

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St, N.W. 36th Floor
Atlanta, GA 30303
September 14, 2016
9:00 a.m.

The following Board members were present:

Mike Faulk, President
Chris Jones, Vice-President
Vicki Arnold
Jim Bracewell
Lisa Harris (*arrived @ 9:31 a.m.*)
Laird Miller
Bill Prather

Staff present:

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

Visitors:

Jeff Cox
Henrietta Harvey
Cynthia Smith
Shayroz Ladhani
Roseane Santos
Derek Norton, MAG
Bethany Sherrer, MAG
Greg Reybold, GPhA
Young Chang, Walgreens
David Eichenblatt, Smart Door and Delivery
Kathy Eichenblatt, Smart Door and Delivery
R. Nathan, Smart Door and Delivery
Ryan Koenig, Roadrunner Pharmacy
Leighanne Jacobson, Publix
Bryan N. Layman, River Edge Behavioral
Kathi Teasley, New Horizons
Cameron Brown, Wal-Mart
George Ray, Nelson Mullins
Kim Hazelwood, DPH
Carrie Moss, Bendin Sumrall and Ladner

President Faulk established that a quorum was present and called the meeting to order at 9:02 a.m.

Jim Bracewell 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, Chris Jones, Laird Miller, and Bill Prather.

Executive Session

Appearances

- J.F.C.

- H.H.
- C.L.S.
- S.L.
- R.M.S.

Attorney General’s Report – Janet Wray

Ms. Wray presented the following consent orders:

- C.V.S.P.
- J.P.
- U.C.P.
- S.L.
- S.U.
- H.S.T.S.
- B.H.S.
- B.D.S.V
- R.C.P.
- W.P.

Ms. Wray discussed the following cases:

- L.L.W.
- W.P.F.E.

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

Open Session

President Faulk welcomed the visitors.

Appearances

Appearance by David Eichenblatt, Smart Door and Delivery, LLC: Mr. Eichenblatt thanked the Board for the opportunity to speak to its members. Mr. Eichenblatt presented the Board with the Smart Door & Delivery system and gave a brief demonstration as to how the product works. He stated the product is designed to securely deliver packages to the patient. Mr. Eichenblatt stated that a law firm has verified that this product meets the signature requirements for shipments and he would like to have confirmation from the Board. Ms. Wray stated that she did have several concerns regarding the product. She stated the concept was great; however, the way the law and rule read is that you do not have a pre-filed signature. The signature is to be received at the time the prescription is delivered. She stated she is also concerned about the lack of a safeguard in checking the person’s driver’s license and verification of the signature. President Faulk informed Mr. Eichenblatt that the Board would do its due diligence and get a response to him as soon as possible regarding the information presented.

Appearance by Kathi Teasley, New Horizons Behavioral Health: Ms. Teasley gave the Board information regarding her background and explained that the rule petition previously submitted by New Horizons Behavioral Health had been denied. She explained the reason for the request for the waiver. After further discussion was held by the Board, Ms. Wray explained O.C.G.A. § 43-34-23 Delegation of authority to nurse or physician assistant. Ms. Wray stated that the facility can do a protocol pursuant to O.C.G.A. § 43-34-23 and operate legally. She also referred Ms. Teasley to the provision called Physician Collaborative Practice agreement.

Approval of Minutes

Bill Prather made a motion to approve the Open Session minutes for the August 3, 2016 meeting. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Laird Miller made a motion to approve the Executive Session minutes for the August 3, 2016 meeting. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Laird Miller made a motion to approve the Public Session minutes for the September 8, 2016 Conference Call. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Chris Jones made a motion to approve the Executive Session minutes for the September 8, 2016 Conference Call. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Ratifications

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

Petition for Rule Waiver – Orexigen Therapeutics, Inc.

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

Petition for Rule Variance – Melody A. Evans

Bill Prather made a motion to deny the rule variance petition. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Riverwoods Behavioral Health System, PHH007784

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

Petition for Rule Waiver - Gateway 341 Pharmacy, PHH005598

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

Correspondence from Laura Davis

The Board considered this correspondence asking if pharmacists in Georgia are approved to administer a penicillin skin test. The Board directed staff to respond to Ms. Davis by stating that there is no authority in the law that would allow pharmacists to do this.

Correspondence from Joshua Coons

The Board considered this correspondence regarding obtaining licensure in Georgia. The Board directed staff to verify individual's status on NABP and send response regarding licensure by reciprocity.

Correspondence from Kimberly Hazelwood, Georgia Department of Public Health

The Board considered this correspondence, which was previously tabled at the August 2016 meeting, regarding the Board's intentions regarding Rule 480-10-18 Utilization of Unused Prescription Drugs since House Bill 987 passed and O.C.G.A. §§ 26-4-190 thru 26-4-195 have been repealed. The Board directed Ms. Foreman to start the repeal process for Rule 480-10-18.

Correspondence from Kimberly Hazelwood, Georgia Department of Public Health

The Board considered this correspondence regarding the Pilot Project for Pandemic Influenza. Ms. Hazelwood was present at the meeting and responded to questions from the Board. President Faulk asked

when the vaccines are drop shipped, are they only to be given at the locations listed in the correspondence from Ms. Hazelwood. Ms. Hazelwood responded that this is a pilot and will be used to create a model. She stated that she thinks it is to contractually figure out what pharmacies in Georgia would be agreeable in terms of logistics and if it is feasible to work with pharmacies and develop a Memorandum of Understanding (MOU). She indicated the MOU would be the first step in the event of a pandemic. Mr. Prather asked if the idea is that these pharmacies would have adequate storage so the vaccine would go to them in a pandemic situation for the purpose of administration. Ms. Hazelwood responded that is part of the pilot and logistics. She does not believe becoming a distribution center would work for a pharmacy, but that is a question that could be asked.

In her correspondence to the Board, Ms. Hazelwood provided a list of independent pharmacies suggested by the Georgia Pharmacy Association (GPhA) that would assist in the event of a pandemic. President Faulk informed Ms. Hazelwood that the Board had no objections to the locations listed.

Correspondence from James Wheeler

The Board considered this correspondence regarding CLIA waived testing. The Board directed staff to respond to Mr. Wheeler by suggesting he contact the Georgia Department of Community Health's Healthcare Facility Regulation Division for more information regarding this matter.

Correspondence from Toni Bowen, Genoa a Qol Healthcare Co

The Board considered this correspondence from Ms. Bowen requesting to appear before the Board to discuss the issues surrounding its Crisis Stabilization Units (CSUs). The Board directed staff to schedule Ms. Bowen for the next available appointment.

Correspondence from Meghan Fields, University of South Carolina Columbia

The Board considered this correspondence regarding the University of South Carolina Columbia's teaching programs in Georgia. The Board directed staff to respond to Ms. Fields by stating that her letter to the Board is not clear. If she will be teaching a pharmacy program that will lead to pharmacy licensure in the State of Georgia, she will need the approval of the Board. However, if she is inquiring about expanding the program from the University of South Carolina Columbia into Georgia, she should contact the Georgia Board of Regents.

Correspondence from Scottie Barton, Riverside Pharmacy

The Board considered this correspondence regarding unused medication and the destruction of medication. The Board directed staff to respond to Mr. Barton by referring him to Chapter 480-50 Drug Disposal and Authorized Collectors for more information.

Correspondence from Noelle Wooten, Kilpatrick Townsend & Stockton, LLP

The Board considered this correspondence requesting clarification regarding sections (c) and (d) of Rule 480-7-.05 Reverse Distributors. Ms. Wray stated that Ms. Wooten has pointed out some items that the Board needs to look at with the new law. She further stated the Board needs to amend its rule regarding reverse distributors. The Board referred this matter to Ms. Foreman to review.

Correspondence from Erin Engsborg, Center for Pharmacy Practice Accreditation (CPPA)

The Board considered this correspondence requesting recognition from the Board for specialty pharmacy practice accreditation. The Board directed staff to schedule Ms. Engsborg for an appearance to present this information to the Board.

Correspondence from Beatriz Duque Long, Epilepsy Foundation

The Board viewed this correspondence for informational purposes only.

Georgia Drugs and Narcotics Agency – Rick Allen

No report.

Attorney General’s Report – Janet Wray

No report.

Executive Director’s Report – Tanja Battle

Renewals: Ms. Battle reported that renewals are up and running. She added that reminder notices have been emailed to those with a valid email address on file. Additionally, paper reminders have been sent to those without an email address.

ACPE Invitation – State Board Observer for On-Site Evaluation: Ms. Battle 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. Mr. Prather stated he would check his schedule and report back to the Board at its October meeting as to whether or not he will be able to attend.

Continuing Education Report: Report presented. Vicki Arnold made a motion to ratify the below named continuing education program approved since the previous meeting. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Sponsoring Group	Program Title
Kaiser Permanente	New Drugs and Tricks: HIV Management in 2016

Newsletter: Ms. Battle reported that she and Mr. Bracewell have worked on newsletter information and will discuss this topic further at the Board’s October meeting.

Miscellaneous

Laird Miller made a motion to post Rules 480-8-.06 Drug Distribution and Control, 480-13-.06 Drug Distribution and Control, 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances or Dangerous Drugs, 480-18-.06 Drug Distribution and Control, 480-33-.06 Drug Distribution and Control, and 480-10-.20 Required Notifications to the Board as amended. Bill Prather seconded and the Board voted unanimously in favor of the motion.

480-8-.06 Drug Distribution and Control.

