

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St, N.W. 36th Floor
Atlanta, GA 30303
October 19, 2016
9:00 a.m.

The following Board members were present:

Mike Faulk, President
Chris Jones, Vice-President
Vicki Arnold
Jim Bracewell
Lisa Harris
Laird Miller
Bill Prather
Bob Warnock

Staff present:

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

Visitors:

William Kennedy
Diane Diver
Ronald Dotzler
Donald Roberts, Jr.
Juanita Roberts
Donald Roberts
Cassie Wilson
Rob Hinzman
Jim Hinzman
Olayinka Olaniyi
Melvin M. Goldstein
Femi Paters
Cecil Cordle, CVS Health
John Rocchio, CVS Health
Travis Lindley, MAG
Helen Sloat, Kaiser Permanente/Hemophilia of GA
Jamie Diagostino, Eldercare Pharmacy
Sonya Nelson, Walmart
Esete Getachew-Smith, Kroger
Dannell Gillespie, Walgreens
Young Chang, Walgreens
Mike King, Publix
Kathy Eichenblatt, SD&D
David Eichenblatt, SD&D
Carrie Moss, BSL
Bethany Sherrer, MAG
Stephen Georgeson
Greg Reybold, GPhA
Nichelle Sims, Hemophilia of Georgia

President Faulk established that a quorum was present and called the meeting to order at 9:13 a.m.

Chris Jones made a motion and Bill Prather 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 Vicki Arnold, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Appearances

- W.K.K.
- R.E.D.
- D.L.R.
- C.A.W.
- O.F.O.

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

Open Session

President Faulk welcomed the visitors.

Approval of Minutes

Bill Prather made a motion to approve the Open Session minutes for the September 14, 2016 meeting. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Laird Miller made a motion to approve the Executive Session minutes for the September 14, 2016 meeting. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Lisa Harris made a motion to approve the minutes for the October 7, 2016 Conference Call. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Ratifications

Chris Jones made a motion to ratify the list of issued licenses. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – Stephanie Stewart

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 Variance – Hold The Line K9, LLC

Bill Prather made a motion to deny the rule variance petition, but advise the applicant that the Board considered the fact that the facility would be in a residential area. Additionally, should the applicant establish the facility in a commercial area and appropriately address the Board's concerns regarding the security of drugs, it will be happy to consider the application. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance - Piedmont Mountainside Hospital-Ellijay

Chris Jones made a motion to deny the rule variance petition. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance/Waiver - Oconee Regional Medical Center, PHH004139

Laird Miller made a motion to deny the rule variance/waiver petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Chestatee Regional Hospital, PHH006578

Vicki Arnold made a motion to deny the rule waiver petition. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Gateway 341 Pharmacy, PHH005598

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

Petition for Rule Waiver - River Edge Recovery Center Pharmacy

Vicki Arnold made a motion to deny the rule waiver petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Dr. Agnes Furst, TheMedsBox

The Board considered this correspondence regarding rules and regulations for vending machines for over the counter (OTC) and behind the counter (BTC) medications. The Board directed staff to respond by stating that strictly OTC medications may be put in a vending machine; however, BTC medications may not be. Additionally, refer Dr. Furst to the law and rules located on the Board's website.

Correspondence from Fara Klein

The Board considered this correspondence requesting a delay of enforcement regarding USP General Chapter 800. The Board directed staff to respond by enforcement would not begin as a result of delayed implementation on the federal level.

Correspondence from Christine Jones

The Board considered this correspondence requesting clarification of pharmacist scope of practice. The Board directed staff to refer Ms. Jones to code sections O.C.G.A. §§ 26-4-4 and 43-34-24 for more information.

Correspondence from Cynthia Rhodes

The Board considered this correspondence requesting clarification on license regulations for drug manufacturers. The Board recommended tabling this correspondence and directed staff to request additional information from Ms. Rhodes.

Correspondence from Ginger Eichler EQ Detroit

The Board considered this correspondence regarding final destination of non-controlled substances. The Board directed staff to respond by stating that the facility to which it sends non-controlled substances must be licensed.

Correspondence from Mike Long, Elements Behavioral Health

The Board considered this correspondence requesting approval of treatment facilities for Elements Behavior Health. The Board directed staff to schedule Mr. Long for an appearance to present this information to the Board.

Correspondence from Katherine Kirby, ACHC

The Board viewed this correspondence for informational purposes only.

Correspondence from Amber Hollar, National Pharmaceutical Returns

The Board considered this correspondence requesting clarification of Rule 480-7-.07(4)(a). The Board directed staff to respond by stating that yes, a wholesaler can deduct up to 7% as the handling fee.

Correspondence from Bryan Green, Premier Drugstore

The Board considered this correspondence regarding a potential afterhours drop box. The Board recommended approving the afterhours drop box pending a satisfactory inspection by GDNA.

Correspondence from David Eichenblatt, Smart Door & Delivery LLC

Mr. Eichenblatt, who met before the Board at its September 2016 meeting regarding the Smart Door & Delivery system, was present and informed the Board that he addressed the Board’s concerns from the previous meeting and incorporated the Board’s suggestions into the product. He stated that this information is in the letter provided to the Board. President Faulk informed Mr. Eichenblatt that the Board is continuing its review of this matter and will advise him of its decision as soon as possible.

