GEORGIA BOARD OF PHARMACY
Board Meeting
Mercer University College of Pharmacy
3001 Mercer University Drive
Atlanta, GA 30341
November 18, 2015
9:00 a.m.

The following Board members were present:
Laird Miller, President
Mike Faulk, Vice-President
Vicki Arnold
Jim Bracewell
Chris Jones
Bill Prather
Bob Warnock

Staff present:
Tanja Battle, Executive Director
Rick Allen, GDNA
Janet Wray, Senior Assistant Attorney General
Brandi Howell, Business Operations Specialist

Visitors:
Lawrence Eaton
Rachel Taggs, Precision Pharmacy
Jordan King
Jim Pinhasov, Quality Specialty Pharmacy
David McPartland, Quality Specialty Pharmacy
R. Scott Lindsay, CAPS
Scott Brunner, GPhA
Greg Reysold, GPhA
Shea Ross, GHA
John Sisto, ESI
Trish Yeatts, MAG
Chris Saboura, HCA
Sonya Nelson, Walmart
Mike Chavez, Publix
Keith Sledge, Pharmaceutical Specialties
Young Chang, Walgreens
Scott Biddulph, Target
Mickey Benson, Premier Kids Care Pharmacy
Brian Robinson, Walgreens

President Miller established that a quorum was present and called the meeting to order at 8:40 a.m.

Bill Prather 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, Chris Jones, Laird Miller, Bill Prather, and Bob Warnock.

Executive Session

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- E.U.
- H.J.

- W.P.
- J.C.
- B.I.V.I.
- B.P.
- P.C.P.
- K.P.

Ms. Wray discussed the following cases:

- R.J.
- R.K.

Appearances

- L.T.E.
- P.P.
- J.G.K.
- Q.S.P.J.

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

Open Session

President Miller welcomed the visitors.

Approval of Minutes

Bill Prather made a motion to approve the Public and Executive Session minutes for the October 14, 2015 meeting and the Public and Executive Session minutes for the October 15, 2015 meeting. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Ratifications

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

Correspondence from Jennifer Schneider

The Board considered this correspondence requesting a letter of exemption for Ozburn-Hessey Logistics, LLC d/b/a OHL. The Board directed staff to respond to Ms. Schneider by stating that it does not require companies that only ship non-prescription OTC drugs to be licensed in this state.

Correspondence from Randy Hu

The Board considered this correspondence regarding USP 797 and sterile compounding. The Board directed staff to respond to Mr. Hu by stating that Georgia's law still requires USP 797.

Correspondence from Emily Salley, Premier Kids Care, Inc.

The Board considered this correspondence requesting the Board recognize Accreditation Commission for Healthcare (ACHC) as an accreditation agency. Bill Prather made a motion to approve the request. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Emily Popp, Mandell's Clinical Pharmacy

The Board considered this correspondence regarding patient counseling. Ms. Popp is asking if making an offer to be counselled by a pharmacist in both a recorded message and verbally, and

additionally providing their toll free phone number, meets the Board's standards. Chris Jones made a motion to direct staff to respond by stating that the Board has determined this does meet its standards of patient counseling. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Lindsay Wells, Henry Schein Animal Health

The Board considered this correspondence regarding a prescription drop ship request. In Ms. Wells' email, she described a situation in which a medication was to be administered to a patient of the veterinarian, but was to be shipped to the patient's address. Bob Warnock made a motion to direct staff to respond by stating that for a non-resident pharmacy permit holder to ship into this state, the drug must be patient specific. Additionally, the facility is permitted to ship directly to the address of the patient under Rule Chapter 480-48, Delivery by Mail and lastly, it must have a patient specific prescription to ship directly to a patient and must comply with the Board rules. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Robert L. Eaton, Jr., Roadrunner Pharmacy, Inc.

The Board viewed this correspondence for informational purposes only.