Drug Distribution and Control shall be as follows:

- (a) General. A drug distribution system is the entirety of that mechanism by which a practitioner's prescription drug order is executed, from the time the prescriber transmits the order either orally or in writing to an authorized health professional through the time the ordered drug is administered to the patient or delivered to the patient for self-administration.
- (b) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution control, and accountability for drugs. The other professional staff of the prison clinic shall cooperate with the Director in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials so as to achieve this purpose. Accordingly the Director shall be responsible for, at a minimum, the following:
 - 1. The drugs must be identified up to the point of administration;
 - 2. The pharmacy must receive a direct copy or mechanical copy of a physician's order before the first dose of medication is dispensed except as defined by prison clinic stat order policy;
 - 3. Utilization of a pharmacy-generated patient profile. This shall be the official record of medications dispensed to the patient. The patient profile shall be maintained under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:
 - (i) Given and last name;

- (ii) DOC I.D. Number or any other assigned I.D. Number;
 - (iii) Date of birth;
 - (iv) Sex;
 - (v) Dorm or permanent housing assignment;
 - (vi) Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;
 - (vii) Identification or differentiation of controlled substances;
 - (viii) Selected medical data; and
 - (ix) Sensitivities and allergies to drugs and foods.
4. Maintaining no more than a 7day's supply of unit dose medication with prison clinic labeling or no more than a 30-day supply of maintenance medication with retail labeling.
 5. Establishment of specifications or use of compendial specifications for procurement of drugs, chemicals, and biologicals, subject to approval of the appropriate committee of the prison clinic;
 6. Participation in development of a drug formulary for the prison clinic;
 7. Filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;
 8. Maintaining and making available a sufficient inventory of antidotes and other emergency drugs. Current antidote information, telephone numbers of regional poison control center(s) and other emergency assistance organizations, and such other materials and information as may be deemed necessary shall also be maintained;
 9. Records of all transactions of the prison clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;
 10. Participation in those aspects of the prison clinic patient care evaluation program which relate to pharmaceutical material utilization and effectiveness, and,
 11. Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.
- (c) Labeling. Labeling shall include:
1. For use inside the prison clinic, all drugs dispensed by a prison clinic pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.
 2. For use outside the prison clinic or institution, all drugs dispensed by a prison clinic pharmacy to inmates housed outside the prison clinic or those about to be released or on leave shall be labeled with the following information:
 - (i) Name, address and telephone number of the prison clinic pharmacy;
 - (ii) Date and identifying serial number;
 - (iii) Full name of patient;
 - (iv) Name of drug, (brand or generic) and strength;
 - (v) Directions for use to the patient;
 - (vi) Name of practitioner prescribing;
 - (vii) Require precautionary information regarding controlled substances; and,
 - (viii) Such other and further accessory cautionary information as may be required or desirable for proper use and safety to the patient.
 - (d) Discontinued drugs. The Director of Pharmacy shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the prison clinic pharmacy for proper disposition according to the following:
 1. The following method of destruction of non-controlled substances is approved by the Board for medications dispensed to patients residing in a prison facility. When noncontrolled drugs are expired, discontinued from use or the patient for whom they are ordered expires, the drugs shall be immediately removed from the active stock and inventoried by a pharmacist, along with another licensed healthcare

professional or a corrections officer. The completed inventory shall be signed and dated by those two individuals. The original inventory shall be maintained by the facility for two years, and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs can either be:

a. Placed in a secure storage area at the facility separated from medications with active orders. The drugs can be destroyed at the facility by the pharmacist and another licensed healthcare practitioner designated by the facility. However, before the destruction can take place, it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction along with the inventory for two years. This record shall include at a minimum the date, time, personnel involved with the destruction and the method of destruction; or

b. The drugs for destruction are removed from the pharmacy by transfer to a reverse distributor with a current permit issued by the Board and a record of the following is maintained by the Prison Clinic for at least two years:

(1) An inventory of the drugs to be transferred including the names of the drugs, the dosage form(s) of the drugs and the quantity of the drugs; the inventory shall be verified by a pharmacy representative and a representative of the reverse distributor;

(2) The date and time the drugs were taken from the pharmacy;

(3) The name, Board permit number, address and telephone number of the destruction firm removing the drugs;

(4) The name and signature of the responsible person representing the reverse distributor who is physically removing the drug(s);

(5) The name and signature of the Pharmacist representing the pharmacy transferring the drug(s) to the reverse distributor.

2. The following methods of destruction of controlled substances are approved by the Board of Pharmacy:

(a) A securely attached wooden or metal cabinet will be made available within a locked limited-access area. When controlled drugs are discontinued or the patient expires, the medication shall be pulled ~~from~~from the active stock immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional or a correction officer. The inventory must be recorded into a permanent record and the drugs shall then be placed in the aforementioned cabinet. This medication would remain within the locked cabinet until such time that it is removed for destruction.

1. The pharmacist will establish a form, which shall include the following data:

i. Date of discontinuance or inventory date;

ii. Name of patient;

iii. Name of issuing pharmacy;

iv. Identifying serial numbers;

v. Name and strength of drug; and

vi. Quantities of drugs in containers when inventoried.

2. A licensed pharmacist must destroy the drugs in the presence of at least two witnesses.

3. Inventory of the drugs included in the final destruction must be taken with one copy retained by the facility. The inventory shall be certified by all three witnesses present at the destruction in the following format:

"We whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____ (location) on _____ (date) _____ o'clock.

Name of drug

Strength of drug

(Signature and Title)

(Signature and Title)

(Signature and Title)

4. The Board and/or the GDNA may prohibit any pharmacist or prison clinic facility from utilizing this method.

(b) A method of off-site destruction allowable by the Board is as follows:

1. The drugs to be destroyed shall be immediately removed from the active stock and stored in a separate and secure location in the pharmacy until they are transferred. When the drugs are transferred to a reverse distributor licensed by the Georgia Board, an inventory including the names of the drugs, the dosage forms of the drugs and the quantities of drugs is taken and witnessed by an authorized representative of the prison clinic pharmacy and the responsible person representing the reverse distributor.

2. The prison clinic pharmacy must maintain a receipt/record with the following information: the date and time the drugs were taken from the pharmacy; the name, Board permit number, address and telephone number of the reverse distributor removing the drugs; the inventory of the drugs; the name, signature and title of the responsible person representing the reverse distributor; and the name, signature and title of the ~~pharmacy~~ pharmacy representative transferring the drugs. This receipt/record must be maintained by the prison clinic pharmacy for a minimum of two years.

(e) Prescription Drug orders. Drugs may be dispensed from the prison clinic pharmacy only upon written orders, direct or copies thereof, of authorized practitioners.

1. Authorization. The appropriate committee of the prison clinic shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.

2. Abbreviations. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the prison clinic.

3. Requirements--orders for drugs for use by inpatients. Orders for drugs for use by inpatients shall, at a minimum, contain:

(i) Patient name and dorm or permanent housing assignment;

(ii) Drug name, strength, directions for use; and

(iii) Date and physician's signature.

4. Requirements--orders for drugs for use by outpatients. Orders for drugs for use by outpatients shall at a minimum, contain all of the items required by Rule 480-8-.06(e)3., and in addition:

(i) Dispensing quantity; and

(ii) Practitioner's address and Drug Enforcement Administration permit number, if applicable.

(f) Accountability of Controlled Drugs--Proof of Use of controlled substances on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the prison clinic, shall be submitted to the pharmacy, on forms provided by the pharmacy.

1. Proof of use forms shall specify at a minimum:

(i) Name of drug, strength, and dosage form;

(ii) Dose;

(iii) Name of ordering physician. This shall include, at a minimum, the initial and last name;

(iv) Given and last name of inmate, DOC I.D. Number, or any other assigned I.D. Number;

(v) Date and time of administration to patient;

(vi) Signature of individual administering the drug, which shall include at a minimum, the initial, last name and title;

(vii) Documentation of destruction of all unused portions by two signature verifications of two licensed staff members;

(viii) Proof of receipt of medications that bears identifying serial numbers; and

(ix) Date the medication was issued and the date that the proof of use form was returned.

2. Use of computer hard copy is permitted where such copy meets all other requirements of the law.

3. Any prison clinic pharmacy licensed by the Board and in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for oral administration provided:

(i) The controlled substance is the remainder of a single-dosage unit; and

(ii) The single-dosage unit from which the ordered dose prepared is the nearest possible size to the dose ordered.

4. Perpetual inventory of Schedule II controlled substances shall be required and accountability of said drugs shall be by proof of use form.

(g) Recall. The Director of Pharmacy shall develop and implement a recall procedure to assure that all drugs within the prison included on the recall are returned to the prison clinic pharmacy for proper disposition.

(h) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering physician, the pharmacy, and to the appropriate committee of the prison clinic. An appropriate entry on the patient's record shall also be made.

(i) Records and reports. The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board or its employees. These shall include, at a minimum, the following:

1. Patient profile;

2. Proof of use documents;

3. Reports of suspected adverse drug reactions;

4. Inventories of night cabinets and emergency kits/crash carts;

5. Inventories of the pharmacy;

6. Biennial controlled substances inventories;

7. Alcohol and flammables reports; and

8. Such other records and reports as may be required by Law and Rules and Regulations of the Board of Pharmacy.

(j) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a prison clinic for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said prison clinic or by an inventory replacement system. These drugs may be administered only pursuant to a physician's order. This physician's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A survey of usage trends of each standard ward inventory shall be made monthly. Such records shall be maintained for a period of two (2) years.

(k) Reports of Loss or Theft.

1. Definitions.

(i) An "immediate notification" is within seventy-two (72) hours of loss or theft being discovered.

Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.

(ii) A "significant amount" is 20% of a manufacturer's stock unit within a six-month period.

