be authorized to exercise the rights granted by O.C.G.A. § 43-34-103(e.1) using a prescription drug order which includes the following:

(a) The name, address, NPI number, and telephone number of both the prescribing physician and the PA;

(b) The patient's name and address;

(c) The drug name, strength and quantity prescribed;

(d) The directions to the patient with regard to taking the drug;

(e) The number of authorized refills, if any;

(f) ~~If applicable, The the~~ DEA permit number of the supervising physician ~~and or, if applicable,~~ the DEA number of the PA; and

(g) ~~Such prescription drug order form shall be valid only if signed by the physician's assistant and the following terminology appears on the prescription drug order: "This prescription authorized through (pre-printed name of the prescribing supervising physician, M.D. or D.O.) by (pre-printed name of the PA printed below the signature line, with such line bearing the signature of the PA), PHYSICIAN'S ASSISTANT" (Physician's Assistant must be spelled out, not abbreviated as PA).~~

~~1. An example, which satisfies the requirements for both Controlled Substance and Dangerous Drug prescription drug order, is as follows: "This prescription authorized through O.C. Cornwallis, M.D. by, Physician's Assistant Jane Doe (pre-printed).~~

(4) Any prescription drug order form containing less information than that described in this subsection shall not be offered to or accepted by any pharmacist.

(5) Under O.C.G.A. § 43-34-26.3(e.1), an advanced practice registered nurse (APRN) who is recognized by the Georgia Board of Nursing as having met the requirements established by the Georgia Board of Nursing to engage in advanced nursing practice, is in good standing with the Georgia Board of Nursing, and who has entered into a nurse protocol agreement, approved by the Composite Board of State Medical Examiners, with a delegating physician is permitted to issue a prescription drug order or orders for any dangerous drug, as defined in O.C.G.A. § 16-13-71 without the co-signature of a delegating physician pursuant to the authority delegated by the APRN's delegating physician and contained in the APRN's nurse protocol.

(a) An APRN can issue a prescription drug order for any Schedule III, IV, or V controlled substance without having such prescription co-signed by his or her delegating physician, if such APRN has his or her own Federal Drug Enforcement Administration (DEA) number; An APRN has no authority to issue a Schedule I or II controlled substance prescription. If an APRN does not have their own federal DEA number, the prescription must be signed by the delegating physician.

(b) An APRN is not authorized to issue refills of any dangerous drug for more than 12 months from the date of the original order, except in the case of oral contraceptives, hormone replacement therapy, or prenatal vitamins which may be refilled for a period of 24 months. An APRN is not authorized to issue more than five (5) refills of any Schedule III, IV, or V controlled substance for more than six (6) months from the date of the original order.

(c) Delegation of such authority shall be contained in the nurse protocol required by O.C.G.A. § 43-34-26.3. The delegating physician shall remain responsible for the medical acts of the APRN.

(6) Nothing in this Rule, Title 16, Chapter 13 or Title 43, Chapter 34, shall be construed to create a presumption of liability, either civil or criminal, on the part of a pharmacist duly licensed under Chapter 4 of Title 26, who in good faith fills a prescription drug order presented by a patient pursuant to this Rule which was issued by an APRN pursuant to an approved nurse protocol agreement.

(a) A pharmacist shall presume that the prescription drug order was issued by an APRN duly licensed and qualified under Title 43, Chapter 34 to prescribe pharmaceutical agents.

(b) A pharmacist shall presume that the drug prescribed by the APRN is a drug approved by the delegating physician in the APRN's nurse protocol, unless the pharmacist has actual or constructive knowledge to the contrary.

(7) The APRN shall only be authorized to exercise the rights granted by O.C.G.A. § 43-34-26.3 using a prescription drug order which includes the following:

(a) The name, address, NPI number, and telephone number of the delegating physician, and the DEA number of the delegating physician if applicable;

(b) The name, address, NPI number, and telephone number of the APRN, and the APRN's DEA number if applicable;

(c) The name and address of the patient;

(d) The drug name, strength and quantity prescribed;

- (e) The directions to the patient with regard to how the medication is to be administered;
 - (f) The number of authorized refills, if any;
 - (g) Such prescription drug order form shall be valid only if signed by the APRN;
 - (h) A prescription drug order which is transmitted either electronically or via facsimile shall conform to the requirements set out in paragraphs (1) and (2) of subsection (c) of Code Section 26-4-80, respectively.
- (8) Any prescription drug order containing less information than that described in this subsection shall not be considered a legal prescription.

Authority: O.C.G.A. §§ 16-13-22, 16-13-34, 26-4-27, 26-4-28, 26-4-130

The Board received an open records request from the Maryland Board of Pharmacy. Tony Moyer made a motion to approve the open records request; Ronnie Wallace seconded the motion, and the Board voted to approve the open records request.

Beau Zimmerman, Natasha M. Perry, and Pauline M. Badiki 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.

Jane H. Smith submitted notice to relinquish her pharmacy license. Tony Moyer made a motion to accept the non-disciplinary surrender of license; Pat McPherson seconded the motion, and the Board voted to accept the non-disciplinary surrender of license.

JoAnn T. Johnson submitted a request for waiver of reinstatement fees, and the Board voted to deny the waiver request.

Marianne Slade submitted an inquiry to the Board. The Board referred this inquiry to the Department of Community Health.

Mark S. McKinney submitted request to lift probation from his license. Ronnie Wallace made a motion to grant the request to lift probation from license; Tony Moyer seconded the motion, and the Board voted to lift probation from license.

Thomas D. Cowan submitted request to lift probation from his license. Tony Moyer made a motion to grant the request to lift probation from license; Ronnie Wallace seconded the motion, and the Board voted to lift probation from license.

J. Keith Herrington submitted request to lift probation from his license. Tony Moyer made a motion to grant the request to lift probation from license; Ronnie Wallace seconded the motion, and the Board voted to lift probation from license.

Austin P. Conner submitted a letter requesting an appearance before the Board. Tony Moyer made a motion to grant the waiver requests for an appearance; Fred Barber seconded the motion, and the Board voted to grant the request for an appearance.

Shakebia T. Baker submitted a letter requesting an appearance before the Board. Fred Barber made a motion to grant the waiver requests for an appearance; Ronnie Wallace seconded the motion, and the Board voted to grant the request for an appearance.

Executive Director's Report: Eric Lacefield informed the Board of a new member appointment, Laird Miller, effective November 21, 2011. The new appointment will replace Chairperson Steve Wilson.

Attorney General's Report: Senior Assistant Attorney General Janet Wray reported that the lawsuit against the Pharmacy Board was voluntarily dismissed.

Miscellaneous

The Board voiced its appreciation for Chairperson Steve Wilson and a job well done during his term of service.

Ronnie Wallace made a motion to amend rules for renewal dates, changing June 30 to September 30. Tony Moye seconded the motion, and the Board voted unanimously in favor of the motion.

Tony Moye made a motion to reciprocate with California if California reciprocates with Georgia. Ronnie Wallace seconded the motion, and the Board voted unanimously in favor of the motion.

No more business was discussed and the meeting adjourned at 3:53 p.m.

The next Pharmacy Board meeting will be Wednesday, December 14, 2011 at 10:00 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