Correspondence from Jeani Henges, Genetox, LLC

The Board considered this correspondence regarding a pharmacist performing DNA testing on patients through a standard order from a licensed physician. Mike Faulk made a motion to direct staff to respond to Ms. Henges that there is currently no authority in the law that would allow genetic testing by a pharmacist. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Andrea Pierce, Appling Healthcare Systems

The Board considered this correspondence from Ms. Pierce requesting a waiver to provide a minimal amount of emergency medications to the Rural Health Care (RHC) Clinics owned by Appling Healthcare System. Bill Prather made a motion to deny the request and direct staff to respond by stating that they have to be a practitioner's office or register as a clinic in order to put an emergency kit in a clinic. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Anna B. Etzkorn, Polsinelli PC

The Board considered this correspondence requesting clarification as to whether a non-resident entity is required to obtain a non-resident pharmacy license to dispense prescription devices to an end user in Georgia. Chris Jones made a motion to direct staff to respond by stating that the entity does not have to be registered as a non-resident pharmacy and it does not qualify for a wholesale distributor license. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waivers

Jim Bracewell made a motion to approve rule waiver petitions from Adapt Pharma, Inc., GE Healthcare, Inc., Roosevelt Warm Springs LTAC Hospital, and Adamis Pharmaceuticals Corporation (Manufacturer). Mike Faulk seconded and the Board voted unanimously in favor of the motion.

In the same motion, the Board voted to deny rule waiver petitions from Adamis Pharmaceuticals Corporation (Wholesaler) and ARJ Infusion Services.

Georgia Drugs and Narcotics Agency Open Session – Rick Allen

Director Allen presented the Board with proposed rule amendments regarding the following subjects:

- Biosimilars
- Defining mode of operation in Rule 480-10-.06(c)

- Intern hours/supervision
- Label requirements for prescription containers
- RAMS renewal requirements
- Pharmacy technician supervision definition
- Changes to 480-10-.02 regarding vaccinations

Ms. Wray discussed changes to the language for each that would need to be made before the Board could consider a vote to post. The Board recommended tabling the proposed changes to allow additional time for consideration.

Attorney General's Report Open Session –Janet Wray
No report.

Executive Director's Report Open Session – Tanja Battle
No report.

Miscellaneous
At the Board's October 14, 2015 meeting, the Board discussed a misfill course by the Oregon Board of Pharmacy called Patient Safety and Medication Error Prevention for Pharmacists. Bill Prather made a motion to amend misfill policy #1 to require the individual complete modules #4 and #5 of this course (Workflow & Processes and Culture & Error Resolution). Additionally, amend policy #2 to require the individual complete all five modules. Lastly, the individual must submit proof of completion of the course(s) to the Board office. Chris Jones seconded and the Board voted unanimously in favor of the motion.

The Board recommended tabling Rules 480-10-.16 Security System Approval, 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel, and 480-15-.06 Other Pharmacy Personnel to allow additional time for consideration.

Bill Prather made a motion to post Rules 480-8-.06 Drug Distribution and Control, 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records, and Security, 480-10-.20 Required Notifications to the Board, 480-16-.03 Return of Previously Dispensed Drugs or Devices, 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances, 480-13-.06 Drug Distribution and Control, 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician, 480-18-.06 Drug Distribution and Control, 480-27-.03 Records of Dispensing, 480-33-.06 Drug Distribution and Control, 480-50 Drug Disposal by Authorized Collectors, and 480-37-.02 Licensure. Jim Bracewell 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 ~~form~~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 ~~pharamcy~~ 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) GDNA Form 215.
1. The Georgia Drugs and Narcotics Agency (GDNA) shall immediately be notified of the occurrence of the loss or theft of any record, any dangerous drug, or any controlled substance on a completed Loss or Theft Notification of Occurrence Form, GDNA Form 215. A GDNA Form 215 shall be

maintained at the licensed or regulated facility for two (2) years for review by the GDNA. Such form shall be made immediately available upon verbal request by the GDNA
2. For a loss of controlled substances, a completed GDNA Form 215 is required to be filed with GDNA in addition to a copy of a completed DEA Form 106. A GDNA Form 215 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.
3. An immediate notification of these occurrences is defined as within "seventy-two (72) hours of loss or theft" being discovered. Immediate notification does not mean reporting aft the completion of an investigation, audit, or reconciliation.
4. The Board may impose a fine and/or sanctions on the license of the licensed or regulated registrant or licensee based on each day a registrant or licensee fails to file a completed GDNA Form 215.
5. 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-.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 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 a 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.
A motion was made by Jim Bracewell, seconded by Bill Prather, and the Board voted that the formulation and adoption of these rules does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rules cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