2. The Georgia Drugs and Narcotics Agency (GDNA) shall immediately be notified of the occurrence of the following: the theft of a significant amount of any controlled substance or any dangerous drug identified by the Board as having the potential for abuse or theft; the theft or any loss of a significant amount of any controlled substance where theft is suspected; or the theft or any loss of any dangerous drug identified by the Board as having the potential for abuse or theft where theft is suspected. The registrant shall send a completed copy of the appropriate form to GDNA. A GDNA Form 215 shall be used to report theft or loss of dangerous drugs, and a DEA Form 106 shall be used to report theft or loss of controlled substances.

3. A GDNA Form 215 or DEA Form 106 shall be maintained at the facility for two (2) years. Such form shall be made immediately available upon verbal request by the GDNA.

4. The submission of a GDNA Form 215 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances.

5. All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.

6. The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed GDNA Form 215 or DEA Form 106 where required under this rule.

7. Copies of a GDNA Form 215 can be found at <http://gdna.georgia.gov/> or <http://gbp.georgia.gov/> or by contacting GDNA at (404) 656-5100 or (800) 656-6568.

480-13-.06 Drug Distribution and Control.

(1) General. A drug distribution system is the entirety of that mechanism by which a prescription drug order is executed, from the time the practitioner transmits the order either orally or in writing to an authorized health professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration.

(2) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the hospital shall cooperate with the Director of Pharmacy in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials to achieve this purpose. The Director of Pharmacy shall establish written procedures for the distribution of parenteral medications to achieve this goal. Accordingly, the Director of Pharmacy shall be responsible for, at a minimum, the following:

(a) The compounding, admixture, and quality control of large volume parenterals is the responsibility of a pharmacist and shall be prepared under a Laminar Flow Hood or utilizing such other equipment to protect the integrity of the product, within the pharmacy department. Individuals who prepare or administer large volume parenterals must have special training to do so. These functions of IV admixture compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas such as Intensive Care Units, Cardiac Catheterization Laboratories Intensive Care Units, etc., during emergency situations, or during unattended hours of the pharmacy department. When any part of the above functions (preparing, sterilizing, and labeling parenteral medications and solutions) is performed within the hospital but not under direct pharmacist supervision, the Director of Pharmacy shall be responsible for providing written guidelines and for approving the procedures to assure that all pharmaceutical requirements are met;

(b) All drugs must be identified up to the point of administration;

(c) The pharmacy must receive a direct copy, electronic or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by hospital stat order policy;

(d) Utilization of a pharmacy-generated patient profile. The patient profile shall be the official record of medications dispensed to the patient. The patient profile or the ability to generate such profile electronically shall be under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:

1. Given and last name of the patient;

2. Age;

3. Sex;

4. Provisional diagnosis;

5. Room number;

6. Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;

7. Identification or differentiation of controlled substances;

8. Intravenous therapy;
 9. Selected medical data;
 10. Drug history interview (when possible); and
 11. Sensitivities and allergies to drugs and foods;
- (e) No more than a 72-hour supply of a patient's medication shall be available at the patient-care area at any time except for those drugs in bulk packages which cannot be repackaged in unit-dose containers;
- (f) Manufacture of drugs, if applicable;
- (g) Establishment of specifications or use of compendia specifications for procurement of drugs, chemicals, devices and biologicals, subject to approval of the appropriate committee of the hospital;
- (h) Participation in the development of a drug formulary for the hospital;
- (i) filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;
- (j) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs. Current antidote information, telephone numbers of regional poison control center(s) and other emergency assistance organizations, and other material and information as may be deemed necessary shall be maintained;
- (k) Records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over the accountability for all pharmaceutical drugs, devices and materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;
- (l) Participation in those aspects of the hospital patient care evaluation program which relate to pharmaceutical drug, device and material utilization and effectiveness; and
- (m) Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.
- (3) Labeling.
- (a) For use inside the hospital, all drugs dispensed by a hospital pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.
- (b) For use outside the hospital, all drugs dispensed by a hospital pharmacy to patients about to be discharged or on leave of absence shall be labeled with the following information:
1. Name, address, and telephone number of the hospital pharmacy;
 2. Date and identifying serial number;
 3. Patient's given and last name;
 4. Name of drug, (brand or generic) and strength;
 5. Directions for use by patient;
 6. Name of prescribing practitioner;
 7. Required precautionary information regarding controlled substances; and
 8. Such other and further accessory cautionary information as may be required or desirable for proper use by and safety of the patient.
- (c) Drugs added to parenteral solutions. Wherever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a licensed pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and the identity of the person so adding.
- (4) Discontinued drugs. The Director of Pharmacy shall develop and implement policies and procedures to insure that outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.
- (a) Full doses of controlled substances prepared for administration and not given must be destroyed by a licensed pharmacist or a licensed nurse and one witness. Any portions of controlled substances discontinued and taken from a medication delivery device shall be destroyed by a licensed pharmacist or a licensed nurse and one witness. The two persons witnessing the destruction must sign the destruction record at the time of destruction. The destruction record shall be returned to the pharmacy and must be

signed by the pharmacist who is ultimately responsible for the accuracy of the information contained therein.

(b) In accordance with the policies and procedures developed by the Director of Pharmacy, discontinued non-controlled substances dispensed to hospital patients shall be returned to the pharmacy and evaluated by the licensed pharmacist to assure the integrity of the medication. If the integrity can be assured, the medication may be returned to the hospital's drug distribution system for re-issue. When the integrity cannot be assured, the medication must be separated immediately from the regular drug inventory and destroyed or transferred to a reverse distributor with a current license issued by the Board. The following method of destruction of noncontrolled substances is approved by the Board for medications dispensed to hospital patients or patients residing in nursing homes or long term care units which are part of a hospital facility;

1. Placed in a secure storage area at the facility separated from other medications. The drugs may be destroyed at the facility by the pharmacist and another licensed healthcare practitioner designated by the facility. However, before the destruction can take place, it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction and the inventory for a two year period. This record shall include at a minimum the date, time, and personnel involved with the destruction and the method of destruction; or

2. If the drugs are to be transferred to a reverse distributor with a current license issued by the Board, a record of the following must be maintained by the hospital pharmacy for a minimum of two years:

(i) An inventory of the drugs to be transferred including the names of the drugs; the dosage form(s) of the drugs and the quantity of the drugs; the inventory shall be verified by a pharmacy representative and a representative of the reverse distributor;

(ii) The date and time the drugs were taken from the pharmacy;

(iii) The name, Board permit number, address and telephone number of the destruction firm removing the drugs;

(iv) The name and signature of the responsible person representing the reverse distributor who is physically removing the drug(s);

(v) The name and signature of the pharmacist representing the pharmacy transferring the drug(s) to the reverse distributor.

(c) The following methods of destruction of controlled substances are approved by the Board of Pharmacy:

1. A securely attached wooden or metal cabinet within a locked limited-access area shall be used to store the drugs until the drugs are destroyed. When controlled drugs are discontinued or the patient expires, the medication shall be pulled from the active stock immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional. The inventory must be recorded into a permanent record and the drugs shall then be placed in the aforementioned cabinet. This medication shall remain within the locked cabinet until such time as it is removed for destruction.

2. The pharmacist shall establish a form, which shall include the following data:

(i) Date of discontinuance or inventory date;

(ii) Name of patient;

(iii) Name of pharmacy;

(iv) Identifying serial numbers;

(v) Name and strength of the drug; and

(vi) Quantity of the drugs in container(s) at the time of inventory.

3. A licensed pharmacist or licensed nurse and one witness must destroy the drugs.

4. Inventory of the drugs included in the final destruction must be taken with one copy retained by the facility. The inventory shall be certified by the two witnesses present at the destruction in the following format:

"We, whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____ (location) on

_____ (date) at _____ o'clock. "

Name of drug
Strength of drug
Dosage form
Quantity of drug

(Signature and Title)

(Signature and Title)

(Signature and Title)

5. The Board and/or the GDNA may prohibit any pharmacist or hospital pharmacy from utilizing this method.

(d) A method of off-site destruction allowable by the Board is as follows:

1. The drugs to be destroyed shall be immediately removed from the active stock and stored in a separate and secure location in the pharmacy until the drugs are transferred. When the drugs are transferred to a reverse distributor licensed by the Board, an inventory must be recorded and include the following information: the names of the drugs, the dosage forms of the drugs and the quantities of the drugs taken and witnessed by an authorized representative of the hospital pharmacy and the responsible person representing the reverse distributor.

2. A receipt including the date and time the drugs were taken from the pharmacy; the name, Board permit number, address and telephone number of the reverse distributor removing the drugs; the inventory of the drugs; the name, signature and title of the responsible person representing the reverse distributor; and the name, signature and title of the pharmacy representative transferring the drugs. This receipt/record must be maintained by the hospital pharmacy for a minimum of two years.

(5) Prescription drug orders. Drugs may be dispensed from the hospital pharmacy only upon written orders, direct or mechanical copies thereof, of authorized practitioners.

(a) Authorization. The appropriate committee of the hospital shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.

(b) Abbreviations. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.

(c) Requirements — Prescription drug orders for drugs, devices or materials for use by inpatients. Prescription drugs orders for use by in-patients shall, at a minimum, contain:

1. Patient name and room number;
2. Drug name, strength, directions for use; and
3. Date and practitioner's signature.

(d) Requirements — Prescription drug orders for drugs, devices or materials for use by outpatients. Prescription drug orders for drugs, devices or materials for use by outpatients shall, at a minimum, contain all of the information required by Rule 480-13-.06(5)(c),

And in addition include:

1. Quantity to be dispensed;
2. Practitioner's address and Drug Enforcement Administration identification code, if applicable, and
3. Patient's address, if applicable.