Correspondence from Brianna Harding

The Board considered this correspondence from Ms. Harding asking if the pharmacy must label repacks using the bottle directions as provided by the original dispensing pharmacy, or if they may label repacks using directions from more recent orders if the medication, strength, and physician name are the same. The Board directed staff to respond by stating that she can label repacks from more recent orders. Additionally, if there are any concerns, the Board suggested she contact the doctor and/or the source sending it and make them aware of the issue.

Georgia Drugs and Narcotics Agency – Rick Allen

No report.

Attorney General’s Report – Janet Wray

Ms. Wray discussed pending administrative cases and attorney time for FY2016.

Executive Director’s Report – Tanja Battle

ACPE Invitation – State Board Observer for On-Site Evaluation: Ms. Battle stated that, at the Board’s September meeting, she discussed ACPE’s correspondence extending an invitation to the Board for an opportunity to designate an officer or member to participate on the site visit as an observer. She reported that a board member will not be available to attend and ACPE has been notified of such.

Continuing Education Report: Report presented. Bill Prather made a motion to ratify the below named continuing education program approved since the previous meeting. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Sponsoring Group	Program Title
Kaiser Permanente	New Therapies in Heart Failure: The Heart of the Matter

Sharepoint: Ms. Battle reported that each board member has been sent a new DCH email address and link to the new site Sharepoint. She stated that all information for the Board will be uploaded to Sharepoint from this point forward. Additionally, she indicated that she would do a demonstration in Executive Session as applications and investigative materials had been uploaded and could not be displayed for public viewing.

January 2017 Practical Examination and Meeting Date: Chris Jones made a motion for the January 2017 meeting date to be held on the 11th with the practical examination to be held on the 12th. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Newsletter: Ms. Battle reported that at the Board's August 2016 meeting, the Board discussed generating a newsletter that would contain essential information that the general population of pharmacy would be interested in knowing. Per Ms. Wray's suggestion, Ms. Battle recently met with the Executive Director of the Georgia Composite Medical Board (GCMB). GCMB does send out a newsletter; but only a very small percentage of licensees has opted in to receive such. She stated that Mr. Bracewell had information regarding another option. Mr. Bracewell reported that he forwarded a copy of the NABP newsletter from the Louisiana Board as an example. The Board discussed costs related to generating a newsletter or webpage containing information on Board actions and ways for possibly sending this information that would not be labor intensive. Ms. Battle stated that she will do further research on the matter and report back to the Board at its November meeting.

Remodeling Plans for Rite Aid Pharmacy #1964: The Board discussed the plans submitted to the Board to review by Rite Aid Pharmacy #1964. The Board recommended approval pending a favorable inspection from GDNA.

Miscellaneous

Bob Warnock made a motion to post notice of intent to repeal Rule 480-10-.18 Utilization of Unused Prescription Drugs. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

~~480-10-.18 — Utilization of Unused Prescription Drugs.—Repealed.~~

~~(1) Definitions:~~

~~(a) "Drug formulary" means any dangerous drug approved by the U.S. Food and Drug Administration, excluding schedule one through five controlled substances and drugs requiring special storage including but not limited to refrigeration. All such drugs must be in the original unit dose or an individually sealed dose as dispensed by the originating pharmacist that remain in intact packaging and must have an expiration date on the label of six months or more from the date of transfer to the pharmacy.~~

~~(b) 'Health care facility' means an institution which is licensed as a nursing home, intermediate care home, personal care home, home health agency, or hospice pursuant to Chapter 7 of Title 31.~~

~~(c) 'Medically indigent person' means:~~

~~1. A person who is Medicaid eligible under the laws of this state; or~~

~~2. A person:~~

~~(i) Who is without health insurance; or~~

~~(ii) Who has health insurance that does not cover the injury, illness, or condition for which treatment is sought; and whose family income does not exceed 200 percent of the federal poverty level as defined annually by the Federal Office of Management and Budget.~~

~~(2) Unused prescription drugs within the drug formulary from a health care facility that are donated by a patient, patient's representative, or guardian pursuant to the Utilization of Unused Prescription Drugs Act may be returned only to a licensed pharmacy approved by the Department of Human Resources. The health care facility must obscure the patient's name, doctor's name, and prescription number from the label on the donated drug container prior to transferring to the pharmacy. The health care facility must package the donated drugs in a sealed container properly addressed and labeled and arrange for a common carrier to pick up and deliver the drugs to the pharmacy, and such common carrier must maintain the drugs in a secure and temperature controlled environment that meets the drug manufacturers recommendations and United States Pharmaceutical (USP) standards.~~

~~(3) A licensed pharmacist from the health care facility donating drugs must sign a document verifying that the drugs have been maintained in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and USP standards. Such documents must accompany the drugs to the receiving pharmacy.~~

~~(4) The receiving pharmacy must document the receipt of such donated drugs on a readily retrievable log, and comply with all record keeping requirements of the Board of Pharmacy. All such donated drugs shall~~

be maintained in a separately designated area from the pharmacy's regular stock of drugs, and such storage shall be in an area to ensure drug integrity.