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

(1) For purposes of this rule, the following terms shall means 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 by 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) (a) GDNA shall immediately be notified of the occurrence of the loss or theft of any record, any dangerous drug, or any controlled substance on a completed Loss or Theft Notification of Occurrence Form, GDNA Form 215. A GDNA Form 215 shall be maintained at the licensed or regulated facility for two (2) years for review by the GDNA. Such form shall be made immediately available upon verbal request by the GDNA
(b) For a loss of controlled substances, a completed GDNA Form 215 is required to be filed with GDNA in addition to a copy of a completed DEA Form 106. A GDNA Form 215 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.
(c) An immediate notification of these occurrences is defined as within “seventy-two (72) hours of loss or theft” being discovered. Immediate notification does not mean reporting aft the completion of an investigation, audit, or reconciliation.
(d) The Board may impose a fine and/or sanctions on the license of the licensed or regulated registrant or licensee based on each day a registrant or licensee fails to file a completed GDNA Form 215.
(e) 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-.03 Return of Previously Dispensed Drugs or Devices.

(1) It shall be unlawful, and a violation of these rules, for any licensed pharmacist or pharmacy licensed under O.C.G.A. 26-4 to accept for refund purposes, or otherwise, any unused portion of a drug which has been previously dispensed via a prescription drug order and delivered to the patient or patient's caregiver, except where permitted under state and/or federal law or regulation.

(a) Such receipt is deemed detrimental to the public health due to the likelihood that such drugs, once out of the control of the pharmacy, could have been tampered with, been adulterated, or become contaminated with communicable diseases and/or contagious diseases under the holder thereof;

(b) In addition, such receipt would tend to create a health problem if placed in stock and could be reused by any licensed pharmacist or pharmacy~~;~~.

~~(c)~~(2) Nothing in this Rule shall be meant to be in conflict with Board Rule 480-10-. 17, which allow a pharmacy to receive unused, manufacturer's unit-dose packaged drugs from a Medicaid patient residing in a long term care facility.

(3) Nothing in this Rule shall prohibit an authorized collector from collecting controlled substances for the purposes of destruction as authorized in the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"), any regulations promulgated thereunder, and Ga. Comp. R. & Regs. c. 480-50. In the same motion, the Board 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§ 50-13-9 16 5 9 4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

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

(1) The theft, loss, or unaccounted for controlled substances 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. This report shall be made by completing a GDNA Loss or Theft Notice of Occurrence Form (Form 215). 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 for two (2) years from the time of occurrence.

(2) Additionally, a~~A~~ written report must be made regarding any theft, loss or unaccounted for controlled substances to the Drug Enforcement Administration (DEA) within three (3) days of its discovery by completing a DEA Form 106.

~~(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~~ (a) A copy of the completed DEA Form 106 must be sent to the GDNA within ten (10) days of completing the form.

(3) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must include a copy of any report from such a department for any occurrence of the loss or theft of dangerous drugs or controlled substances when filing a GDNA Form 215 as provided for in Board Policy.

~~The report shall include the following information:~~

~~(a) Full name and address of the pharmacy;(c) 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.~~

480-13-.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 give n 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 s 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) GDNA Form 215.
(a) The Georgia Drugs and Narcotics Agency (GDNA) shall be immediately notified of the occurrence of the loss or theft of any record, any dangerous drug, or any controlled substance on a

completed Loss or Theft Notification of Occurrence Form, GDNA Form 215. A GDNA Form 215 shall be maintained at the licensed or regulated facility for two (2) years for review by the GDNA. Such form shall be made immediately available upon verbal request by the GDNA.
(b) For a loss of controlled substances, a completed GDNA Form 215 is required to be filed with the GDNA in addition to a copy of a completed DEA Form 106. A GDNA Form 215 does not relieve any DEA registration from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances.
(c) An immediate notification of these occurrences is defined as "within seventy-two (72) hours of the loss or theft" being discovered. Immediate notification does not mean reporting at the completion of an investigation, audit, or reconciliation.
(d) The Board may impose a fine and/or sanctions on the license of the licensed or regulated registrant or licensee based on each day a registrant or licensee fails to file a completed GDNA Form 215.
(e) Copies of a GDNA Form 215 can be found at http://gdna.georgia.gov/ or http://gbp.georgia.gov/ or by contacting the GDNA at (404) 656-5100 or (800) 656-6568.

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.