(6) Accountability of controlled drugs.

(a) Proof of use of controlled drugs on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the hospital, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:

1. Name of drug, strength, and dosage form;
2. Dose administered;
3. Name of authorized practitioner. This shall include, at a minimum, the initial and last name;

4. Given and last name of the patient;
5. Date and time of administration to the patient;
6. Signature of the individual administering, which shall include at a minimum, the initial, last name, and title;
7. Documentation of the destruction of any and all unused portions by two signature verifications;
8. Proof of receipt of the medications that bears identifying serial numbers; and
9. Date the medication was issued and the date that the proof of use form was returned to the pharmacy.
 - (b) Anesthesia departments that obtain controlled drugs from the hospital pharmacy must show accountability of the controlled drugs by proof of use as defined above.
 - (c) Use of computer generated hard copy is permitted where such copy meets all other requirements of the law.
 - (d) Any hospital pharmacy licensed by the Georgia State Board of Pharmacy and in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:
 1. The controlled substance is either a whole dose or a partial dose of a single-dosage unit; and
 2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.
 - (e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.
 - (7) Recall. The Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper disposition.
 - (8) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering authorized practitioner, the pharmacy, and to the appropriate committee of the hospital. An appropriate entry on the patient's medical record shall also be made.
 - (9) Records and reports. The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety and welfare. Such records shall be readily available and subject to inspections by the Board of Pharmacy, the GDNA or its employees. These shall include, at a minimum, the following:
 - (a) Patient profile;
 - (b) Proof of use;
 - (c) Reports of suspected adverse drug reactions;
 - (d) Inventories of night cabinets and emergency kits/crash carts;
 - (e) Inventories of the pharmacy;
 - (f) Biennial controlled substances inventories;
 - (g) Alcohol and flammables reports; and
 - (h) Such other records and reports as may be required by state Law and the Rules and Regulations of the Board of Pharmacy.
 - (10) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a hospital for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said hospital or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order. This practitioner's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A record of administration of drugs administered to patients in ancillary areas such as but not limited to the operating room, emergency room, anesthesiology, and x-ray shall be forwarded to the pharmacy and these medications shall be recorded on the patient profile. A survey of usage trends of each standard ward inventory shall be prepared monthly. Such records shall be retained for a period of two years.
 - (11) Emergency room dispensing. An authorized practitioner may, when drugs or controlled substances are not otherwise available from a licensed pharmacy, dispense an emergency amount of medication, but only sufficient quantities until such time as medication can be obtained from a pharmacy licensed as a retail pharmacy. Nurses or other unauthorized personnel may not dispense medication from the

emergency room. The total act of dispensing shall be performed by an authorized practitioner in accordance with Pharmacy Laws, Rules and Regulations. Such medications shall be labeled as required in Section 480-13-.06(3)(b).

(12) Reports of Loss or Theft.

(a) Definitions.

1. An “immediate notification” is within seventy-two (72) hours of loss or theft being discovered. Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.

2. A “significant amount” is 20% of a manufacturer’s stock unit within a six-month period.

(b) The Georgia Drugs and Narcotics Agency (GDNA) shall immediately be notified of the occurrence of the following: the theft of a significant amount of any controlled substance or any dangerous drug identified by the Board as having the potential for abuse or theft; the theft or any loss of a significant amount of any controlled substance where theft is suspected; or the theft or any loss of any dangerous drug identified by the Board as having the potential for abuse or theft where theft is suspected. The registrant shall send a completed copy of the appropriate form to GDNA. A GDNA Form 215 shall be used to report theft or loss of dangerous drugs, and a DEA Form 106 shall be used to report theft or loss of controlled substances.

(c) A GDNA Form 215 or DEA Form 106 shall be maintained at the facility for two (2) years. Such form shall be made immediately available upon verbal request by the GDNA.

(d) The submission of a GDNA Form 215 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances.

(e) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.

(f) The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed GDNA Form 215 or DEA Form 106 where required under this rule.

(g) Copies of a GDNA Form 215 can be found at <http://gdna.georgia.gov/> or <http://gbp.georgia.gov/> or by contacting GDNA at (404) 656-5100 or (800) 656-6568.

480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances or Dangerous Drugs.

(1) Definitions.

(a) An “immediate notification” means within “seventy-two (72) hours of loss or theft being discovered.” Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.

(b) A “significant amount” means 20% of a manufacturer’s stocking unit within a six month period.

~~(1)~~(2) The theft, loss, or unaccounted inability to account for a significant amount of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft stolen suffered by a pharmacy licensed by the Board to keep controlled substances must, be reported to the Georgia Drugs and Narcotics Agency (GDNA) immediately upon discovery of the occurrence as required in O.C.G.A. §26-4-112. The registrant shall send a completed copy of the appropriate form to GDNA. A GDNA Form 215 shall be used to report theft or loss of dangerous drugs, and a DEA Form 106 shall be used to report theft or loss of controlled substances. This report shall be faxed or mailed to the GDNA office address on the form or emailed to the GDNA Special Agent responsible for the area in which the facility is located, within three (3) days of its discovery, must be reported to the Drug Enforcement Administration and the GDNA.

(a) All pharmacies must maintain a copy of a completed GDNA Form 215 of DEA Form 106 for two (2) years from the time of occurrence.

~~(3) (2) A written report must be made regarding any theft, loss or unaccounted for controlled substances by completing a DEA Form 106. The submission of a GDNA Form 215 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances or dangerous drugs.~~

~~(a) Within ten (10) days of receiving such DEA Form 106, the original and one copy of the report must be sent to the Drug Enforcement Administration; and~~

~~(b) One copy must be sent to the GDNA.~~

~~(4) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.~~

~~(3) The report shall include the following information:~~

~~(a) Full name and address of the pharmacy; (e) List of cost codes, or identification symbols on package stolen; and~~

~~(b) Pharmacy DEA registration number;~~

~~(c) Date of theft, loss, or discovery of missing controlled substance;~~

~~(d) Type of incident, i.e. theft, loss, etc.;~~

~~(e) List of cost codes, or identification symbols on package stolen; and~~

~~(f) List of the controlled substances missing.~~

480-18-.06 Drug Distribution and Control.

(1) General. A drug distribution system is the entirety of that mechanism by which a physician's drug order is executed, from the time the practitioner transmits the order either orally, in writing, or electronically to a licensed health care professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration. No drugs can be dispensed or administered without a physician's medication drug order.

(2) Responsibility. The Director shall be responsible for the safe and efficient distribution, control, and accountability for drugs. The other professional staff, including the physicians, at the OTP clinic shall cooperate with the Director in meeting this responsibility and in ordering, administering, and accounting for the drugs and devices so as to achieve this purpose.

(a) The Director shall establish written policies and procedures for the distribution of medications including emergency kits, etc. to achieve this goal.

1. The drugs must be identified up to the point of administration;

2. The pharmacy must receive a direct, electronic (only for drugs to be administered on site) or mechanical copy of a physician's order before the first dose of medication is dispensed as defined by the clinic stat order policy.

3. At a minimum, the pharmacy must maintain a patient profile for each OTP clinic patient for use in prospective and retrospective drug reviews, for comparing with the central registry as required by the DHR and to report violators to the GDNA and DHR, for discharge from another OTP, and for urine or blood tests to check for drug positive test results.

4. Records of all transactions of the OTP clinic pharmacy, such as daily drug dosing summaries, daily drug inventory sheets, patient medication profiles, and bulk drug inventory records must be maintained by the clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all drugs and devices within the scope of the clinic practice.

5. All drug invoices must be attached to their accompanying DEA form 222 order form and must be filed separately from all other drug records. A biennial inventory of all controlled substances on hand must be taken every two years from the date of the pharmacy opening for business. This inventory must be an accurate count of all such drugs, signed in indelible ink by the pharmacist taking the inventory and dated on the date it is taken.

6. Any drug compounded by the pharmacy must be accounted for by use of a compounding log form. This form, at a minimum must display the date the drug was compounded, the name of the drug, the strength,

quantity made, manufacturer's lot number, manufacturer's expiration date, and the signature of the pharmacist compounding the drug.

7. Nothing in this section shall prohibit the use of computerized records, where such records meet all other requirements of the law. An OTP clinic pharmacy may not dispense or administer prescription medications other than OTP program medications; and

8. The pharmacy must participate in those aspects of the OTP clinic patient care evaluation program which relate to drug and device utilization and effectiveness.

(b) All records must be maintained by the pharmacy for a minimum of two years and be readily retrievable upon request by an agent of the Board.

(3) Labeling:

(a) For use inside the clinic, all drugs dispensed by an OTP clinic pharmacy, including those for use in an after hours safe or emergency kit shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum:

1. Brand name or generic name of the drug;
2. Drug strength;
3. Lot number assigned by either the drug manufacturer or the clinic pharmacy; and
4. Expiration date assigned either by the drug manufacturer or the clinic pharmacy.

(b) Any drug container dispensed by the pharmacy for take-home use by an OTP clinic patient must display a label which contains at least the following:

1. Patient name;
2. Name of the prescribing physician;
3. Name, address and telephone number of the OTP clinic pharmacy;
4. Drug name (either brand or generic name);
5. Drug strength;
6. Date of dispensing;
7. Expiration date of the drug as determined by the pharmacy;
8. "Federal Caution" for controlled substances;
9. Clinic Pharmacy serial number for that specific prescription drug order;
10. Any other labeling or information as required by the DEA;

(c) All take-home medication dispensed by the pharmacy, including one-time use containers, must be in child-proof containers which meet the requirements of the U.S. Consumer Product Safety Commission.