~~(5) Donated drugs can only be dispensed to medically indigent persons pursuant to a valid prescription drug order. The receiving pharmacy must dispense the donated drugs in the original packaging as received from the donating health care facility, and the receiving pharmacy must place a label on the donated drug container in conformance with Board of Pharmacy rules and any other applicable state or federal law. The dispensing records for donated drugs must be maintained in the same manner as all other dispensed drugs and according to Georgia law and Board of Pharmacy Rules.~~

~~(6) Dispensing pharmacies of donated drugs may only charge a restocking fee pursuant to Code Section 49-4-152.5. Pharmacies and pharmacist shall not be subject to liability for dispensing unused donated drugs pursuant to this rule when such services are provided without reimbursement (except the restocking fee), and in good faith and compliance with these rules and law.~~

Bob Warnock made a motion to post Rule 480-49-.03 Bad Checks and Reversals as amended. Chris Jones seconded and the Board voted unanimously in favor of the motion.

480-49-.03 Bad Checks and Reversals.

(1) It is the policy of the Board of Pharmacy to pursue its legal remedies under O.C.G.A. § 16-9-20 when a bad check is issued in payment of examination, license or renewal fees, application fees, or similar fees, and to take such other action as outlined herein. Any person issuing a bad check will be subject to the service charge as provided in O.C.G.A. § 16-9-20 (a)(2).

(2) Bad Checks.

(a) If an applicant for licensure by examination or reciprocity issues a bad check to cover required licensure or examination fees, such applicant shall not be issued a license until the applicant has paid the appropriate fees and the service charge. If a license is issued prior to determining that the applicant issued a bad check, such license will be deemed to have been issued in error and deemed not current unless the applicant pays the licensure or examination fees and service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The applicant must pay the licensure fees and the service charge by cashier's check or money order.

(b) If an applicant for registration or permit issues a bad check to cover required application fees, such applicant shall not be issued a registration or permit until the applicant has paid the appropriate fees and the service charge. If a registration or permit is issued prior to determining that the applicant issued a bad check, such registration or permit will be deemed to have been issued in error and deemed not current unless the applicant pays the appropriate fees and service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The applicant must pay the application fees and the service charge by cashier's check or money order.

(c) If a licensee, permit-holder, or registrant attempts to renew a license, permit, or registration by the issuance of a bad check, the license, permit, or registration will not be renewed until the licensee, permit-holder, or registrant pays all fees due including any applicable late renewal fees plus the service charge. If the license, permit, or registration is renewed and reissued to the licensee, permit-holder, or registrant prior to determination that the licensee, permit-holder, or registrant issued a bad check, the licensee, permit-holder, or registrant will be notified by certified or registered mail that the renewed license, permit, or registration will be deemed not current unless the licensee, permit-holder, or registrant remits all fees due for renewal plus the service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The licensee, permit-holder, or registrant must pay the fees and service charge by cashier's check or money order.

(3) Reversals or chargebacks.

(a) If a license by examination or reciprocity is issued and the licensee initiates a chargeback, such license will be deemed to have been issued in error and deemed not current unless the applicant pays the licensure or examination fees and service charge within ten (10) days of the Board mailing the notice by certified or

registered mail. The applicant must pay the licensure fees and the service charge by cashier's check or money order.

(b) If a registration or permit is issued and the applicant initiates a chargeback, such registration or permit will be deemed to have been issued in error and deemed not current unless the applicant pays the licensure or examination fees and service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The applicant must pay the application fees and the service charge by cashier's check or money order.

(c) If the license, permit, or registration is renewed and reissued to the licensee, permit-holder, or registrant and the licensee, permit-holder, or registrant initiates a chargeback, the licensee, permit-holder, or registrant will be notified by certified or registered mail that the renewed license, permit, or registration will be deemed not current unless the licensee, permit-holder, or registrant remits all fees due for renewal plus the service charge within ten (10) days of the Board mailing the notice by certified or registered mail. The licensee, permit-holder, or registrant must pay the fees and service charge by cashier's check or money order.

Chris Jones made a motion and 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 receive the Assistant Attorney General's report. Voting in favor of the motion were those present who included Vicki Arnold, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Attorney General's Report – Janet Wray

- Legal advice regarding Rule 480-27-.03 Records of Dispensing and Chapter 480-7B Third Party Logistics Providers.

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

Open Session

Miscellaneous

Laird Miller made a motion to post Rule 480-10-.10 Prescription Drug Order Copies. Chris Jones seconded and the Board voted unanimously in favor of the motion.

480-10-.10 Prescription Drug Order Copies.

~~(1) For the transfer of prescription drug orders between pharmacies, refer to Ga. Comp. R. & Reg. r. 480-27-.07. Only a licensed pharmacist or a licensed pharmacy intern/extern, acting under the direct supervision of a licensed pharmacist, may prepare, receive, read, or transfer a copy of a prescription drug order to any person, and then only to a licensed pharmacist or licensed pharmacy intern/extern, acting under the direct supervision of a licensed pharmacist, who is authorized to receive and give such information as follows:~~

~~(a) When a copy of prescription drug order is received manually, meaning without the use of a computer or other electronic means, the person receiving such copy shall immediately reduce the information to writing by creating a hard copy prescription drug order which, besides the required prescription data, should include at a minimum the following information;~~

- ~~1. The name of the pharmacist or pharmacy intern/extern who received the prescription drug order;~~
- ~~2. The name of the transferring pharmacy and its telephone number along with the name of the pharmacist or pharmacy intern/extern who provided the information for the prescription drug order copy;~~
- ~~3. The date the prescription drug order copy was received.~~

(b) When a prescription drug order copy is sent and handled manually, meaning without the use of a computer or other electronic means, the person giving such copy shall record immediately upon his or her hard copy prescription drug order the following information:

1. That a copy of the prescription has been given and the prescription drug order is null and void, with the word "VOID" being marked on its face;
2. The name of the pharmacy, and telephone number, where the prescription drug order was transferred;
3. The name of the pharmacist, or pharmacy intern/extern who received the transferred prescription drug order information; and
4. The date on which the prescription drug order was transferred.