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) GDNA Form 215.
(a) The Georgia Drugs and Narcotics Agency (GDNA) shall be immediately notified of the occurrence of the loss or theft of any record, any dangerous drug, or any controlled substance on a completed Loss or Theft Notification of Occurrence Form, GDNA Form 215. A GDNA Form 215 shall be maintained at the licensed or regulated facility for two (2) years for review by the GDNA. Such form shall be immediately made available upon verbal request by GDNA.
(b) For a loss of controlled substances, a completed GDNA Form 215 is required to be filed with GDNA in addition to a copy of a completed DEA Form 106. A GDNA Form 215 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.
(c) An immediate notification of these occurrences is defined as "within seventy-two (72) hours of the loss or theft" being discovered. Immediate notification does not mean reporting at the completion of an investigation, audit, or reconciliation.
(d) The Board may impose a fine and/or sanctions on the license of the licensed or regulated registrant or licensee based on each day a registrant or licensee fails to file a completed GDNA Form 215.
(e) Copies of 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.

480-27-.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 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, 2016, all pharmacies licensed by the Board must maintain a perpetual inventory of all controlled substances 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 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 a perpetual inventory is maintained by electronic means instead of manually, a pharmacist must perform a personal reconciliation at least every seven (7) days to verify the accuracy of the electronic inventory. Only a pharmacist can reconcile or correct a perpetual inventory. 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.

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) GDNA Form 215.
(a)The Georgia Drugs and Narcotics Agency (GDNA) shall be immediately notified of the occurrence of the loss or theft of any record, any dangerous drug, or any controlled substance on a completed Loss or Theft Notification of Occurrence From, GDNA Form 215. A GDNA Form 215 shall be maintained at the licensed or regulated facility for two (2) years for review by the GDNA. Such form shall be made immediately available upon verbal request by GDNA.
(b) For a loss of a controlled substance, a completed GDNA Form 215 is required to be filed with the GDNA in addition to a copy of a completed DEA Form 106. A GDNA Form 215 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.
(c) An immediate notification of these occurrences is defined as "within seventy-two (72) hours of the loss of theft" being discovered. Immediate notification does not mean reporting at the completion of an investigation, audit, or reconciliation.
(d) The Board may impose a fine and/or sanctions on the license or the licensed or regulated registrant or licensee based on each day a registrant or licensee fails to file a completed GDNA Form 215.
(e) Copies of a GDNA Form 215 can be found at http://gdna.georgia.gov/ or http://gbp.georgia.gov/ or by contacting the GDNA at (404) 656-5100 or (800) 656-6568.

480-50: Drug Disposal and Authorized Collectors

480-50-.01 Definitions.

(1) "Authorized Collectors" or "Collectors" means retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment programs, manufacturers, distributors, and reverse distributors which have registered with the DEA to become authorized collectors of drugs for disposal, are authorized to handle controlled substances, and are currently licensed by the Georgia Board of Pharmacy.
(2) "Authorized Employees" means employees of authorized collectors that have met the DEA employment standards and are pharmacists licensed by the Georgia Board of Pharmacy.
(3) "Collection Receptacle" means a lockable and sturdy container with a permanent outer container and a removable numbered inner-liner with a small opening that allows contents to be added but not removed and which container is securely fastened to a permanent structure in a secure area.
(4) "Drugs" means controlled substances and dangerous drugs (non-controlled substances) as those terms are defined in O.C.G.A. Title 16, Chapter 13.
(5) "Mail-back Packages" means pre-paid postage packages provided by authorized collectors at a price or at no cost to the patient or patient's family
(6) "Mail-back Programs" means programs that utilize mail-back packages provided by authorized collectors in which the packages are mailed directly to a reverse distributor and can never be mailed back to the authorized collector.

(7) "Numbered Inner-liner" means a removable, tamper-evident, and tear-resistant liner that bears a unique identification number that is used inside a collection receptacle and which can be securely sealed for transfer to a reverse distributor for transportation to a drug destruction site.
(8) "Ultimate user" means a person who has lawfully obtained and who possesses a drug for his/her own use or for the use of a member of his/her household or for an animal owned by him/her or a member of his/her household.
(9) "Unique Identification Number" means a number traceable to a specific authorized collector.

480-50-.02 Collection Receptacles Located at Authorized Collectors.