(4) Discontinued drugs. The Director shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(5) Accountability of controlled substances.

(a) Nothing shall prohibit the use of controlled substance drugs issued via proof of use forms for general or emergency use for specific patients. Proof of use controlled substances forms shall be provided by the pharmacy.

(b) Each proof of use form shall display the name of the patient to or for which it has been issued and an indication that the drugs are for general or emergency use and a serial number. The form shall also show the date the form was issued and the signature of the pharmacist issuing the form and the signature of the licensed medical practitioner receiving the form for storage in the after-hour safe. A detachable receipt reflecting all the previous information must be returned and filed by the pharmacy as a safeguard to prevent drug diversion.

(c) Each proof of use sheet shall provide space to record the administration information necessary to account for each dose of medication. This information shall specify at a minimum:

1. Drug name, strength, and dosage form;
2. Dose administered;
3. Name of prescriber. This shall include, at a minimum, the first initial and complete last name of the prescriber;
4. First and last name of the patient;
5. Date and time of administration to patient;
6. Signature of individual administering the dose, which shall include at a minimum, the first and last name and title;

7. Documentation of destruction of all unused portions by two signature verifications of licensed healthcare professionals;
 8. Proof of receipt of medication bearing identifying serial numbers;
 9. Date the medication was issued and date the proof of use form was returned.
- (6) Any OTP clinic pharmacy licensed by the Board may make on-premises destruction of small quantities of controlled substances prepared for oral administration provided:
- (a) The controlled substance is the remainder of a single-dose unit; and,
 - (b) The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.
- (7) Perpetual inventory of Schedule II controlled substances shall be required and accountability of said drugs shall be by an appropriate form indicating at a minimum the date used, name of shipper or drug recipient, corresponding serial number of a drug order, invoice or proof of use form, and quantity received or issued.
- (8) Recall. The Director shall develop and implement a recall policy and procedure to assure that all drugs within the clinic included on the recall are returned to the pharmacy for proper disposition.
- (9) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering physician, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's pharmacy profile shall also be made.
- (10) Security. All areas occupied by an OTP clinic pharmacy shall be capable of being locked by key or combination, so as to prevent unauthorized personnel access except by force. Such areas shall meet the security requirements of all applicable Federal and State laws and rules. Only those persons so authorized shall be permitted to enter these areas.
- (a) All drugs shall be stored in designated areas within the clinic pharmacy or all dispensing medications shall be stored in designated areas within the clinic which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage areas shall be locked or otherwise secured when licensed health care professionals are not present.
 - (b) Storage for Schedule II controlled substances shall be in an enclosed room or space with controlled limited access capable of showing forced entry is preferable. However, a safe or a lockable metal cabinet that is permanently affixed to the structure is acceptable.
 - (c) Whenever any area of an OTP clinic pharmacy is not under the personal and direct supervision of authorized licensed personnel, such areas shall be locked and secured.
- (11) Reports and records. The Director shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board, the GDNA or its designated agents. All such records shall be maintained for a minimum of two years. These shall include, at a minimum, the following:
- (a) Patient profile, chart or other appropriate record;
 - (b) Proof of use forms for controlled substances;
 - (c) Reports of suspected adverse drug reactions;
 - (d) Inventories of after hours safe(s) and emergency drug kits,
 - (e) All perpetual inventories maintained by the pharmacy, and all other records pertaining to controlled substances, including a biennial controlled substances inventory;
 - (f) Such other records and reports as may be required by Federal or State laws and/or rules;
- (12) The compounding, labeling and quality control of large volumes of opioid treatment medication is the responsibility of a pharmacist and shall be prepared within the on-site pharmacy.
- (13) Reports of Loss or Theft.
- (a) Definitions.
1. An "immediate notification" is within seventy-two (72) hours of loss or theft being discovered. Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.
 2. A "significant amount" is 20% of a manufacturer's stock unit within a six-month period.
- (b) The Georgia Drugs and Narcotics Agency (GDNA) shall immediately be notified of the occurrence of the following: the theft of a significant amount of any controlled substance or any dangerous drug identified by the Board as having the potential for abuse or theft; the theft or any loss of a significant amount of any controlled substance where theft is suspected; or the theft or any loss of any dangerous drug identified by the Board as having the potential for abuse or theft where theft is suspected. The registrant shall send a completed

copy of the appropriate form to GDNA. A GDNA Form 215 shall be used to report theft or loss of dangerous drugs, and a DEA Form 106 shall be used to report theft or loss of controlled substances.

(c) A GDNA Form 215 or DEA Form 106 shall be maintained at the facility for two (2) years. Such form shall be made immediately available upon verbal request by the GDNA.

(d) The submission of a GDNA Form 215 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances.

(e) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.

(f) The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed GDNA Form 215 or DEA Form 106 where required under this rule.

(g) Copies of a GDNA Form 215 can be found at <http://gdna.georgia.gov/> or <http://gbp.georgia.gov/> or by contacting GDNA at (404) 656-5100 or (800) 656-6568.

480-33-.06 Drug Distribution and Control.

(1) General. A drug distribution system is the entirety of that mechanism by which a prescription drug order is executed, from the time the practitioner transmits the order either orally, in writing, or electronically to an authorized health professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration.

(2) Responsibility. The pharmacist-in-charge shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the clinic shall cooperate with the pharmacist-in-charge in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials so as to achieve this purpose. The pharmacist-in-charge shall establish written procedures for the distribution of medications including standard ward inventory, emergency kits, etc. to achieve this goal.

(a) The drugs must be identified up to the point of administration;

(b) The pharmacy must receive a direct, electronic (only for drugs to be administered on site) or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by the clinic stat order policy;

(c) Records of all transactions of the clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials within the scope of the clinic practice. Nothing in this section shall prohibit the use of computerized records, where such records meet all other requirements of the law. If an outpatient clinic pharmacy elects to dispense prescription medications other than outpatient prescriptions as defined herein, the pharmacy must meet all applicable State and Federal Laws and regulations and must also obtain a retail pharmacy permit; and

(d) Participation in those aspects of the clinic patient care evaluation program which relate to pharmaceutical material utilization and effectiveness.

(3) Labeling.

(a) For use inside the clinic, all drugs dispensed by a clinic pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.

(b) Drugs added to parenteral admixtures. Wherever any drugs are added to parenteral admixtures, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time, if applicable, and identity of person preparing the admixture.

(4) Discontinued drugs. The pharmacist-in-charge shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(5) Accountability of controlled drugs.

(a) Proof of use of controlled drugs on standard ward inventory and/or those issued for a specific patient. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the clinic, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:

1. Drug name, strength, and dosage form;
2. Dose;
3. Name of prescriber. This shall include, at a minimum, the given and last name;
4. Given and last name of patient;
5. Date and time of administration to patient;
6. Signature of individual administering, which shall include at a minimum, the initial, last name and title;
7. Documentation by two signature verifications of destruction of all unused portions;
8. Proof of receipt of medications that bears identifying serial numbers; and
9. Date medication was issued and the date that the proof of use form was returned.

(b) Anesthesia, surgical, diagnostic and treatment departments that obtain controlled drugs from the clinic pharmacy must show accountability of the controlled drugs by proof of use as defined above.

(c) Use of computer hard copy is permitted where such copy meets all other requirements of the law.

(d) Any outpatient clinic pharmacy licensed by the Georgia State Board of Pharmacy in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:

1. The controlled substance is the remainder of a single-dose unit; and
2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.

(e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.

(f) Recall. The pharmacist-in-charge shall develop and implement a recall policy and procedure to assure that all drugs within the clinic included on the recall are returned to the pharmacy for proper disposition.

(g) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering practitioner, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's record shall also be made.

(h) Records and reports. The pharmacist-in-charge shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board or its agents. These shall include, at a minimum, the following:

1. Patient profile, chart or other appropriate record;
2. Proof of use forms for controlled substances;
3. Reports of suspected adverse drug reactions;
4. Inventories of night cabinets, cabinets or enclosures; emergency drug kits; and standard ward inventories;
5. Inventories of the pharmacy;
6. Biennial controlled substances inventories;
7. Alcohol and flammables reports; and
8. Such other records and reports as may be required by law and the rules and regulations of the Georgia State Board of Pharmacy.

(i) Standard Ward Inventory. The outpatient clinic pharmacy may distribute drugs within a clinic for the purpose of establishing and/ or maintaining a standard ward inventory.

Such drugs may be supplied only upon a signed requisition from an authorized licensed health care professional of said clinic or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order and shall be documented in the patient's record. A record of drugs administered to patients in ancillary areas such as surgical suite, treatment rooms, anesthesiology and diagnostic areas will become a part of the patient's record and shall be retrievable by the pharmacy. A

survey of usage trends of each standard ward inventory shall be made monthly. Such records shall be maintained for a period of two years.

(j) Security of controlled substances. Controlled drugs that are maintained as authorized standard ward inventory in patient care/ treatment areas outside the pharmacy shall be stored in secured cabinets or areas that provide a double lock system.

(6) Reports of Loss or Theft.

(a) Definitions.

1. An “immediate notification” is within seventy-two (72) hours of loss or theft being discovered. Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.

2. A “significant amount” is 20% of a manufacturer’s stock unit within a six-month period.

(b) The Georgia Drugs and Narcotics Agency (GDNA) shall immediately be notified of the occurrence of the following: the theft of a significant amount of any controlled substance or any dangerous drug identified by the Board as having the potential for abuse or theft; the theft or any loss of a significant amount of any controlled substance where theft is suspected; or the theft or any loss of any dangerous drug identified by the Board as having the potential for abuse or theft where theft is suspected. The registrant shall send a completed copy of the appropriate form to GDNA. A GDNA Form 215 shall be used to report theft or loss of dangerous drugs, and a DEA Form 106 shall be used to report theft or loss of controlled substances.

