GEORGIA BOARD OF PHARMACY
Board Meeting
Georgia Baptist College of Nursing – Mercer University
3001 Mercer University Drive, Room 137
Atlanta, GA 30341
April 12, 2017
9:00 a.m.

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

Staff present:
Tanja Battle, Executive Director
Rick Allen, Director, GDNA
Janet Wray, Senior Assistant Attorney General
Max Changus, Assistant Attorney General
Anil Foreman, Attorney
Brandi Howell, Business Support Analyst I

Visitors:
Jack H. Mills
Ronnie Lane
Willie Gorman
Mel Goldstein
Shaun Riney, Qualgen
Emmanuel Iyamu
Young Chang, Walgreens
Jeenu Philip, Walgreens
Mike King, Publix
Heidi Bragg, Cardinal Health
Bryan Forlines, Navicent Health
Leotis Bloodworth, Encore Renewable
JT Marburger, Encore Renewable
Curtis Schultz, Mercer
Diane Sanders, Kaiser Permanente
William Hill, Walmart
Kallarin Mackey, Emory
Natalie Morgan, UGA
Jennifer Bellis, Bendin Sumrall & Ladner
Ryan Koenig, Roadrunner Pharmacy
TJ Kaplan, JL Morgan Company
Greg Reybold, GPhA
Aquila Ingram, Encore Renewable
Maria Graham, Encore Renewable
Megan Freeman, GSHP
Michael Oblen, Asteres
Joey Sturgeon, Silvergate
Cecil Cordle, CVS Health

President Jones established that a quorum was present and called the meeting to order at 9:04 a.m.

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

Executive Session

Appearances

- J.H.M.
- W.C.G.
- Q.L.
- R.A.I.P.

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

Open Session

President Jones welcomed the visitors.

Appearance from Aquila Ingram, Encore Renewable Merchandise. Ms. Ingram thanked the Board for the opportunity to speak to its members. Ms. Ingram appeared with several representatives of the company. One of the representatives explained that the company has begun to take steps towards drug diversion. He stated that the purpose of today's meeting is to see if the Board can give them some guidance on issues related to disposal of waste.

Ms. Ingram gave a brief demonstration of the RxCycler and discussed how the machine works. She asked the Board how the company would go about having this particular mechanism approved as it is trying to help decrease the possibilities for diversion on site with this machine grinding the pills. She explained they are aware of the Controlled Substance Act and procedures they have to take into account. A representative of the company asked the Board how they should proceed and how they should address the DEA. Vice-President Warnock responded by stating that the Board does not have any authority to speak on behalf of the DEA. After further discussion, the Board advised that the company would first need to receive approval from the DEA and suggested they read Chapter 480-50 for additional information.

Approval of Minutes

Bill Prather made a motion to approve the Public Session minutes from the March 8, 2017 meeting. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to approve the Executive Session minutes from the March 8, 2017 meeting. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Vicki Arnold made a motion to approve the minutes from the March 31, 2017 Conference Call. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

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

Petition for Rule Variance from Andrea Brown
Bill Prather made a motion to deny the rule variance petition. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance Petition from Optim Medical Center-Jenkins, PHH006257
Vicki Arnold made a motion to deny the rule variance petition. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Aries Pharmaceuticals, Inc.
Bob Warnock made a motion to approve the rule waiver petition. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Toni Bowen, Genoa
The Board viewed this correspondence for informational purposes only.

Correspondence from Marilyn Goodrich
The Board considered this correspondence regarding drug diversion and dangerous drugs. Laird Miller made a motion to direct staff to respond by stating that, in response to the various questions she had, the Board suggests she refer to the law and rules located on the Board's website.

Correspondence from Angela C. Humrich
The Board considered this correspondence asking if the facility were to apply in the state of Georgia as a non-resident drug distributor, would that license allow it to send clinical trial materials to clinical sites and potentially patients. Bob Warnock made a motion to direct staff to respond by stating if the facility is dispensing patient-specific drugs, it would need to be licensed in Georgia as a non-resident pharmacy. Additionally, if it does not want to put the 1-800 number because it is a clinical trial, the facility would need to submit a petition for a rule waiver regarding such. Lastly, if the facility is just sending the drug to the physician and the physician decides what patient would receive it, it would need to be licensed as a wholesaler pharmacy. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Heidi Bragg
The Board considered this correspondence regarding hospitals moving some of their functions to an address away from the main hospital campus address. Ms. Bragg was present at the meeting and spoke to the Board regarding her inquiry. She stated she reviewed the rules and regulations; however, there was not a clear answer. She asked how Georgia looks at the campus of a hospital when a facility is going outside of the four (4) walls of the hospital, but is across the street and part of the campus. She explained that the facilities are still within the main campus, but may not be a part of the main building. Services are right within the vicinity of the main hospital and will still be part of same provider number. President Jones responded by stating that what the Board looks at is what comprised the campus. If it is miles down the road, it is not considered part of the hospital. Ms. Wray added that it depends on what is being done. She stated that you have to look at the hospital, its function, location and how they are managing and operating it. There are different sets of rules for hospital pharmacies and retail pharmacies. She stated that the Board cannot give one blanket answer. She added that the Board would require the hospital to come in and demonstrate how it is operating.