(c) When a prescription drug order copy is either sent or received by aid of a computer, or other electronic means, the pharmacist or pharmacy intern/extern should use the procedures for prescription drug order transfers detailed in Rule 480-27-.07.

Bill Prather made a motion to post Rule 480-27-.07 Prescription Drug Order Transfer. Chris Jones seconded and the Board voted unanimously in favor of the motion.

480-27-.07 Dangerous Prescription Drug Order Transfer.

(1) A pharmacy utilizing an automated electronic data processing system must satisfy all the information following requirements as that used in a manual mode when transferring an original dangerous drug a prescription drug order.

(a) The transfer of original prescription information for a dangerous drug for the purpose of refill dispensing is permissible between pharmacies as long as there are authorized refills.

(b) The transfer of original prescription information for a controlled substance in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online computerized database may transfer the prescription drug order information as many times as there are authorized refills, up to the maximum (5) times, if it is within (6) months from the date of issuance.

(2) The transfer of original prescription drug information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(a) The prescription drug order is transmitted directly to the pharmacy of the patient's choice.

(b) The transfer is communicated directly between licensed pharmacists or licensed interns or externs under the direct supervision of a licensed pharmacist and the transferring pharmacist or intern or extern records the following information: in the pharmacy automated data processing system for that prescription.

1. The word "VOID" is written on the face of the invalidated prescription drug order, and/or indicate in the pharmacy's electronic data system this prescription is void;

2. 1. Record on the reverse of the invalidated prescription drug order the name and address of the pharmacy to which it was transferred and the name of the pharmacist or intern or extern under the direct supervision of a licensed pharmacist receiving the prescription drug order information, or have the electronic data system reflect the fact that the prescription drug order has been transferred, the name and address of the pharmacy to which it was transferred and the name of the pharmacist or intern or extern under the direct supervision of a licensed pharmacist to which it was transferred, and the date of the transfer; and

3. 2. Record the date of the transfer and the name of the pharmacist or intern or extern under direct supervision of a licensed pharmacist transferring the information.

(e) 3. The pharmacist or intern or extern under the direct supervision of a licensed pharmacist receiving the transferred prescription drug order shall reduce to writing, or cause the computer to reduce to writing, the following information which shall be filed as required by O.C.G.A. Title 16, Chapter 13 and Title 25, Chapter 4: record the following in the pharmacy in the pharmacy automated data processing system for that prescription:

1. The word "TRANSFER" shall be written on the face of the transferred prescription and/or indicate in the pharmacy's electronic data system this prescription was a transfer;

2. (i) All information required to be included on the prescription drug order pursuant to all State and Federal laws and regulations shall be provided which shall include at a minimum the following:

(i) (I) Date of issuance of the original prescription drug order;

(ii) (II) Original number of refills authorized on the original prescription drug order;

(iii) (III) Date of original dispensing;

(iv) (IV) Number of valid refills remaining and date of last refill;

(v) (V) The pharmacy's name, address, and original prescription serial number from which the prescription drug order information was transferred; and

(vi) (VI) Name of transferring pharmacist.

3. (ii) Both the original and transferred prescription must be maintained for a period of two years from the date of last refill.

(d) 4. Pharmacies utilizing an accessing a common electronic file or database used to maintain required dispensing information are not required to record on the original hard copy prescription drug order any information when transferring or refilling prescription drug orders ~~as required for pharmacies not utilizing a common electronic file as noted in this Chapter~~. However, a hard copy of the prescription drug order must be generated and maintained by the ~~pharmacist~~ pharmacy refilling or receiving the electronically transferred prescription drug order information. The common database must contain complete records of each prescription drug order transferred.

(c) If the original prescription was received from a prescriber or if the patient presented the original prescription to a pharmacy to be held for future dispensing, and if this prescription has not been filled, it can be transferred to another pharmacy and be treated as an original prescription by the pharmacy to which it was transferred.

Chris Jones made a motion to post Rule 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes.

(1) The transfer of original prescription drug order information for a C-III, IV, or V substance for the purpose of refill dispensing is permissible between pharmacies one time only.

(a) However, pharmacies electronically sharing a real-time, online computerized database may transfer the prescription drug order information as many times as there are authorized refills, up to the maximum of five (5) times, if it is within six (6) months from the date of issuance.

(b) If the original prescription was received from a prescriber or if the patient presented the original prescription to a pharmacy to be held for future dispensing and if this prescription has not been filled, it can be transferred to another pharmacy and be treated as an original prescription by the pharmacy to which it was transferred.