(1) Authorized collectors may place, utilize, and maintain collection receptacles at their DEA registered location. Receptacles can only be available to receive drugs when the collector is open for business and only when an authorized employee is present.
(a) An authorized collector may only begin receiving drugs for disposal at the facility after providing thirty (30) days of advance notification to the Board and the Georgia Drugs and Narcotics Agency of its qualification for and intention to serve as an authorized collector.
(2) Collection receptacles must be lockable, sturdy, securely fixed within the collector's location. If the authorized collector is in a pharmacy, then the collection receptacle must be in the immediate vicinity of and can be observed from the prescription department areas where controlled substances are stored by registrants and where an authorized employee is present, and display a sign stating that non-controlled and controlled drugs in Schedule II, III, IV, or V can be accepted and placed in the receptacle. If the collection receptacle is in a hospital/clinic, it must be in an area monitored by employees, but shall not be in an area where emergency or urgent care is provided. If the collection receptacle is in an opioid treatment facility, it must be located in a room that does not contain other controlled substances and is securely locked with controlled access.
(3) Each receptacle must also be capable of holding a removable, tamper-evident, and tear- resistant inner-liner bearing a unique identification number to receive the drugs.
(a) To dispose of the contents of a receptacle, the sealed liners may be promptly delivered or transferred to a representative for a licensed reverse distributor for destruction. No on-site disposal of any drug is permitted. Only authorized employees can remove and seal an inner-liner and maintain records required by this rule.
(b) Authorized collectors may store inner-liners that have been sealed upon removal from a collection receptacle in a securely locked, substantially constructed cabinet or a securely locked room with controlled access for up to three business days until the liners can be transferred for destruction, and then transferred to a representative for a licensed reverse distributor for destruction.
(c) Collectors are encouraged to schedule inner-liner removals and installations as frequently as necessary.
(d) Drugs placed in the authorized receptacle and stored in secure inner-liners can only be removed from the authorized collector location for destruction by transfer to a reverse distributor with a current permit issued by the Board and authorized by the DEA as a collector.
(e) The date and time that the numbered inner-liners were taken from the collector and the numbers of the inner-liners must be recorded in logs: one maintained by the collector for two years and one maintained by the reverse distributor for each facility for two years.
(f) The name, Board permit/license number, address, and telephone number of the reverse distributor removing the drugs must be recorded in logs maintained by the collector and by the reverse distributor for a period of at least two years; and
(g) The name and signature of the responsible person representing the reverse distributor physically removing the inner-liners must be recorded in logs maintained by the collector and by the reverse distributor for a period of at least two years. Nothing in this rule shall prevent a DEA authorized common carrier from serving as the authorized representative of the reverse distributor.

480-50-.03 Collection Receptacles Located at Long Term Care Facilities (LTCF).

(1) Collection receptacles in long-term care facilities ("LTCF") must be located in a secured area monitored by long-term care facility employees. Collection receptacles can only be used in facilities where a consultant pharmacist's services are required.

(a) A LTCF may only begin receiving drugs for disposal at the facility after providing thirty (30) days of advance notification to the Board and the Georgia Drugs and Narcotics Agency of its qualification for and intention to set up a collection receptacle.

(2) A LTCF may dispose of drugs on behalf of an ultimate user who resides, or has resided, at such LTCF by transferring those drugs into an authorized collection receptacle located at such LTCF. When using this method of destruction, the drugs must be transferred into the collection receptacle within three (3) business days after discontinuation of use by the ultimate user. This provision applied to drugs that are expired, discontinued from use, or when the patient for whom they were ordered is no longer a patient.

(3) When the drugs are expired, discontinued from use, or the patient for whom they were ordered is no longer a patient, the drugs shall be immediately removed from the active stock and inventoried by two people who shall be licensed either as a pharmacists, a nurses, or a licensed practical nurses. The completed inventory record shall be signed and dated by these two individuals. The original inventory record shall be maintained by the facility for two years by one supervisor-level employee, and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs must be placed in a collection receptacle at the facility containing a numbered secure Inner-liner which has been provided by an authorized collector (retail pharmacy).

(a) If the numbered inner-liner becomes full prior to collection by a reverse distributor, one supervisor-level employee of the LTCF (e.g., charge nurse or supervisor) and one authorized employee designated by the authorized collector or two authorized employees of the authorized collector pharmacy may change the collection receptacle inner-liner. Upon removal, sealed inner-liners may be stored at the LTCF for up to three (3) business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.