Correspondence from Ian Lundberg
The Board considered this correspondence requesting clarification on waste hauling. Bill Prather made a motion to have Ms. Arnold review the request and once reviewed, direct staff to send the appropriate response. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jennifer M. Hoppe, Joint Commission

The Board considered this correspondence requesting the Board consider approval of the Medication Compounding Certification program as a means of validating that a compounding pharmacy is compliant with the USP standards. Laird Miller made a motion to deny the request. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from John K. Fuller, PharmaCare Services

The Board considered this correspondence regarding its Pharmacy Management Company. Laird Miller made a motion to direct staff to respond by stating that the facility would need to be licensed as a wholesaler pharmacy. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Charlotte De Moor

The Board considered this correspondence asking whether central fill either by a licensed retail pharmacy or non-resident pharmacy is allowed. Laird Miller made a motion to direct staff to respond by stating Georgia does not permit such. Should a facility hold a Non-resident pharmacy license, it must follow the laws and rules of its home state. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Steve Georgeson and Leigh Knotts

The Board considered this correspondence containing comments on proposed Chapter 480-51 Interchangeable Biological Products. Ms. Wray stated these comments will be discussed at the Board's public hearing scheduled in June.

Correspondence from Svein Øie, University of Georgia

The Board considered this correspondence requesting the Board's response concerning what conditions the Board would set for reinstating a student's intern license after illicit drug use and would the Board be willing to share with the College whether and when in their opinion a student has met the conditions for reinstatement. Laird Miller made a motion to direct staff to respond by stating that the Board would look at a number of factors regarding readmission to a school to determine whether a person could safely practice in a pharmacy. This may include, but not be limited to, information regarding whether or not the person had a disqualifying criminal conviction under federal law, an addiction issue, any diversion occurrence at the workplace, whether or not drugs had been diverted for self-use or for distribution, how much time had elapsed since the incident, if there has been drug treatment, whether or not there is advocacy to return to the practice of pharmacy, if there has been a determination that the person can practice safely, how long has there been an addiction issue, etc. While it cannot list every factor it considers, the Board's main purpose is two-fold: to protect the general welfare, health and safety of the public and to keep drugs from getting illegally distributed. The Board would like pharmacists who have a history regarding substance abuse to have the best chance at rehabilitation with a timely and thorough evaluation. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency - Rick Allen

Legislative update provided.

Attorney General's Report - Janet Wray

No report.

Executive Director's Report - Tanja Battle

Renewals: Ms. Battle reported that pharmacy technicians and facilities are currently renewing. She requested the Board and guests to remind licensees about renewals as the expiration date is approaching.

NABP Annual Meeting Delegate: Ms. Battle discussed the upcoming NABP national meeting and stated that the Board would need to decide on a voting delegate for the Board. The meeting is May 20-23, 2017. Bill Prather made a motion to appoint Chris Jones as the voting delegate for the Board. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

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

Date of Program	Sponsoring Group	Program Title	Contact Person	CE Code	Date Notified
03/29/17	The Medical Center, Navicent Health	Hypercalcemia of Malignancy	Glenn Kelley	2017-0001	Approved 3/2/17
03/28/17	Kaiser Permanente	Lupus nephritis: When trouble comes in pairs and race against the clock, Pesky Infections when you really need a heart transplant	Katheryn McDaniel/ Sara Ly	2017-0002	Approved 3/13/17
05/08/17	The Medical Center Navicent Health	Acute Complications of Sickle Cell Disease	Glenn Kelley	2017-0003	Approved 4/4/2017

Miscellaneous

Bob Warnock made a motion to post Rule 480-8-.06 Drug Distribution and Control. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Lisa Harris made a motion to table Rule 480-27-.03 Records of Dispensing. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to post Rules 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security, 480-10-.10 Prescription Drug Order Copies, 480-13-.06 Drug Distribution and Control, 480-13-.11 Required Notifications to the Board, 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician, 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances, 480-18-.06 Drug Distribution and Control, 480-22-.11 Transfer between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes, 480-27-.07 Prescription Drug Order Transfer, 480-33-.06 Drug Distribution and Control, and 480-34-.11 Levocetirizine Dihydrochloride. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Rule 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 recon~~d~~iled, 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) Reports of Loss or Theft.
1. Definitions.
(i) "Immediately notify" shall mean "report within seventy-two (72) hours." Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.
(ii) A "significant amount" shall mean an amount consistent with what is considered to be a significant loss as explained in the Pharmacist's Manual of the U.S. Drug Enforcement Administration (DEA).
2. A pharmacy shall immediately notify the Georgia Drugs and Narcotics Agency (GDNA) upon discovery of the suspected loss or theft of a significant amount of any controlled substance. A DEA Form 106 shall be used to report the suspected loss or theft of a significant amount of any controlled substance. The registrant shall send a completed copy of the appropriate form to GDNA.