(c) A GDNA Form 215 or DEA Form 106 shall be maintained at the facility for two (2) years. Such form shall be made immediately available upon verbal request by the GDNA.

(d) The submission of a GDNA Form 215 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances.

(e) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.

(f) The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed GDNA Form 215 or DEA Form 106 where required under this rule.

(g) Copies of a GDNA Form 215 can be found at <http://gdna.georgia.gov/> or <http://gbp.georgia.gov/> or by contacting GDNA at (404) 656-5100 or (800) 656-6568.

480-10-.20 Required Notifications to the Board.

(1) For purposes of this rule, the following terms shall mean as follow:

(a) “Board” shall mean the Georgia Board of Pharmacy;

(b) “Immediate notification” shall mean written notification sent within twenty-four hours of the event;

(c) “Significant adverse drug reaction” shall mean any reaction which requires any medical treatment beyond a consultation between Pharmacist/patient, Pharmacist/Prescriber, patient/prescriber or Pharmacist/patient/Prescriber; and

(d) “Written notification” shall mean in writing and sent by statutory overnight delivery or sent electronically via email.

(2) The following occurrences require immediate notification to the Board at its address of record, unless otherwise provided:

(a) Permanent closing of a licensed pharmacy. Notification shall include the name and contact information for the person responsible for maintaining the pharmacy records after the pharmacy has closed and location of the records.

(b) Change of ownership or location of a licensed pharmacy. Since a pharmacy license cannot be transferable, unless such change has been previously approved by the Board following the submission of

the appropriate applications, the existing pharmacy license is void and there is no continuing authority to operate as a pharmacy.

(c) Change in management of a licensed pharmacy.

(d) Change of the pharmacist in charge of a licensed pharmacy. When the Board receives notice that a pharmacy no longer has a pharmacist in charge and no replacement pharmacist in charge is named, the pharmacy's license is suspended pending further action by the Board.

(e) Any theft or loss of drugs or devices of a licensed pharmacy. This notification must ~~also~~ be made to the Georgia Drugs and Narcotics Agency (GDNA), and if involving controlled substances, the pharmacy must comply with Rule 480-16-.06.

(f) Any known conviction of any employee of a licensed pharmacy of any state or federal drug laws, not previously reported.

(g) Disasters or accidents involving the licensed pharmacy.

(h) Thefts or break-ins at the licensed pharmacy. Notifications of thefts or break-ins at a licensed pharmacy must also be made to the GDNA.

(i) Theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law. Notification of theft, destruction, or loss of records required to be maintained by state or federal law must be made to the GDNA.

(j) Occurrence at a licensed pharmacy of a significant adverse drug reaction by a customer or person receiving medication dispensed or compounded by the licensed pharmacy.

(3) Reports of Loss or Theft.

(a) Definitions.

1. An "immediate notification" is within seventy-two (72) hours of loss or theft being discovered. Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.

2. A "significant amount" is 20% of a manufacturer's stock unit within a six-month period.

(b) The Georgia Drugs and Narcotics Agency (GDNA) shall immediately be notified of the occurrence of the following: the theft of a significant amount of any controlled substance or any dangerous drug identified by the Board as having the potential for abuse or theft; the theft or any loss of a significant amount of any controlled substance where theft is suspected; or the theft or any loss of any dangerous drug identified by the Board as having the potential for abuse or theft where theft is suspected. The registrant shall send a completed copy of the appropriate form to GDNA. A GDNA Form 215 shall be used to report theft or loss of dangerous drugs, and a DEA Form 106 shall be used to report theft or loss of controlled substances.

(c) A GDNA Form 215 or DEA Form 106 shall be maintained at the facility for two (2) years. Such form shall be made immediately available upon verbal request by the GDNA.

(d) The submission of a GDNA Form 215 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances.

(e) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.

(f) The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed GDNA Form 215 or DEA Form 106 where required under this rule.

(g) Copies of a GDNA Form 215 can be found at <http://gdna.georgia.gov/> or <http://gbp.georgia.gov/> or by contacting GDNA at (404) 656-5100 or (800) 656-6568.

Laird Miller made a motion to post Rule 480-27-.03 Records of Dispensing as amended. Bill Prather seconded and the Board voted unanimously in favor of the motion.

480-27-.03 Records of Dispensing.

(1) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for two years and shall include, but not be limited to:

- (a) Quantities dispensed;
- (b) Date of dispensing;
- (c) Serial Prescription number (or equivalent if an institution);
- (d) The identification of the pharmacist responsible for dispensing;
- (e) Documentation of satisfaction of state requirements for drug product selection;
- (f) Records of refills to date to include date(s) of refills, and identification of pharmacist(s) dispensing refills.

(2) Effective May 1, 2017, all pharmacies licensed by the Board must maintain a perpetual inventory of all controlled substances received, stored, distributed and dispensed by the pharmacy and of all dangerous drugs identified by the Board as having the potential for abuse or theft that are received, stored, distributed and dispensed by the pharmacy for a period of two years.

(3) A physical inventory count must be made of all controlled substances and all dangerous drug identified by the Board as having the potential for abuse or theft on hand and maintained in a printed form. The inventory must conform to all DEA inventory requirements and must be signed and dated by the pharmacist conducting the inventory. The date on which the inventory was made becomes the new biennial inventory date for that licensee and the controlled substances must be inventoried biennially thereafter.

(4) All biennial inventories must be maintained for two (2) years and must be made available to the Board or its representative, upon request.

(5) If there is a discrepancy in the inventory of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft, a pharmacist must perform a personal reconciliation within 7 days to verify the accuracy of the inventory.

(a) If this is considered a significant discrepancy, the discrepancy shall be reported to GDNA using the DEA Form 106 or GDNA Form 215. A GDNA Form 215 shall be used to report theft or loss of dangerous drugs, and a DEA Form 106 shall be used to report theft or loss of controlled substances. A “significant discrepancy” means 20% of a manufacturer’s stocking unit within a six month period.

(b) Only a pharmacist can reconcile or correct a perpetual inventory.

(c) A reconciliation log must be created which contains the printed name, license number, and signature of both the person doing the reconciliation or correction along with the person verifying the reconciliation or correction. Each entry on the log must be dated and accompanied by an explanation for the reconciliation or correction.

(6) All perpetual inventories and reconciliation logs must be maintained for a minimum of two (2) years and be immediately available to the GDNA for inspection and copying.

Bill Prather made a motion to post Rule 480-49-.03 Bad Checks as amended. Vicki Arnold 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 to post Chapter 480-51 Interchangeable Biological Products. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

CHAPTER 480-51: INTERCHANGEABLE BIOLOGICAL PRODUCTS

480-51-.01 Definitions.

(1) "Biological product" means a biological product as defined in subsection (i) of the section 351 of the Public Health Service Act, 42 U.S.C. 262.

(2) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in subsection (k)(4) of 42 U.S.C. 262 or has been deemed therapeutically equivalent by the federal Food and Drug Administration.

480-51-.02 Substituting Interchangeable Biological Products.

(1) A pharmacist may substitute a biological product with an interchangeable biological product, except as provided below.

(2) If a practitioner of the healing arts prescribes a biological product by its non-proprietary name, then the pharmacist shall dispense the lowest retail-priced interchangeable biological product, which is in stock.

(3) Whenever a substitution is made, the pharmacist shall record on the original prescription the fact that there has been a substitution and the identity of the dispensed interchangeable biological product and its manufacturer. Such prescription shall be made available for inspection by the board or its representative in accordance with the rules of the Board.

(4) If a pharmacist substitutes an interchangeable biological product for a prescribed biological product when dispensing a prescribed medication, the name of the interchangeable biological product, with an explanation of “interchangeable biological product for [insert name of prescribed biological product]” or similar language to indicate that substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the biological product may not appear upon the prescription label; provided, however, that this paragraph shall not apply to biological products dispensed for in-patient hospital services, to hospital-administered biological products for outpatients, or to biological products in specialty packaging for dosing purposes as defined by the Board. This paragraph shall apply to hospital retail pharmacies and to any biological products dispensed by a hospital for a patient’s use or administration at home.

(5) The substitution of any biological product by a registered pharmacist pursuant to this rule section does not constitute the practice of medicine.

(6) A patient for whom a prescription biological product order is intended may instruct a pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product.

(7) A practitioner of the healing arts may instruct the pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product by including the words “brand necessary” in the body of the prescription.

(a) When a prescription is a hard copy biological product order, such indication of brand necessary must be in the practitioner’s own handwriting and shall not be printed, applied by rubber stamp, or any such similar means.

(b) When the prescription is an electronic prescription drug or biological product order, the words “brand necessary” are not required to be in the practitioner’s own handwriting and may be included on the prescription in any manner or by any method.

(c) When a practitioner has designated “brand necessary” on an electronic biological product order or interchangeable biological product shall not be substituted without the practitioner’s express consent, which shall be documented by the pharmacist on the prescription and by the practitioner in the patient’s medical record.

(8) Within forty-eight (48) hours, excluding weekends and holidays, following the dispensing of a biological product, the dispensing pharmacist or the pharmacist’s designee shall communicate to the prescriber the specific product provided to the patient, including the name of the biological product and the manufacturer.

(a) The communication shall be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber by using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

1. There is no interchangeable biological product approved by the federal Food and Drug Administration for the prescribed product; or

2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(9) A link for the current list of all biological products determined by the federal Food and Drug Administration to be interchangeable with a specific biological products is available on the Board's website.