(2) Follow the procedures set forth in Ga. Comp. R. & Regs. r. 480-27-.07 for transfers of prescriptions. ~~A transfer is considered a communication between two licensed pharmacists and/or pharmacy interns/externs. Transfers are subject to the following requirements:~~

~~(a) The transferring pharmacist or pharmacy intern/extern shall record the following information in either real time or at the first opportunity after the transfer:~~

~~1. The word "VOID" must be written on the face of the original, hard copy, invalidated prescription drug order;~~

~~2. The following must be written on the back of the original, invalidated prescription drug order: the name, address, telephone number, and DEA number of the pharmacy to which it is transferred, and the name of the pharmacist receiving the prescription information; and~~

3. The date of the transfer and the name of the pharmacist transferring the information must be recorded on the back of the prescription drug order.

(b) The pharmacist or pharmacy intern/extern receiving the transferred prescription drug order information shall reduce it to writing and record the following information:

1. The word "TRANSFER" shall be written on the face of the transferred prescription drug order hard-copy;

2. All information required to be recorded on a prescription drug order pursuant to this chapter, which shall include:

(i) Date the prescription drug order was originally issued by the prescribing practitioner;

(ii) The number of refills authorized on the original prescription drug order.

(c) Date the prescription drug order was originally dispensed by the transferring pharmacy;

(d) Number of valid refills remaining, and date(s) and pharmacy location(s) where any previous refills were dispensed;

(e) The pharmacy's name, address, telephone number, DEA number, and prescription serial number from which the prescription information was transferred; and

(f) The name of the pharmacist who transferred the prescription drug order.

(3) The original and transferred prescription(s) must be maintained for a period of two years from the date of the last refill.

(4) Pharmacies electronically transferring a prescription drug order for the purpose of refills must maintain the same information and record keeping requirements as do pharmacies with manual, non-electronic record keeping systems.

Chris Jones made a motion to post notice of intent to repeal Rule 480-27-.08 Controlled Substance Prescription Drug Order Transfer. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

~~480-27-.08 Controlled Substance Prescription Drug Order Transfer. Repealed.~~

~~Pharmacies utilizing automated data processing systems must satisfy all information requirements of a manual mode for prescription transferal. The transfer of original prescription information for a controlled substance list in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. Transfers are subject to the following requirements:~~

~~(a) The transfer is communicated directly between licensed pharmacists or intern or extern under the direct supervision of a licensed pharmacist, and the transferring pharmacist or intern or extern records the following information:~~

~~1. The word "VOID" is written on the face of the invalidated prescription drug order;~~

~~2. Record on the reverse side of the invalidated prescription drug order the name and address of the pharmacy to which it was transferred and the name of the pharmacist or intern or extern receiving the prescription drug order;~~

~~3. The date of the transfer and the name of the pharmacist or intern or extern transferring the information is recorded;~~

~~4. The computer record shall reflect the fact that the prescription drug order has been transferred, the name of the pharmacy to which it was transferred, and the date of the transfer, except as otherwise set forth in this Chapter relating to pharmacies utilizing common databases.~~

~~(b) The pharmacist or intern or extern receiving the transferred prescription information shall reduce to writing the following:~~

~~1. The word "TRANSFER" is written on the face of the transferred prescription drug order;~~

~~2. All information required to be on a prescription drug order pursuant to State and Federal laws and regulations shall be provided to the receiving pharmacist which shall include at a minimum the following:~~

~~(i) Date of issuance of the original prescription drug order;~~

~~(ii) Original number of refills authorized on the original prescription drug order;~~

- ~~(iii) Date of original dispensing;~~
- ~~(iv) Number of valid refills remaining and date of last refill;~~
- ~~(v) Pharmacy's name, address, DEA registration number, telephone number and original prescription drug order serial number from which the prescription information was transferred;~~
- ~~(vi) Name of transferring pharmacist or intern or extern.~~
- ~~(c) Both the original and transferred prescription drug order must be maintained for a period of two years from the date of last refill.~~
- ~~(d) Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to record on the original prescription drug order any information when transferring or refilling prescription drug orders as required for pharmacies not utilizing a common electronic file as noted in this Chapter. A hard copy of the prescription drug order must be generated and maintained by the pharmacist refilling the electronically transferred prescription drug order. The common database must contain complete records of each prescription drug order transferred.~~

Bob Warnock made a motion to post Rule 480-7-.05 Reverse Distributors. Laird Miller seconded and the Board voted unanimously in favor of the motion.

480-7-.05 Reverse Distributors.

- (1) Every firm, whether located inside or outside the State of Georgia, which receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant located in the State of Georgia which holds a permit or license to dispense or possess drugs, shall be known as a Reverse Distributor or a Reverse Drug Distributor.
- (2) In order or any Reverse Distributor, wherever located, to engage in the business of receiving drugs for destruction, return credit, or other disposal from a registrant located in Georgia, it must be licensed as a Reverse Distributor by the Georgia State Board of Pharmacy ("Board").
- (3) The minimum information required by the Board in order to register a Reverse Distributor will be the same as required under Rule 480-7-.03(2).
- (4) The minimum requirements for applications for registration as a Reverse Distributor with the Board will be the same as required under Rule 480-7-.03(3).
- (5) Personnel: The licensed Reverse Distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the process of receiving drugs for destruction, credit return, or other means of disposal. Each such person shall have a working knowledge of the requirements for the law and rules for handling such drugs.
- (6) Violations:
 - (a) A license issued to a Reverse Distributor pursuant to this part shall be subject to revocation or suspension upon conviction of the license holder or an employee of a reverse distributor for violations related to federal, state or local laws and/or rules.
 - (b) Violation of any provisions of any applicable Board Rules shall be grounds for the suspension, revocation, or other sanctions of the permit issued hereunder.
 - (c) Any action taken on a license pursuant to this part shall be carried out pursuant to the Georgia Administrative Procedure Act, O.C.G.A. Title 50, Chapter 13.
- (7) Minimum requirements for the storage and handling of prescription drugs and or the establishment and maintenance of prescription drug distribution records by Reverse Distributors. A Reverse Distributor shall follow the same requirements as listed under Board Rule 480-7-.03(7), except as follows:
 - (a) A Reverse Distributor does not have to maintain a separate quarantine area for storing drugs which are outdated, damaged, etc., as noted under Rule 480-7-.03;
 - (b) A Reverse Distributor does not have to maintain drugs under controlled temperature and humidity as required under Rule 480-7-.03;
 - (c) A Reverse Distributor does not have to ensure the condition of drugs that are received or shipped as required under Rule 480-7-.03(7)(d) or (e);