3. A DEA Form 106 shall be maintained at the facility for two (2) years from the time of the discovery of the suspected loss or theft. Such form shall be made immediately available upon verbal request by the GDNA.
4. The submission of a DEA Form 106 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the loss or theft of controlled substances.
5. All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of a significant amount of controlled substances within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.
6. The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed DEA Form 106 where required under this rule.

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

(1) Every retail pharmacy, possessing or having possessed any controlled substances and/or dangerous drugs, within a period of two years, and/or possessing any record related to the same, which is required to be kept by O.C.G.A. T. Ch. 16-13, shall exercise diligent care in protecting such controlled substances and/or dangerous drugs and/or records related to the same from loss or theft.
(a) Every licensed retail pharmacy shall ensure that all controlled substances and/or dangerous drugs are purchased from and/or returned to firms holding a current permit issued by the Georgia State Board of Pharmacy (Board). This requirement can be met by a pharmacy maintaining a copy of such firms' current Georgia Board permit.
(2) All controlled substances and/or dangerous drugs shall be kept in ~~a secure place~~ the prescription department, accessible only to an authorized person, except where contained in a collection receptacle compliant with state and federal law and regulation.
(3) ~~Special Agents or Deputy Directors of the~~ The Georgia Drugs and Narcotics Agency (GDNA) shall have the authority to conduct inspections of any place or premises used by any such licensed retail pharmacy in relation to such controlled substances and/or dangerous drugs and/or any records pertaining to their acquisition, dispensing, disposal, or loss.
(4) The GDNA ~~Special Agents or Deputy Directors~~ shall have the authority to examine, copy, or remove all such records, and to examine, copy, remove, or inventory all such controlled substances and/or dangerous drugs.
(a) It shall be the responsibility to such person possessing such controlled substances and/or dangerous drugs and/or records to make the same available for such inspection, copying, examination, or inventorying by said GDNA. ~~Special Agents or Deputy Directors.~~
(b) At the conclusion of an inspection, the GDNA ~~Special Agents or Deputy Director~~ personnel examining said drugs and/or records shall have the responsibility of providing to such retail pharmacy a copy of an ~~written~~ inspection report on which any deficiencies or violations are made along with any recommendations, if any, concerning the satisfactory storage, keeping, handling and security of controlled substances and/or dangerous drugs.
(5) Any person possessing controlled substances and/or dangerous drugs and/or records may request that such an inspection be made, and upon receipt of such written request, the GDNA Director shall make, or cause to be made, without reasonable delay, an inspection in compliance with said request.

Rule 480-10-.10 Prescription Drug Order Copies.

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

~~under the direct supervision of a licensed pharmacist, who is authorized to receive and give such information as follows:~~
~~(a) When a copy of prescription drug order is received manually, meaning without the use of a computer or other electronic means, the person receiving such copy shall immediately reduce the information to writing by creating a hard-copy prescription drug order which, besides the required prescription data, should include at a minimum the following information;~~
~~1. The name of the pharmacist or pharmacy intern/extern who received the prescription drug order;~~
~~2. The name of the transferring pharmacy and its telephone number along with the name of the pharmacist or pharmacy intern/extern who provided the information for the prescription drug order copy;~~
~~3. The date the prescription drug order copy was received.~~
~~(b) When a prescription drug order copy is sent and handled manually, meaning without the use of a computer or other electronic means, the person giving such copy shall record immediately upon his or her hard copy prescription drug order the following information:~~
~~1. That a copy of the prescription has been given and the prescription drug order is null and void, with the word "VOID" being marked on its face;~~
~~2. The name of the pharmacy, and telephone number, where the prescription drug order was transferred;~~
~~3. The name of the pharmacist, or pharmacy intern/extern who received the transferred prescription drug order information; and~~
~~4. The date on which the prescription drug order was transferred.~~
~~(c) When a prescription drug order copy is either sent or received by aid of a computer, or other electronic means, the pharmacist or pharmacy intern/extern should use the procedures for prescription drug order transfers detailed in Rule 480-27-.07.~~

Rule 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) Reports of Loss or Theft.
(a) Definitions.
1. "Immediately notify" means "report within seventy-two (72) hours." Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.
2. A "significant amount" shall mean an amount consistent with what is considered to be a significant loss as explained in the Pharmacist's Manual of the U.S. Drug Enforcement Administration (DEA).
(b) A pharmacy shall immediately notify the Georgia Drugs and Narcotics Agency (GDNA) upon discovery of the suspected loss or theft of a significant amount of any controlled substance. A DEA Form 106 shall be used to report the loss or theft of a significant amount of any controlled substance. The registrant shall send a completed copy of the appropriate form to GDNA.
(c) A DEA Form 106 shall be maintained at the facility for two (2) years from the time of the discovery of the suspected loss or theft. Such form shall be made immediately available upon verbal request by the GDNA.
(d) The submission of a DEA Form 106 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the loss or theft of controlled substances.
(e) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.
(f) The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed DEA Form 106 where required under this rule.