(4) The drugs placed in the authorized receptacle and stored in secure inner-liner and those secured inner-liners stored by the LTCF can only be removed from the LTCF for disposal for destruction by transfer to a representative for a reverse distributor with a current permit issued by the Board and authorized by the DEA as a collector.

(a) The date and time that the numbered inner-liners were taken from the facility and the numbers of the inner-liners recorded in logs, one maintained by the facility for two years and one maintained by the reverse distributor for each facility for two years;

(b) The name, Board permit/license number, address, and telephone number of the reverse distributor removing the drugs;

(c) The name and signature of the responsible person representing the reverse distributor physically removing the Inner-liners; and

(d) The name and signature of the persons transferring the drugs Inner-liners to the reverse distributor.

(5) Authorized collectors may not transfer sealed inner-liners from LTCFs to their primary registered location (i.e., the hospital/clinic or retail pharmacy location). Instead, collectors should deliver sealed inner-liners to a reverse distributor or distributor's registered location by common or contract carrier pick-up or by reverse distributor or distributor pick-up at the LTCF.

480-50-.04 Numbered Inner-Liner Requirements.

(1) A numbered inner-liner shall meet the following requirements:

(a) The inner-liner shall be waterproof, tamper-evident, and tear-resistant;

(b) The inner-liner shall be removable and sealable immediately upon removal without emptying or touching the contents;

(c) The contents of the inner-liner shall not be viewable from the outside when sealed;

(d) The size of the inner-liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and
(e) The inner-liner shall bear a permanent, unique identification number that enables the inner-liner to be tracked.
(2) Access to the inner-liner shall be restricted to authorized employees for the collector.
(3) The inner-liner shall be sealed by two authorized employees immediately upon removal from the permanent outer container, and the sealed inner-liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.
(4) The authorized collector shall maintain a sequential log of all numbered inner-liners. The log shall indicate, at a minimum:
(a) If the Inner-liner has been placed in a receptacle;
(b) If the Inner-liner has been damaged and rendered not usable;
(c) If the Inner-liner has been sealed and removed from the receptacle;
(d) The names of the collector employees sealing and removing the inner-liner from the collector; and
(e) The date and name of the reverse distributor, and authorized representative, by which the inner-liner was removed from the collector's facility.

480-50-.05 Mail-back Programs
(1) Pre-paid mail-back packages may be provided by authorized collectors to patients and their families for a price or at no cost to the patient.
(2) In Georgia, mail-back packages cannot be returned or mailed back to the authorized collector, unless that collector is a licensed reverse distributor. Collectors that are pharmacies cannot receive or dispose of mail back packages. All such mail-back packages must be shipped directly to a licensed reverse distributor for disposal.

480-50-.06 Reverse Distributors
(1) Any person that reverse distributes a controlled substance shall be registered with the United States Drug Enforcement Administration as a reverse distributor and actively licensed by the Georgia Board of Pharmacy as a reverse distributor.
(2) A reverse distributor shall acquire controlled substances and non-controlled drugs from a collector in the following manner:
(a) Pick-up of sealed inner liner from a collector at the collector's licensed location or authorized receptacle collection site such as a LTCF; or
(b) Receive a sealed inner-liner delivered by common or contract carrier or delivered directly by a registrant or a LTCF to the reverse distributor.
(i) Delivery to the reverse distributor by common or contract carrier may only be made to the reverse distributor at the reverse distributor's registered location. Once *en route,* such deliveries may not be re-routed to any other location or person, regardless of registration status.
(ii) All controlled substance and non-controlled drug deliveries to a reverse distributor shall be personally received by an employee of the reverse distributor at the registered location.
(3) Upon acquisition of a drug by delivery or pick-up, a reverse distributor shall:
(a) Immediately store the controlled substance, in accordance with the security controls in accordance with DEA rules at the reverse distributor's registered location or immediately transfer the drugs to the reverse distributor's registered location for secure storage, in accordance with the security controls in DEA rules, until timely destruction.
(4) A reverse distributor shall destroy or cause the destruction of any drug received for the purpose of destruction no later than 30 calendar days after receipt.