~~(d) In addition to a Reverse Distributor having to follow all of the requirements of Rule 480-7-.03(7),~~
pPrior to a Reverse Distributor removing or receiving drugs from a registrant, the Reverse Distributor must generate paperwork, a copy of which must be provided to and maintained by the registrant and a copy to be maintained by the Reverse Distributor, both for two (2) years, which at minimum records the following:

1. The date and time that the drugs left or were taken from the registrant;
2. A complete inventory of the drugs being transferred to the Reverse Distributor;
3. The name, Board permit number, address, and telephone number of the Reverse Distributor removing the drugs;
4. The name and signature of the responsible person representing the Reverse Distributor physically removing the drugs ~~or receiving the drugs~~; and
5. The name and signature of the pharmacist representing a pharmacy, or responsible person representing another type of registrant transferring the drugs to the Reverse Distributor and the name and principal address of the pharmacy or other registrant from which the drugs are removed; and
6. Any and all other information required under Ga. Comp. R. & Reg. c. 480-50 and applicable federal law and regulation.

(e) Upon a Reverse Distributor's receipt of drugs from a registrant by contract or common carrier, the Reverse Distributor must generate paperwork, a copy of which must be maintained by the Reverse Distributor for two (2) years, which at minimum records the following:

1. The date and time that the drugs were received by the Reverse Distributor;
2. A complete inventory of the drugs received by the Reverse Distributor;
3. The name and signature of the pharmacist representing a pharmacy or responsible person representing another type of registrant sending the drugs to the Reverse Distributor and the name and principal address of the pharmacy or other registrant from which the drugs are sent; and
4. Any and all other information required under Ga. Comp. R. & Reg. c. 480-50 and applicable federal law and regulation.

Discussion was held regarding amendments to Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed. Mr. Prather stated that several months ago he, along with Mr. Jones, were tasked with defining direct supervision. Mr. Prather indicated he conferred with Ms. Wray regarding whether or not the Board had authority to define such and understood, from Ms. Wray, that it did. Additionally, he stated that, at the GPhA meeting last year, the question was asked about whether or not the Board would willing to work with other associations regarding possible amendments to this rule. This led to discussions between him, Mr. Jones, Greg Reybold and Steve Georgeson. He stated the purpose of this amendment is to free up the pharmacist. He explained that pharmacists are coming under a lot of pressure to give various types of vaccines, which requires the pharmacist to be out of the line of sight and out of the pharmacy in addition to patient counseling. He did indicate that some situations, such as bathroom and lunchbreaks were not included in the amendment, but could be considered in the future. With that said, Mr. Prather made a motion to post Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed. Ms. Harris seconded the motion. Director Allen strongly expressed his concerns with the proposed amendments. He further relayed that the amendments would be difficult for the agents to enforce and expressed disappointment that GDNA was not asked for input regarding the amendments. He did emphasize that GDNA would certainly do what the Board would require of them but wanted to go on record that they were opposed to the proposed language. Mr. Miller asked if the Board could possibly take an additional thirty days (30) days to speak to the agents and consider this topic at a future date. President Faulk stated that he wants this to be enforceable. Mr. Prather commented that he does not understand what is not enforceable. Mr. Bracewell suggested voting to post the rule and that would allow time for a comment period. Mr. Prather stated that anyone who is opposed to the rule can address the Board with his/her comments at the public hearing. He stated that the Board has always taken comments into consideration before adopting any amendments. After further discussion was held, Ms. Harris withdrew her second of the motion made by Mr. Prather. Mr. Bracewell

seconded the motion and the Board voted in favor of the motion, with the exception of Ms. Harris and Ms. Arnold who opposed.

480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed.

(1) For the purposes of this rule, the following definitions apply:

(a) “Direct supervision” shall mean that a pharmacist is on duty; is either in the prescription department or is providing care in a consultation room, vaccination room, or area where over-the-counter drugs, devices, and durable medical equipment are displayed; is aware of all activities performed by authorized pharmacy personnel; and is available to provide assistance and direction to authorized pharmacy personnel. This shall not require a pharmacist to maintain a direct line of sight to authorized pharmacy personnel. The supervising pharmacist shall provide a final check of prepared products and document final checks before dispensing.