Rule 480-13-.11 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 seventy-two (72) hours of the event;
(c) "Sentinel event" shall mean any unanticipated patient death from medication not related to the natural course of the patient's illness or underlying condition;
(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 Director of Pharmacy of a licensed pharmacy. When the Board receives notice that a pharmacy no longer has a Director of Pharmacy and no replacement Director of Pharmacy is named, the pharmacy's license is suspended pending further action by the Board.
(e) Any theft or loss of drugs of a licensed pharmacy. This notification must also be made to the Georgia Drugs and Narcotics Agency, and if involving controlled substances, the pharmacy must comply with Rule 480-13-.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.
(i) Theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law.
(j) Occurrence of a sentinel event, where the Director of Pharmacy has reasonable cause to believe that a sentinel event occurred.
1. The immediate notification from the Director of Pharmacy to the Board shall include but not be limited to the name of the licensed pharmacy and its pharmacy number; the date of the sentinel event and the date on which the Director of Pharmacy became aware that a sentinel event may have occurred; a brief description of the sentinel event; and any immediate corrective or preventative action taken by the licensed pharmacy to ensure against any future occurrences prior to the completion of the hospital's investigation.
2. Within forty-five (45) business days of the completion of any internal investigation or review of the sentinel event, the Director of Pharmacy shall provide a supplemental report to the Board that includes but is not limited to the following:
(i) An explanation of the circumstances surrounding the sentinel event, including the results of a root cause analysis or other systematic analysis;
(ii) Any finding or conclusions associated with the investigation or review;
(iii) A summary of any actions taken to correct identified problems associated with the sentinel event and to prevent recurrence of a similar incident;
(iv) Any changes in procedure or practices resulting from the internal evaluation using the hospital's peer review and quality management processes or the pharmacy's internal investigation or review.

Rule 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) Verify controlled substance deliveries to a licensed pharmacy. Once a shipment is received in a pharmacy from a licensed wholesaler and a package that contains controlled substances is located within that shipment, a pharmacist shall verify the inventory of the package containing controlled substances and confirm the accuracy of the invoice from the licensed wholesaler.
(15)(16) Any other act prohibited by Board rule, or law.

Rule 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances.
(1) Definitions.
(a) "Immediately notify" means "report within seventy-two (72) hours." Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.
(b) A "significant amount" shall mean an amount consistent with what is considered to be a significant loss as explained in the Pharmacist's Manual of the U.S. Drug Enforcement Administration (DEA).
(1) The theft, loss, or unaccounted for controlled substances must, within three (3) days of its discovery, must be reported to the Drug Enforcement Administration and the GDNA.
(2) A pharmacy licensed by the Board to keep controlled substances must immediately notify the Georgia Drugs and Narcotics Agency (GDNA) upon discovery of the suspected theft, loss, or inability to account for a significant amount of any controlled substance, pursuant to O.C.G.A. §26-4-112. A DEA Form 106 shall be used to report the suspected theft, loss, or inability to account for a significant amount of any controlled substance. The pharmacy shall send a completed copy of the appropriate form to GDNA. This report shall be faxed or mailed to the GDNA office or emailed to the GDNA Special Agent responsible for the area in which the facility is located.
(a) All pharmacies must maintain a copy of a completed DEA Form 106 for two (2) years from the time of the discovery of the theft, loss, or inability to account.
(3) (2) A written report must be made regarding any theft, loss or unaccounted for controlled substances by completing a DEA Form 106. The submission of a DEA Form 106 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances.
(a) Within ten (10) days of receiving such DEA Form 106, the original and one copy of the report must be sent to the Drug Enforcement Administration; and
(b) One copy must be sent to the GDNA.
(4) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss, theft, or inability to account for controlled substances within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.
(3) The report shall include the following information:
(a) Full name and address of the pharmacy;(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.~~

Rule 480-18-.06 Drug Distribution and Control.

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

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

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

1. The drugs must be identified up to the point of administration;
2. The pharmacy must receive a direct, electronic (only for drugs to be administered on site) or mechanical copy of a physician's order before the first dose of medication is dispensed as defined by the clinic stat order policy.
3. At a minimum, the pharmacy must maintain a patient profile for each OTP clinic patient for use in prospective and retrospective drug reviews, for comparing with the central registry as required by the DHR and to report violators to the GDNA and DHR, for discharge from another OTP, and for urine or blood tests to check for drug positive test results.
4. Records of all transactions of the OTP clinic pharmacy, such as daily drug dosing summaries, daily drug inventory sheets, patient medication profiles, and bulk drug inventory records must be maintained by the clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all drugs and devices within the scope of the clinic practice.
5. All drug invoices must be attached to their accompanying DEA form 222 order form and must be filed separately from all other drug records. A biennial inventory of all controlled substances on hand must be taken every two years from the date of the pharmacy opening for business. This inventory must be an accurate count of all such drugs, signed in indelible ink by the pharmacist taking the inventory and dated on the date it is taken.
6. Any drug compounded by the pharmacy must be accounted for by use of a compounding log form. This form, at a minimum must display the date the drug was compounded, the name of the drug, the strength, quantity made, manufacturer's lot number, manufacturer's expiration date, and the signature of the pharmacist compounding the drug.
7. Nothing in this section shall prohibit the use of computerized records, where such records meet all other requirements of the law. An OTP clinic pharmacy may not dispense or administer prescription medications other than OTP program medications; and
8. The pharmacy must participate in those aspects of the OTP clinic patient care evaluation program which relate to drug and device utilization and effectiveness.