Chris Jones made a motion to post Rule 480-48-.02 Conditions for Use of Delivery by Mail. Laird Miller seconded and the Board voted unanimously in favor of the motion.

480-48-.02 Conditions for Use of Delivery by Mail.

(1) Any pharmacy can regularly employ the U.S. Postal Service or a common commercial carrier to deliver a drug which requires a prescription to a patient only after the patient has requested that a pharmacy deliver by mail his/her filled prescription drugs. Any pharmacy providing delivery by mail to its patients is required to follow applicable Georgia laws and rules.

(2) A mail order pharmacy located outside this state is required to follow all applicable pharmacy and drug rules and laws of the state in which the pharmacy is physically located.

(3) A mail order pharmacy shall ensure that all prescription drug order medications are delivered to the patient in accordance with ~~standards~~ of the drug manufacturer's temperature standards as set by the Food and Drug Administration (FDA). ~~The P~~pharmacy shall ~~insure~~ ensure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by mail order by enclosing in each medication's packaging a USP-recognized method by which the patient can easily detect improper storage or temperature variations, which may include the use of temperature tags, time temperature strips, or a combination of these.

(4) Any pharmacy using delivery by mail to deliver dispensed prescription drugs shall comply with the following conditions:

(a) Any pharmacy that uses delivery by mail is accountable to the Board to arrange for the appropriate mailing/shipping process.

(b) A mail order pharmacy shall provide a method by which a patient or patient's caregiver can notify the mail order pharmacy as to any irregularity in the delivery of their medication to include but not be limited to:

1. Timeliness of delivery;
2. Condition on the prescription drug upon delivery; and
3. Failure to receive the proper prescription drug.

(c) Medications designated as requiring special handling by this rule must be signed for upon delivery by the patient or patient's designee. In the event that the medication cannot be delivered, the package will not be left behind and shall be returned to the mailing or shipping service to be held for pickup until signed for by the patient or the patient's designee, or redelivered to the patient if so requested by the patient or the patient's caregiver. The Board has designated the following drugs as requiring special handling:

1. All Schedule II, III, IV, and V controlled substances

(d) A mail order pharmacy shall provide a process by which, if the delivery of a prescription medication is in any way compromised, the pharmacy will replace the patient's medication, to be delivered by next-day delivery or the mail order pharmacy will immediately contact the patient's prescriber to arrange for a prescription for a minimum seven (7) day supply of the medication to be dispensed to the patient by a licensed pharmacy of the patient's choice.

(e) A pharmacy that employs delivery by mail must provide written information, set forth in Board Rule 480-31-.01, for each drug that is delivered, and a method of electronic or telephonic communications for a pharmacist or a Georgia-licensed pharmacy intern under direct supervision of the pharmacist to provide consultation or counseling in accordance with the obligations of O.C.G.A. § 26-4-85. All such counseling will be documented in the pharmacy's patient records. It is sufficient proof to show counseling was refused if a patient or patient's caregiver does not contact the pharmacy.

(f) The pharmacy shall provide information to the patient on the procedure that the patient should follow if any prescription drug does not arrive in a timely manner, or if the integrity of the packaging or medication has been compromised during shipment and delivery by mail.

(g) A pharmacy using delivery by mail shall document in its records when the prescription drug was sent to the patient.

(h) A pharmacy using delivery by mail shall document the instances when prescription drugs have been compromised during shipment and delivery by mail or when drugs do not arrive in a timely manner, and shall maintain such documentation for two (2) years. In addition, the mail order pharmacy shall maintain reports of patient complaints and internal/external audits about timeliness of deliveries, condition of the medication when received by patient including medication that was compromised in delivery, misfills of prescriptions, and the failure of a patient to receive medication. Such records shall be provided to the Board, upon request.

(i) A pharmacy or a pharmacist shall refuse to deliver by mail a prescription drug which, in the professional opinion of the pharmacy or pharmacist may be clinically compromised by delivery by mail.

(j) A mail order pharmacy shall make available to the patient or the patient's caregiver contact information of the Board of Pharmacy.

Bill Prather made a motion to post Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security. Chris Jones seconded and the Board voted unanimously in favor of the motion.

480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security.

(1) Every retail pharmacy, possessing or having possessed any controlled substances and/or dangerous drugs, within a period of two years, and/or possessing any record related to the same, which is required to be kept by O.C.G.A. T. Ch. 16-13, shall exercise diligent care in protecting such controlled substances and/or dangerous drugs and/or records related to the same from loss or theft.

(a) Every licensed retail pharmacy shall ensure that all controlled substances and/or dangerous drugs are purchased from and/or returned to firms holding a current permit issued by the Georgia State Board of Pharmacy (Board). This requirement can be met by a pharmacy maintaining a copy of such firms' current Georgia Board permit.

(2) All controlled substances and/or dangerous drugs shall be kept in ~~a secure place~~ the prescription department, accessible only to an authorized person.

(3) ~~Special Agents or Deputy Directors of the~~ The Georgia Drugs and Narcotics Agency (GDNA) shall have the authority to conduct inspections of any place or premises used by any such licensed retail pharmacy in relation to such controlled substances and/or dangerous drugs and/or any records pertaining to their acquisition, dispensing, disposal, or loss.

(4) ~~The GDNA Special Agents or Deputy Directors~~ shall have the authority to examine, copy, or remove all such records, and to examine, copy, remove, or inventory all such controlled substances and/or dangerous drugs.

(a) It shall be the responsibility to such person possessing such controlled substances and/or dangerous drugs and/or records to make the same available for such inspection, copying, examination, or inventorying by said GDNA, ~~Special Agents or Deputy Directors~~.

(b) At the conclusion of an inspection, the GDNA ~~Special Agents or Deputy Director~~ personnel examining said drugs and/or records shall have the responsibility of providing to such retail pharmacy a copy of an ~~written~~ inspection report on which any deficiencies or violations are made along with any recommendations, if any, concerning the satisfactory storage, keeping, handling and security of controlled substances and/or dangerous drugs.

(5) Any person possessing controlled substances and/or dangerous drugs and/or records may request that such an inspection be made, and upon receipt of such written request, the GDNA Director shall make, or cause to be made, without reasonable delay, an inspection in compliance with said request.

Lisa Harris made a motion to post Rule 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician.

(a) In dispensing drugs, no individual other than a licensed pharmacist shall perform or conduct those duties or functions which require professional judgment. It shall be the responsibility of the supervising pharmacist to ensure to that no other employee of the pharmacy, excluding pharmacy interns or externs but including registered pharmacy technicians, performs, or conducts those duties or functions which require professional judgment. The following functions require the professional judgment of a pharmacist, or a pharmacy intern or extern, under the direct supervision of a pharmacist, and may not be performed by a registered pharmacy technician:

- (1) Acceptance of telephoned or other oral prescriptions;
- (2) Transfers of prescription drug orders from another pharmacy or transfers of a prescription drug order to another pharmacy;
- (3) Patient counseling;
- (4) Receiving information or providing information about a prescription drug order;
- (5) Making the determination as to whether to refill the prescription drug order;
- (6) Certification of a filled and finished prescription drug order;
- (7) Weighing or measuring active ingredients without a mechanism of verification;
- (8) Compounding of medication without a mechanism of verification;
- (9) Giving a completed prescription to the patient requesting same without the label and contents and the label being verified by a pharmacist;
- (10) Reconstitution of prefabricated medication without a mechanism of verification;
- (11) Verification of the constituents of final IV admixtures for accuracy, efficacy, and patient utilization;
- (12) Enter of order on patient medication profiles without verification by a pharmacist;
- (13) Provision of drug information that has not been prepared or approved by the pharmacist;
- (14) Review of the patient record for therapeutic appropriateness; ~~and~~
- (15) Accept and/or verify controlled substance deliveries to a licensed pharmacy; and
- ~~(15)~~(16) Any other act prohibited by Board rule, or law.

The Board recommended tabling Rules 480-10-.10 Prescription Drug Order Copies, 480-22-.11 Transfer between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes, 480-27-.07 Dangerous Prescription Drug Order Transfer, and 480-27-.08 Controlled Substance Prescription Drug Order Transfer for its October 2016 meeting to allow additional time for consideration.

A motion was made by Jim Bracewell, seconded by Lisa Harris, 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.

Proposed 2017 Board Meeting Dates: Chris Jones made a motion to approve the 2017 meeting dates and exam dates as presented. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Report from Mr. Prather and Vice-President Jones regarding discussions with GPhA and chain drug stores on direct supervision: Mr. Prather reported that he and Vice-President Jones have been in discussions with GPhA and chain drug stores concerning direct supervision with the idea of trying to free of pharmacists to provide better pharmaceutical care. He stated that they will continue to work on this matter and report back to the Board.

Vicki Arnold made a motion and Jim Bracewell seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and §43-1-2(k) to deliberate and to receive information on applications, investigative reports and the Assistant Attorney General's report. Voting in favor of the motion were those present who included Vicki Arnold, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, and Bill Prather.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

- Staffing update
- C.D.P.
- Audit update

Cognizant's Report – Chris Jones

- GDNA Case # A-31782
- GDNA Case # A-16-06
- GDNA Case #T-31908
- GDNA Case # A-13-52
- GDNA Case # A-16-11
- GDNA Case # A-16-14
- GDNA Case # A-16-13
- GDNA Case # T-31926
- GDNA Case # T-31922
- GDNA Case # T-31913
- GDNA Case # T-31912
- GDNA Case # T-31945
- GDNA Case # T-31947
- GDNA Case # T-31944
- GDNA Case # A-16-15
- GDNA Case # B-31817
- GDNA Case # B-31726
- GDNA Case # B-31796
- GDNA Case # B-31706
- GDNA Case # B-31804
- GDNA Case # B-31880
- GDNA Case # A-31911

Applications

- L.N.F.
- R.L.C.
- L.B.
- M.C.J.
- R.L.N.