(b) “Pharmacy care” shall mean those services related to the interpretation, evaluation, or dispensing of prescription drug orders, the participation in drug or device selection, drug administration, and drug regimen reviews, and the provision of patient counseling related thereto.

(2) Except for pharmacy benefit manager retail pharmacies, the owner, manager or proprietor of each pharmacy shall designate an area, room or rooms, which shall be known as the "Prescription Department," and which is primarily devoted to activities related to prescriptions.

~~(2)~~(3) A licensed pharmacist shall be in charge of each pharmacy. His or her name shall be upon the application for the license of the pharmacy; he or she shall be the pharmacist in charge of and have supervision of not more than one pharmacy at one time; and he or she shall be responsible for the conduction of business related to prescriptions within and access to said retail pharmacy.

(a) This regulation is not intended to prohibit any pharmacist from engaging in the practice of pharmacy at more than one pharmacy, if conducted in compliance with the other provisions of this rule and regulation.

(b) This regulation does not prohibit a pharmacist from being in charge of one separately licensed Home Health Care Pharmacy, as defined by Board Rule 480-21, and/or one Nursing Home Pharmacy, and/or one Long Term Health Care Facility Pharmacy, as both are defined in Board Rule 480-24, in addition to being in charge of a retail pharmacy, licensed under Rule 480-10, as long as each pharmacy is operated under the same ownership and is located under the same roof, provided that there is a physical separation of the two pharmacies and separate inventories are maintained for the two pharmacies.

~~(3)~~(4) Except for pharmacy benefit manager retail pharmacies, a Licensed Pharmacist shall be present and on duty in a licensed retail pharmacy as follows:

(a) Entire business establishments which are licensed under O.C.G.A. §26-4-110 as a pharmacy shall have a pharmacist on duty at all time the pharmacy is open for business as follows:

1. Such times when the pharmacist is absent from the pharmacy cannot exceed three (3) hours daily, or more than one and one half (1 1/2) hours at any one time.
2. In the absence of a pharmacist from the pharmacy, the area designated as the prescription department shall be closed and locked in such a manner as to prevent unauthorized entry; and
3. Whenever the pharmacist is absent from the pharmacy, a sign shall be prominently displayed on the entrance to the prescription department announcing "Prescription Department Closed" and such sign shall be clear and legible with letters not less than three (3) inches in size.

(b) If a pharmacy is located in a general merchandising establishment, or if the owner of a business licensed as a pharmacy so chooses, a portion of the space in the business establishment may be set aside and permanently enclosed or otherwise secured; only the permanently enclosed area shall be subject to provisions of this rule and shall be licensed as a pharmacy;

1. In such cases, the area to be licensed or registered as a pharmacy shall be permanently enclosed with a partition built from the floor to the ceiling or in a manner which meets security guidelines submitted to and approved by the Board and upon inspection by the GDNA;
2. In the absence of a pharmacist from the Prescription Department, consultation room, vaccination room, and area where over-the-counter drugs, devices, and durable medical equipment are displayed, the area

designated as the Prescription Department shall be closed and locked in such a manner as to prevent unauthorized entry; and

3. Whenever the pharmacist is absent from the Prescription Department, consultation room, vaccination room, and area where over-the-counter drugs, devices, and durable medical equipment are displayed, a sign shall be prominently displayed on the entrance to the Prescription Department announcing "Prescription Department Closed" and such sign shall be clear and legible with letters not less than three (3) inches in size.

(c) No prescriptions shall be filled, compounded, or dispensed in the absence of a licensed pharmacist, but prescriptions may be dropped off by patients provided there is a "drop box" which can only be accessed by a licensed pharmacist.

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

In the same motion, the Board also 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. § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rule amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Ms. Battle reported that only 2,100 licensees have renewed to date. She requested that everyone please spread the word regarding licensure renewal.

Chris Jones made a motion and Bill Prather 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 Vicki Arnold, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

No report.

Cognizant's Report – Chris Jones

- GDNA Case # T-31956
- GDNA Case # A-16-17
- GDNA Case # B-31755
- GDNA Case #A-31061
- GDNA Case # A-31931
- GDNA Case # A-31733
- GDNA Case # A-31886
- GDNA Case # B-31775
- GDNA Case # B-31906
- GDNA Case # A-31923

Attorney General's Report – Janet Wray

Ms. Wray discussed the following case:

- P.P.S.

Ms. Wray presented the following consent orders:

- A.P.
- W.D.P.

Executive Director's Report – Tanja Battle

Presentation regarding confidential file sharing and agenda items through Sharepoint.

Applications

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

Correspondences/Requests

- A.A.
- A.H.C.
- D.P.S.
- F.S.S.P.
- G.R.
- H.M.C.P.I.
- M.V.S.P.
- W.P.N.
- I.P.
- H.S.I.
- R.A.H.
- S.P.
- T.P.

- Z.P.
- D.C.H.
- A.R.P.
- J.W.
- S.J.G.
- S.S.
- G.R.J.
- P.S.H.
- C.H.F.
- C.P.F.
- U.C.P.
- V.R.J.
- T.H.M.