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

(3) Labeling:

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

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

(b) Any drug container dispensed by the pharmacy for take-home use by an OTP clinic patient must display a label which contains at least the following:
1. Patient name;
2. Name of the prescribing physician;
3. Name, address and telephone number of the OTP clinic pharmacy;
4. Drug name (either brand or generic name);
5. Drug strength;
6. Date of dispensing;
7. Expiration date of the drug as determined by the pharmacy;
8. "Federal Caution" for controlled substances;
9. Clinic Pharmacy serial number for that specific prescription drug order;
10. Any other labeling or information as required by the DEA;
(c) All take-home medication dispensed by the pharmacy, including one-time use containers, must be in child-proof containers which meet the requirements of the U.S. Consumer Product Safety Commission.
(4) Discontinued drugs. The Director shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.
(5) Accountability of controlled substances.
(a) Nothing shall prohibit the use of controlled substance drugs issued via proof of use forms for general or emergency use for specific patients. Proof of use controlled substances forms shall be provided by the pharmacy.
(b) Each proof of use form shall display the name of the patient to or for which it has been issued and an indication that the drugs are for general or emergency use and a serial number. The form shall also show the date the form was issued and the signature of the pharmacist issuing the form and the signature of the licensed medical practitioner receiving the form for storage in the after-hour safe. A detachable receipt reflecting all the previous information must be returned and filed by the pharmacy as a safeguard to prevent drug diversion.
(c) Each proof of use sheet shall provide space to record the administration information necessary to account for each dose of medication. This information shall specify at a minimum:
1. Drug name, strength, and dosage form;
2. Dose administered;
3. Name of prescriber. This shall include, at a minimum, the first initial and complete last name of the prescriber;
4. First and last name of the patient;
5. Date and time of administration to patient;
6. Signature of individual administering the dose, which shall include at a minimum, the first and last name and title;
7. Documentation of destruction of all unused portions by two signature verifications of licensed healthcare professionals;
8. Proof of receipt of medication bearing identifying serial numbers;
9. Date the medication was issued and date the proof of use form was returned.
(6) Any OTP clinic pharmacy licensed by the Board may make on-premises destruction of small quantities of controlled substances prepared for oral administration provided:
(a) The controlled substance is the remainder of a single-dose unit; and,
(b) The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.
(7) Perpetual inventory of Schedule II controlled substances shall be required and accountability of said drugs shall be by an appropriate form indicating at a minimum the date used, name of shipper or drug recipient, corresponding serial number of a drug order, invoice or proof of use form, and quantity received or issued.