- H.S.
- F.D.R.
- J.S.B.
- J.E.C.
- A.M.B.
- D.M.I.
- D.G.A.
- R.W.C.
- C.S.B.
- G.K.A.
- J.V.S.
- J.R.M.
- N.J.
- J.B.O.
- M.K.Q.
- K.E.A.
- L.T.H.
- G.M.J.
- O.F.O.
- R.M.E.
- S.E.T.
- L.G.A.
- D.O.O.
- C.M.M.
- D.L.
- M.R.

Correspondences/Requests

- C.T.C.C.
- C.P.
- O.P.S.
- P.P.
- X.G.P.
- L.M.W.
- R.M.P.
- C.H.M.
- G.E.T.
- D.D.L.
- J.L.H.
- G.A.Q.H.C.
- P.M.H.
- H.G.H. and T.M.C.
- A.R.P.
- J.W.
- M.B.H.
- P.D.D.
- A.L.L.
- J.R.M.

- K.E.A.
- L.M.B.
- S.U.K.
- S.J.G.
- M.D.D.
- T.E.C.
- V.R.J.
- N.P.
- I.P.
- A.H.G.
- A.P.
- R.P.S.
- F.S.S.P.
- T.P.I.
- C.M.C.
- C.M.C.
- C.N.H.
- D.H.A.
- E.M.C.
- F.P.H.
- R.R.M.C.

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

Open Session

The Board discussed establishing a policy concerning the number of attempts an applicant may retake the NAPLEX and MPJE examinations and recommended putting this topic on its October agenda for further discussion.

Laird Miller made a motion for the Board to take the following actions:

Appearances

- | | | |
|--|---|---|
| <ul style="list-style-type: none"> • J.F.C. • H.H. • C.L.S. • S.L. • R.M.S. | <ul style="list-style-type: none"> Request to discuss reinstatement Denied Pharmacy Technician Denied Pharmacy Technician Pharmacist Reinstatement Request for extension of intern license | <ul style="list-style-type: none"> Request denied Overturn denial and approve for registration Overturn denial and approve for registration Table pending receipt of additional information Uphold denial of request and suggest individual reapply for intern license |
|--|---|---|

Attorney General’s Report – Janet Wray

Ms. Wray presented the following consent orders:

- | | |
|--|--|
| <ul style="list-style-type: none"> • C.V.S.P. • J.P. • University Compounding Pharmacy • Shaquan Liverpool | <ul style="list-style-type: none"> Private Consent Order accepted Private Consent Order accepted Public Consent Order accepted Public Consent Order accepted |
|--|--|

- S.U. Private Consent Order accepted
- H.S.T.S. Private Consent Order accepted
- B.H.S. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- B.D.S.V. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- R.C.P. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- W.P. Private Consent Order to be accepted and signed with express permission upon receipt of the original

Ms. Wray discussed the following cases:

- L.L.W. Schedule Investigative Interview
- W.P.F.E. Close case with letter of concern

Georgia Drugs and Narcotics Agency – Rick Allen

- Staffing update No action taken
- C.D.P. No action taken
- Audit update No action taken

Cognizant’s Report – Chris Jones

- GDNA Case # A-31782 Refer to the Attorney General’s office for discipline
- GDNA Case # A-16-06 Refer to the Attorney General’s office for discipline
- GDNA Case #T-31908 Close case with no action and approve pharmacy technician application
- GDNA Case # A-13-52 Refer to the Attorney General’s office for discipline
- GDNA Case # A-16-11 Rescind suspension and accept Private Interim Consent Order
- GDNA Case # A-16-14 Accept Private Interim Consent Order
- GDNA Case # A-16-13 Accept Private Interim Consent Order
- GDNA Case # T-31926 Accept Voluntary Surrender, if received. If individual does not return the Voluntary Surrender, revoke technician registration
- GDNA Case # T-31922 Accept Voluntary Surrender
- GDNA Case # T-31913 Revoke Technician Registration
- GDNA Case # T-31912 Accept Voluntary Surrender
- GDNA Case # T-31945 Revoke Technician Registration
- GDNA Case # T-31947 Accept Voluntary Surrender
- GDNA Case # T-31944 Revoke Technician Registration
- GDNA Case # A-16-15 Offer inactive status. If inactive status application not received, refer to the Attorney General’s office
- GDNA Case # B-31817 Close case with no action
- GDNA Case # B-31726 Close case with letter of concern
- GDNA Case # B-31796 Refer to the Attorney General’s office for discipline for PIC; send letter of concern to second RPh
- GDNA Case # B-31706 Refer to the Attorney General’s office for discipline
- GDNA Case # B-31804 Close case with letter of concern
- GDNA Case # B-31880 Close case with no action
- GDNA Case # A-31911 Refer to the Attorney General’s office for discipline

Applications

• Laporisha N. Franklin	Pharmacy Technician	Approve for registration
• R.L.C.	Pharmacy Technician	Denied registration
• L.B.	Pharmacy Technician	Denied registration
• M.C.J.	Pharmacy Technician	Denied registration
• Rasheema L. Neely	Pharmacy Technician	Approve for registration
• Henry Stadford Jr.	Pharmacy Technician	Approved for registration
• Felisa D. Rodrigues	Pharmacy Technician	Approved for registration
• J.S.B.	Pharmacy Technician	Denied registration
• J.E.C.	Pharmacy Technician	Denied registration
• Austin M. Billings	Pharmacist Intern	Approved application
• D.M.I.	Pharmacist Intern	Denied application
• D.G.A.	Pharmacist Intern	Approved application
• R.W.C.	Pharmacist Intern	Schedule for Investigative Interview
• Catherine S. Boardman	Pharmacist Intern	Approved renewal
• Gagandeep K. Atwal	Pharmacist Intern	Approved renewal
• Joseph V. Spada	Pharmacist Intern	Approved renewal
• J.R.M.	Pharmacist Intern	Denied renewal
• N.J.	Pharmacist Intern	Denied request to extend intern license
• J.B.O.	Pharmacist Intern	Denied request to extend intern license
• M.K.Q.	Pharmacist Intern	Denied request to extend intern license
• K.E.A.	Pharmacist Intern	Denied renewal
• L.T.H.	Pharmacist Intern	Table pending receipt of additional information
• G.M.J.	Pharmacist Reinstatement	Table pending receipt of additional information
• O.F.O.	Pharmacist Reinstatement	Schedule to meet with the Board
• R.M.E.	Pharmacist Reciprocity	Denied application
• S.E.T.	Pharmacist Reciprocity	Denied application
• L.G.A.	Temporary Pharmacist	Denied application
• David O. Owiredu	Pharmacist Examination	Approved application
• Candis M. McGraw	Pharmacist Cert of DTM	Approved application
• D.L.	Non-Resident Pharmacy	Denied application
• M.R.	Non-Resident Pharmacy	Denied application

Correspondences/Requests

• C.T.C.C.	Notice of discipline	No action taken
• C.P.	Notice of discipline	No action taken
• O.P.S.	Notice of discipline	No action taken
• P.P.	Notice of discipline	No action taken
• X.G.P.	Notice of discipline	No action taken
• L.M.W.	Appearance request	Request approved
• R.M.P.	Request to reactivate license	Schedule to meet with the Board
• C.H.M.	Request to terminate C.O.	Request approved
• G.E.T.	Request to lift supervised practice restriction	Request approved
• D.D.L.	Request for extension	Request denied
• J.L.H.	Request for approval of intern hrs	Request approved

• G.A.Q.H.C.	Lockbox approval request	Request denied
• P.M.H.	Remote Order Entry	Approved
• H.G.H. and T.M.C.	Remote Order Entry	Approved
• A.R.P.	Request to take NAPLEX a 4th time	Request denied
• J.W.	Request to take NAPLEX a 4th time	Request denied
• M.B.H.	Request to take NAPLEX a 4th time	Request denied
• P.D.D.	Request for additional NAPLEX attempt	Request denied
• A.L.L.	Request to take NAPLEX before the required 91 day wait period	Request denied
• J.R.M.	Request to take NAPLEX before the required 91 day wait period	Request denied
• K.E.A.	Request to take NAPLEX before the required 91 day wait period	Request denied
• L.M.B.	Request to take NAPLEX before the required 91 day wait period	Request denied
• S.U.K.	Request to take NAPLEX before the required 91 day wait period	Request denied
• S.J.G.	Request to take NAPLEX before the required 91 day wait period	Request denied
• M.D.D.	Request to take MPJE a 4 th time	Approved request
• T.E.C.	Request to take MPJE a 4 th time	Approved request
• V.R.J.	Request to take MPJE a 4 th time	Approved request
• N.P.	Request to take NAPLEX before the required 91 day wait period	Request denied
• I.P.	Notice of discipline	No action
• A.H.G.	Notice of discipline	No action
• A.P.	Notice of discipline	No action
• R.P.S.	Notice of discipline	No action
• F.S.S.P.	Notice of discipline	No action
• T.P.I.	Notice of discipline	No action
• C.M.C.	Remote Order Entry	Denied
• C.M.C.	Remote Order Entry	Denied
• C.N.H.	Remote Order Entry	Denied
• D.H.A.	Remote Order Entry	Denied
• E.M.C.	Remote Order Entry	Denied
• F.P.H.	Remote Order Entry	Denied
• R.R.M.C.	Remote Order Entry	Denied

Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 5:51 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, October 19, 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