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

Open Session

Bill Prather made a motion for the Board to take the following actions:

Appearances

- | | | |
|----------|----------------------------------|---|
| • W.K.K. | Request to discuss reinstatement | Request denied |
| • R.E.D. | Denied Pharmacist Exam Applicant | Denial upheld |
| • D.L.R. | Denied Pharmacist Exam Applicant | Overturn denial and approve to sit for the exam |
| • C.A.W. | Request to discuss reinstatement | Request approved |
| • O.F.O. | Pending Pharmacist Reinstatement | Request approved |

Attorney General’s Report – Janet Wray

- Legal advice regarding Rule 480-27-.03 Records of Dispensing and Chapter 480-7B Third Party Logistics Providers. No action taken.

Georgia Drugs and Narcotics Agency – Rick Allen

No report.

Cognizant’s Report – Chris Jones

- | | |
|-----------------------|---|
| • GDNA Case # T-31956 | Revoke Technician Registration |
| • GDNA Case # A-16-17 | Close case with letter of concern |
| • GDNA Case # B-31755 | Close case with letter of concern |
| • GDNA Case #A-31061 | Refer to the Attorney General’s office for discipline |
| • GDNA Case # A-31931 | Refer to the Attorney General’s office for discipline |
| • GDNA Case # A-31733 | Refer to the Attorney General’s office for discipline |
| • GDNA Case # A-31886 | Refer to the Attorney General’s office for discipline |
| • GDNA Case # B-31775 | Close case with no action |
| • GDNA Case # B-31906 | Close case with no action |
| • GDNA Case # A-31923 | Refer to the Attorney General’s office for discipline |

Attorney General’s Report – Janet Wray

Ms. Wray discussed the following case:

- P.P.S. No action taken

Ms. Wray presented the following consent orders:

- Amit Patel Public Consent Order accepted
- W.D.P. Private Consent Order accepted

Executive Director’s Report – Tanja Battle

Presentation regarding confidential file sharing and agenda items through Sharepoint.

Applications

- | | | |
|-----------------------|--------------------------|---|
| • M.A.H. | Pharmacy Technician | Table pending receipt of additional information |
| • Peggy M. Hampton | Pharmacy Technician | Approve for registration |
| • D.A.G. | Pharmacy Technician | Table pending receipt of additional information |
| • C.L.W. | Pharmacy Technician | Table pending receipt of additional information |
| • A.M.C. | Pharmacy Technician | Denied registration |
| • Lindsay T. Hall | Pharmacist Intern | Approved application |
| • Aakash A. Patel | Pharmacist Intern | Approved application |
| • Aaron J. Chu | Pharmacist Intern | Approved application |
| • Alex S. Kilgore | Pharmacist Intern | Approved application |
| • C.E.W. | Pharmacist Intern | Table pending receipt of additional information |
| • Kim-Gung T. Phung | Pharmacist Intern | Approved application |
| • Phillip C. Smith | Pharmacist Intern | Approved application |
| • Steve H. Cho | Pharmacist Intern | Approved application |
| • T.S.S. | Pharmacist Intern | Denied application |
| • Traci B. Mobley | Pharmacist Intern | Approved renewal |
| • Kristin L. King | Pharmacist Intern | Approved renewal |
| • H.R. | Pharmacist Reciprocity | Approved to sit for the exam |
| • R.D.B. | Pharmacist Reciprocity | Approved to sit for the exam |
| • L.J.B. | Pharmacist Examination | Denied application |
| • Radina V. Raytcheva | Pharmacist | Approved renewal |
| • Robert J. Conaway | Pharmacist Reinstatement | Approved application |
| • Keyur R. Patel | Pharmacist | Approved renewal |
| • Dalia L. Zall | Pharmacist Cert of DTM | Approved application |
| • Kathryn B. McDaniel | Pharmacist Cert of DTM | Approved application |

Correspondences/Requests

- | | | |
|--------------|-------------------------|---|
| • A.A. | Notice of adverse event | No action taken |
| • A.H.C. | Notice of discipline | No action taken |
| • D.P.S. | Notice of discipline | No action taken |
| • F.S.S.P. | Notice of discipline | No action taken |
| • G.R. | Notice of discipline | No action taken |
| • H.M.C.P.I. | Notice of discipline | No action taken |
| • M.V.S.P. | Notice of discipline | No action taken |
| • W.P.N. | Notice of discipline | Table pending receipt of additional information |

• I.P.	Notice of discipline	No action taken
• H.S.I.	Notice of discipline	No action taken
• R.A.H.	Notice of discipline	No action taken
• S.P.	Notice of discipline	No action taken
• T.P.	Notice of discipline	No action taken
• Z.P.	Notice of discipline	No action taken
• D.C.H.	Remote order entry	Denied
• A.R.P.	Appealing Board's decision to deny request for a 4 th attempt to take NAPLEX	Denial upheld
• J.W.	Appealing Board's decision to deny request for a 4 th attempt to take NAPLEX	Denial upheld
• S.J.G.	Appealing Board's decision to deny request to take the NAPLEX before the 91 day wait period	Denial upheld
• S.S.	Request to take NAPLEX before the required 91 day wait period	Request denied
• G.R.J.	Request to terminate probation	Request approved
• P.S.H.	Appearance request	Request approved
• C.H.F.	Appearance request	Request approved
• C.P.F.	Notice of discipline	No action taken
• U.C.P.	Compliance information	No action taken
• V.R.J.	Request to take MPJE a 4 th time	Request approved
• T.H.M.	Correspondence regarding Inspection	Table pending receipt of information

Chris Jones seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 5:14 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, November 9, 2016 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director