(8) Recall. The Director shall develop and implement a recall policy and procedure to assure that all drugs within the clinic included on the recall are returned to the pharmacy for proper disposition.
(9) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering physician, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's pharmacy profile shall also be made.
(10) Security. All areas occupied by an OTP clinic pharmacy shall be capable of being locked by key or combination, so as to prevent unauthorized personnel access except by force. Such areas shall meet the security requirements of all applicable Federal and State laws and rules. Only those persons so authorized shall be permitted to enter these areas.
(a) All drugs shall be stored in designated areas within the clinic pharmacy or all dispensing medications shall be stored in designated areas within the clinic which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage areas shall be locked or otherwise secured when licensed health care professionals are not present.
(b) Storage for Schedule II controlled substances shall be in an enclosed room or space with controlled limited access capable of showing forced entry is preferable. However, a safe or a lockable metal cabinet that is permanently affixed to the structure is acceptable.
(c) Whenever any area of an OTP clinic pharmacy is not under the personal and direct supervision of authorized licensed personnel, such areas shall be locked and secured.
(11) Reports and records. The Director shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board, the GDNA or its designated agents. All such records shall be maintained for a minimum of two years. These shall include, at a minimum, the following:
(a) Patient profile, chart or other appropriate record;
(b) Proof of use forms for controlled substances;
(c) Reports of suspected adverse drug reactions;
(d) Inventories of after hours safe(s) and emergency drug kits,
(e) All perpetual inventories maintained by the pharmacy, and all other records pertaining to controlled substances, including a biennial controlled substances inventory;
(f) Such other records and reports as may be required by Federal or State laws and/or rules;
(12) The compounding, labeling and quality control of large volumes of opioid treatment medication is the responsibility of a pharmacist and shall be prepared within the on-site pharmacy.
(13) Reports of Loss or Theft.
(a) Definitions.
1. "Immediately notify" shall mean "report within seventy-two (72) hours." Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.
2. A "significant amount" shall mean an amount consistent with what is considered to be a significant loss as explained in the Pharmacist's Manual of the U.S. Drug Enforcement Administration (DEA).
(b) A pharmacy shall immediately notify the Georgia Drugs and Narcotics Agency (GDNA) upon discovery of the suspected loss or theft of a significant amount of any controlled substance. A DEA Form 106 shall be used to report the suspected loss or theft of a significant amount of any controlled substance. The registrant shall send a completed copy of the appropriate form to GDNA.
(c) A DEA Form 106 shall be maintained at the facility for two (2) years from the time of the discovery of the suspected loss or theft. Such form shall be made immediately available upon verbal request by the GDNA.
(d) The submission of a DEA Form 106 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses or thefts of controlled substances.
(e) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The transfer of original prescription information for a dangerous drug for the purpose of refill dispensing is permissible between pharmacies as long as there are authorized refills.
(b) The transfer of original prescription information for a controlled substance in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online computerized database may transfer the prescription drug order information as many times as there are authorized refills, up to the maximum (5) times, if it is within (6) months from the date of issuance.
(2) The transfer of original prescription drug information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:
(a) The prescription drug order is transmitted directly to the pharmacy of the patient's choice.
(b) The transfer is communicated directly between licensed pharmacists or licensed interns or externs under the direct supervision of a licensed pharmacist and the transferring pharmacist or intern or extern records the following information~~:~~ in the pharmacy automated data processing system for that prescription:
~~1. The word "VOID" is written on the face of the invalidated prescription drug order, and/or indicate in the pharmacy's electronic data system this prescription is void;~~
~~2.~~ 1. Record ~~on the reverse of the invalidated prescription drug order~~ the name and address of the pharmacy to which it was transferred and the name of the pharmacist or intern or extern under the ~~direct~~ supervision of a licensed pharmacist receiving the prescription drug order information, or have the electronic data system reflect the fact that the prescription drug order has been transferred, the name and address of the pharmacy to which it was transferred and the name of the pharmacist or intern or extern under the ~~direct~~ supervision of a licensed pharmacist to which it was transferred, and the date of the transfer; and
~~3.~~2. Record the date of the transfer and the name of the pharmacist or intern or extern under ~~direct~~ supervision of a licensed pharmacist transferring the information.
~~(c)~~3. The pharmacist or intern or extern under the ~~direct~~ supervision of a licensed pharmacist receiving the transferred prescription drug order shall ~~reduce to writing, or cause the computer to reduce to writing, the following information which shall be filed as required by O.C.G.A. Title 16, Chapter 13 and Title 25, Chapter 4:~~ record the following in the pharmacy in the pharmacy automated data processing system for that prescription:
~~1. The word "TRANSFER" shall be written on the face of the transferred prescription and/or indicate in the pharmacy's electronic data system this prescription was a transfer;~~
~~2.~~(i) All information required to be included on the prescription drug order pursuant to all State and Federal laws and regulations shall be provided which shall include at a minimum the following:
~~(i)~~(I) Date of issuance of the original prescription drug order;
~~(ii)~~(II) Original number of refills authorized on the original prescription drug order;
~~(iii)~~(III) Date of original dispensing;
~~(iv)~~(IV) Number of valid refills remaining and date of last refill;
~~(v)~~(V) The pharmacy's name, address, and original prescription serial number from which the prescription drug order information was transferred; and
~~(vi)~~(VI) Name of transferring pharmacist.
~~3.~~(ii) Both the original and transferred prescription must be maintained for a period of two years from the date of last refill.
~~(d)~~4. Pharmacies utilizing an ~~accessing a common~~ electronic file or database used to maintain required dispensing information are not required to record on the original hard copy prescription drug order any information when transferring or refilling prescription drug orders ~~as required for pharmacies not utilizing a common electronic file as noted in this Chapter~~. However, a hard copy of the prescription drug order must be generated and maintained by the ~~pharmacist~~ pharmacy refilling or receiving the electronically transferred prescription drug order information. The common database must contain complete records of each prescription drug order transferred.

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

Rule 480-33-.06 Drug Distribution and Control.

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

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

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

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

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

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

(3) Labeling.

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

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

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

(5) Accountability of controlled drugs.

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

1. Drug name, strength, and dosage form;
2. Dose;
3. Name of prescriber. This shall include, at a minimum, the given and last name;
4. Given and last name of patient;
5. Date and time of administration to patient;
6. Signature of individual administering, which shall include at a minimum, the initial, last name and title;
7. Documentation by two signature verifications of destruction of all unused portions;