480-50-.07 Inspections

(1) The Georgia Drugs and Narcotics Agency (GDNA) shall have the authority to conduct inspections of any place, premises, or receptacle utilized by any authorized collector in relation to collection, retention, and disposal of drugs.
(2) GDNA shall have the authority to examine, copy, or remove all records required by this rule, and to examine, remove, or inventory all numbered inner-liners.
(3) It shall be the responsibility of any authorized collector to make same available for such inspection, copying, examination, or inventorying by said GDNA.
(4) Following any such examination, inventory, or inspection of records or receptacles, GDNA shall provide to the authorized collector a copy of any written inspection report produced on which any deficiencies or violations are made along with any recommendations, if any, concerning the satisfactory storage, record-keeping, handling, and security of drugs for disposal.
(5) The Pharmacist-in-Charge of each authorized collector shall obtain a copy of the current Board permit of every reverse distributor to which inner-liners are returned. Such copies shall be made available during the GDNA's inspection.
(6) The Pharmacist-in-Charge of each authorized collector shall respond in a written report addressing any discrepancies or deficiencies noted in a GDNA inspection report within two weeks after receipt of the inspection notice. The deficiencies shall be corrected within ten (10) business days.

480-37-.02 Licensure.

(a) In order to install or operate a RAMS, a Georgia licensed pharmacy must make application for licensure to the Board on a form approved by the Board, and pay a fee. No person other than an approved licensed pharmacy may install or operate a RAMS. Each location having a RAMS must have a separate license from the Board. If more than one licensed pharmacy operates a RAMS at the same skilled nursing facility or hospice, each licensed pharmacy must maintain a registration at the skilled nursing facility or hospice. A Georgia licensed pharmacy that has paid a fee for one RAMS location will ~~not~~ be required to pay fees for the additional locations.
(b) Licenses are renewed for two years and expire on June 30th of each odd-numbered year. Renewals are contingent upon the renewal of the pharmacy facility license. If the application for renewal is not made and the fee paid before September 1st of the odd-numbered year, the license shall lapse, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.
~~(b)~~(c) A Georgia licensed pharmacy may only use the RAMS at a skilled nursing facility or hospice licensed as such pursuant to O.C.G.A. T. 31, Ch. 7, that does not have an on-site licensed pharmacy.
~~(c)~~(d) The Pharmacist-in-Charge (PIC) for a licensed pharmacy shall be considered the PIC for each separate license to operate a RAMS at a skilled nursing facility or hospice.
~~(d)~~(e) The RAMS must collect, control, and maintain all transaction information.

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

In the same motion, the Board 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§ 50-13-9 16 5 9 4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Mr. Prather reported that he and Director Allen spoke to an incoming class at Mercer University recently. He stated that one question that was repeatedly asked was whether or not the Board planned to take any action on pharmacy staffing levels and following up with places that were filling an extremely high number of prescriptions. He asked if the Board was considering any regulation to address this. He commented that each pharmacy must have adequate staffing. Mr. Jones agreed that this is a public safety issue. He stated that pharmacies are being run with very limited staff and most are realizing they are not doing their jobs the way they need to. Ms. Wray commented that if the Board is interested in going down that path, it should be addressed in the law. She suggested that legislation could be passed that would allow a legislative study committee to look into the matter.

Jim Bracewell made a motion and Chris Jones 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, Bill Prather, and Bob Warnock.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen
No report.

Cognizant's Report – Mike Faulk

- GDNA Case #A-31565
- GDNA Case #A-31401
- GDNA Case #B-31089A
- GDNA Case #B-31089B
- GDNA Case #A-14-12
- GDNA Case #A-31405
- GDNA Case #T-31605
- GDNA Case #T-31581
- GDNA Case #A-31537
- GDNA Case #B-31518
- GDNA Case #B-31508
- GDNA Case #B-31562
- GDNA Case #T-31625
- GDNA Case #A-15-29

Applications

- J.F.K.
- M.P.

Correspondences

- K.L.T.
- A.T.
- D.K.S.
- C.J.O.
- D.E.
- C.P.C.
- A.H.

- S.Y.
- M.M.W.
- C.H.F.
- P.C.
- R.D.H.
- M.I.
- S.R.P.
- J.H.M.
- D.E.L.
- L.D.I.P.
- M.P.I.
- P.B.S.
- R.M.S.
- P.S.C.
- M.D.

Applications

- S.N.C.
- T.G.
- D.D.D.
- L.R.M.
- A.C.S.
- D.L.S.
- L.N.F.
- A.C.E.
- C.N.R.
- R.D.P.
- K.C.H.