8. Proof of receipt of medications that bears identifying serial numbers; and
9. Date medication was issued and the date that the proof of use form was returned.
(b) Anesthesia, surgical, diagnostic and treatment departments that obtain controlled drugs from the clinic pharmacy must show accountability of the controlled drugs by proof of use as defined above.
(c) Use of computer hard copy is permitted where such copy meets all other requirements of the law.
(d) Any outpatient clinic pharmacy licensed by the Georgia State Board of Pharmacy in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:
1. The controlled substance is the remainder of a single-dose unit; and
2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.
(e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.
(f) Recall. The pharmacist-in-charge shall develop and implement a recall policy and procedure to assure that all drugs within the clinic included on the recall are returned to the pharmacy for proper disposition.
(g) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering practitioner, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's record shall also be made.
(h) Records and reports. The pharmacist-in-charge shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board or its agents. These shall include, at a minimum, the following:
1. Patient profile, chart or other appropriate record;
2. Proof of use forms for controlled substances;
3. Reports of suspected adverse drug reactions;
4. Inventories of night cabinets, cabinets or enclosures; emergency drug kits; and standard ward inventories;
5. Inventories of the pharmacy;
6. Biennial controlled substances inventories;
7. Alcohol and flammables reports; and
8. Such other records and reports as may be required by law and the rules and regulations of the Georgia State Board of Pharmacy.
(i) Standard Ward Inventory. The outpatient clinic pharmacy may distribute drugs within a clinic for the purpose of establishing and/ or maintaining a standard ward inventory.
Such drugs may be supplied only upon a signed requisition from an authorized licensed health care professional of said clinic or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order and shall be documented in the patient's record. A record of drugs administered to patients in ancillary areas such as surgical suite, treatment rooms, anesthesiology and diagnostic areas will become a part of the patient's record and shall be retrievable by the pharmacy. A survey of usage trends of each standard ward inventory shall be made monthly. Such records shall be maintained for a period of two years.
(j) Security of controlled substances. Controlled drugs that are maintained as authorized standard ward inventory in patient care/ treatment areas outside the pharmacy shall be stored in secured cabinets or areas that provide a double lock system.
(6) Reports of Loss or Theft.
(a) Definitions.
1. "Immediately notify" shall mean "report within seventy-two (72) hours." Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.
2. A "significant amount" shall mean an amount consistent with what is considered to be a significant loss as explained in the Pharmacist's Manual of the U.S. Drug Enforcement Administration (DEA).

(b) A pharmacy shall immediately notify the Georgia Drugs and Narcotics Agency (GDNA) upon discovery of the suspected loss or theft of a significant amount of any controlled substance. A DEA Form 106 shall be used to report the suspected loss or theft of a significant amount of any controlled substance. The registrant shall send a completed copy of the appropriate form to GDNA.
(c) A DEA Form 106 shall be maintained at the facility for two (2) years from the time of the discovery of the suspected loss or theft. Such form shall be made immediately available upon verbal request by the GDNA.
(d) The submission of a DEA Form 106 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the thefts or losses of controlled substances.
(e) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.
(f) The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed DEA Form 106 where required under this rule.

Rule 480-34-.11 Levocetirizine Dihydrochloride.
(1) This rule was adopted to protect the health, safety, and welfare of the public. Levocetirizine dihydrochloride in 5 mg tablets or an oral solution of 2.5 mg per 5 mL (.05 mg per mL), as identified in Official Code of Georgia Annotated (O.C.G.A.) §16-13-71(b)(516.75), is hereby removed from the list of dangerous drugs of the Georgia Dangerous Drugs Act.
(2) This rule is based on the following findings of the Board:
(a) that levocetirizine dihydrochloride does not have a high potential for abuse;
(b) that the Board has considered the scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; the potential of the drug to produce psychic or physiological dependence liability; and
(c) that the drug, when in 5 mg tablets or an oral solution of 2.5 mg per 5 mL (.05 mg per mL), has been approved for non-prescription status by the Federal Food and Drug Administration.

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

In the same motion, the Board also voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rule amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Bill Prather made a motion to adopt Emergency Rule 480-34-0.32-.11 Naloxone. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

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

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

- Z.G.

Cognizant's Report – Bob Warnock

- GDNA Case #B-32089
- GDNA #B-32086
- GDNA #B-32087
- GDNA Case # A16-12
- GDNA Case # A17-04
- GDNA Case # T-32113
- GDNA Case # T-32150
- GDNA Case # T-32149
- GDNA Case # T-32143
- GDNA Case # T-32134
- GDNA Case # B-32076
- GDNA Case # B-32008A
- GDNA Case # B-32008B
- GDNA Case # B-31971
- PHAR170206

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- A.P.
- M.P.
- J.J.
- R.S.S.
- M.J.S.
- B.Z.
- D.C.Z.
- M.
- S.L.

Ms. Wray discussed the following individual:

- R.A.S.

Mr. Changus discussed the following case:

- P.P.S.

Executive Director's Report - Tanja Battle

- C.J.G. and J.J.G.
- A.M.H.
- P.P.

Applications

- T.D.Y.
- A.P.M.
- S.M.K.

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

Correspondences/Requests

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

- S.M.A.P.
- T.P.S.I.
- W.M.S.I.
- T.P.S.I.
- T.L.C.
- A.A.L.
- H.T.L.
- A.H.C.
- R.R.
- G.R.C.
- M.R.C.I.