Executive Director's Report Open Session – Tanja Battle

- C.M.
- Device Manufacturers

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

Open Session

Mike Faulk made a motion for the Board to take the following actions:

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

E.U.	Amended public consent order to be accepted and signed with express permission upon receipt of the original
H.J.	Private consent order accepted
W.P.	Private consent order accepted
J.C.	Private consent order accepted
B.I.V.I.	Private consent order accepted

B.P.	Private consent order to be accepted and signed with express permission upon receipt of the original
P.C.P.	Private consent order accepted
K.P.	Private consent order to be accepted and signed with express permission upon receipt of the original

Ms. Wray discussed the following cases:

R.J.	Accept inactive status application upon receipt
R.K.	Accept reinstatement application upon receipt

Appearances

L.T.E.	Denied Pharmacy Technician	Uphold denial
P.P.	Denied Non-Resident Pharmacy	Table pending receipt of additional information
J.G.K.	Denied Pharmacy Technician	Overturn denial and approve registration
Q.S.P.J.	Denied Non-Resident Pharmacy	Overturn denial and approve registration upon receipt of additional information

Cognizant's Report – Mike Faulk

GDNA Case #A-31565	Revoke technician registration; deny intern license
GDNA Case #A-31401	Refer to the Attorney General's office
GDNA Case #B-31089A	Refer to the Attorney General's office
GDNA Case #B-31089B	Refer to the Attorney General's office
GDNA Case #A-14-12	Accept Private Consent Order
GDNA Case #A-31405	Accept Private Consent Order
GDNA Case #T-31605	Accept Voluntary Surrender
GDNA Case #T-31581	Revoke technician registration
GDNA Case #A-31537	Refer to the Attorney General's office
GDNA Case #B-31518	Close case with no action
GDNA Case #B-31508	Close case with letter of concern
GDNA Case #B-31562	Close case with no action
GDNA Case #T-31625	Approve renewal
GDNA Case #A-15-29	Summary suspension of pharmacist license

Correspondences

K.L.T.	Appearance request.	Request approved
A.T.	Appearance request.	Request approved
D.K.S.	Request to lift PIC restriction	Request approved
C.J.O.	Correspondence	Approved renewal with letter stating the Board is not waiving its right to take disciplinary action should the final disposition result in a conviction.
D.E.	Request to lift probation	Request approved
C.P.C.	Request to lift probation	Request approved
A.H.	Notice of discipline	No action taken
S.Y.	Correspondence	No action taken
M.M.W.	Request to lift probation	Request approved
C.H.F.	Correspondence	Revoke technician registration and deny renewal

+-------	Notice of discipline	No action taken
R.D.H.	Request to lift supervised practice restriction	Request approved
M.I.	Notice of discipline	No action taken
S.R.P.	Correspondence	Issue letter of concern
J.H.M.	Request to reinstate license	Schedule for an appearance upon receipt of a completed reinstatement application
D.E.L.	Request regarding intern hours	Request approved
L.D.I.P.	Notice of discipline	No action taken
M.P.I.	Notice of discipline	No action taken
P.B.S.	Correspondence	Request denied
R.M.S.	Request to renew intern license	Request denied
P.S.C.	Request regarding intern hours	Request approved
M.D.	Correspondence	Directed staff to respond that if the facility wishes to conduct business in the State of Georgia, it must get the appropriate license

Applications

S.N.C.	Pharmacy Technician	Denied registration
T.G.	Pharmacy Technician	Denied registration
Darrin D. Davis	Pharmacy Technician	Approved registration
Laci R. Mullis	Pharmacy Technician	Approved registration
A.C.S.	Pharmacy Technician	Denied registration
DeAndrea L. Stephens	Pharmacy Technician	Approved registration
L.N.F.	Pharmacy Technician	Denied registration
A.C.E.	Pharmacy Technician	Denied registration
C.N.R.	Pharmacy Technician	Denied registration
R.D.P.	Pharmacy Technician	Table pending receipt of additional information
Kelley C. Hart	Pharmacy Technician	Approved registration

Executive Director's Report Open Session – Tanja Battle

C.M.	Correspondence	Directed staff to respond that the facility is not required to be a non-resident pharmacy; however, it is required to be licensed as a pharmacy under another provision.
Device Manufacturers:	The Board directed staff to submit applications for such to GDNA for a background check. Once the background check has been completed, staff may administratively process.	

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 4:15 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, December 16, 2015 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 P. Howell, Business Operations Specialist
Minutes edited by Tanja D. Battle, Executive Director