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

Open Session

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

Appearances

• J.H.M.	Denied Reinstatement	Refer to the Attorney General's Office
• W.C.G.	Denied Reinstatement	Uphold denial
• Q.L.	Denied Manufacturing Pharmacy Denied Non-Resident Pharmacy	Table pending receipt of additional information
• R.A.I.P.	Retail Pharmacy	Table until May meeting to allow additional time to review

Georgia Drugs and Narcotics Agency – Rick Allen

• Z.G.	Denied Pharmacy Technician	Uphold denial

Cognizant's Report – Bob Warnock

• GDNA Case #B-32089	Table pending receipt of additional information
• GDNA #B-32086	Deny pharmacy technician application
• GDNA #B-32087	Reschedule investigative interview
• GDNA Case # A16-12	No action
• GDNA Case # A17-04	Summary suspension and accept Voluntary Surrender upon receipt of the original
• GDNA Case # T-32113	Revoke Technician Registration
• GDNA Case # T-32150	Accept Voluntary Surrender upon receipt of the original
• GDNA Case # T-32149	Revoke Technician Registration
• GDNA Case # T-32143	Revoke Technician Registration
• GDNA Case # T-32134	Revoke Technician Registration
• GDNA Case # B-32076	Close with a letter of concern
• GDNA Case # B-32008A	Close with no action
• GDNA Case # B-32008B	Close with no action
• GDNA Case # B-31971	Close with a letter of concern
• PHAR170206	Close with a letter of concern

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- Aavis Pharmaceuticals — Public Consent Order accepted
- Medaus Pharmacy — Public Consent Order accepted
- J.J. — Private Consent Order accepted
- R.S.S. — Private Consent Order accepted
- M.J.S. — Private Consent Order accepted
- Brant Zauner — Public Consent Order accepted
- D.C.Z. — Private Consent Order accepted
- M. — Private Consent Order accepted
- S.L. — Public Consent Order to be accepted and signed with express permission upon receipt of the original

Ms. Wray discussed the following individual:

- R.A.S. — Update provided

Mr. Changus discussed the following case:

- P.P.S. — Update provided

Executive Director's Report - Tanja Battle

• C.J.G. and J.J.G.	Request for waiver of reinstatement fee	Denied request
• A.M.H.	Request for waiver of reinstatement fee	Denied request
• P.P.	Correspondence	The Board viewed this correspondence for informational purposes only.

Applications

• T.D.Y.	Pharmacy Technician	Approve pending receipt of additional information
• A.P.M.	Pharmacy Technician	Table pending receipt of additional information
• Sonja M. King	Pharmacy Technician	Approved application
• Felicia L. Davis	Pharmacy Technician	Approved application
• La'Nora C. Williams	Pharmacy Technician	Approved application
• Ray C. Lee, II	Pharmacy Technician	Approved application
• Edward U. Ndem, Jr.	Pharmacy Technician	Approved application
• Takia Suarez	Pharmacy Technician	Approved application
• Kriston Youmans, Sr.	Pharmacy Technician	Approved application
• A.A.A.	Pharmacist Reciprocity	Approved to sit for the exam
• G.A.M.	Pharmacy Reinstatement	Denied application
• C.C.A.	Pharmacist Intern	Table pending receipt of additional information
• Catherine A. Bourg	Pharmacist Cert of DTM	Approved application
• Rebecca H. Stone	Pharmacist Cert of DTM	Approved application
• P.R.S.	Wholesaler Pharmacy	Refer to the Attorney General's Office
• Midwest Vet Supply	Wholesaler Pharmacy	Approved renewal
• Midwest Vet Supply	Wholesaler Pharmacy	Approved renewal
• Midwest Vet Supply	Wholesaler Pharmacy	Approved renewal
• Diamond Pharm Serv	Wholesaler Pharmacy	Approved renewal

Correspondences/Requests

• B.Z.	Request to terminate C.O.	Approved request
• B.K.H.	Request to terminate C.O.	Approved request
• T.E.D.	Request to terminate C.O.	Approved request
• J.F.M.	Request to terminate probation and reporting req	Denied request
• C.J.	Request to terminate C.O.	Approved request
• J.D.P.	Request for appearance	Approved request
• K.L.B.	Request to terminate C.O.	Denied request
• S.L.Y.	Correspondence	Board directed staff to send letter stating individual was approved to practice
• S.M.A.	Correspondence	Letter of concern
• T.I.N.	Reciprocity Applicant	Board directed staff to respond by providing instructions on how to reapply
• P.V.	Req to take NAPLEX a 4th time	Denied request
• C.E.	Request for waiver of reinstatement fee	Fee for each renewal period not renewed waived
• A.U.M.C.	License type clarification	Schedule to meet with the Board
• A.M.I.	Request for waiver of application fee	Denied request
• A.H.G.I.	Notice of discipline	No action
• A.S.P.	Notice of discipline	No action
• A.E.P.	Notice of discipline	No action
• A.H.	Notice of discipline	No action
• A.P.	Notice of discipline	No action
• B.T.	Notice of discipline	No action
• C.W.P.	Notice of discipline	No action
• D.C.R.I.P.C.A.	Notice of discipline	No action
• E.P.C.	Notice of discipline	No action
• G.R.	Notice of discipline	No action
• I.W.P.	Notice of discipline	No action
• L.S.L.	Notice of discipline	No action
• I.C.S.	Notice of discipline	No action
• C.V.S.C.	Notice of discipline	No action
• A.H.P.	Notice of discipline	No action
• P.P.	Notice of discipline	No action
• S.M.A.P.	Audit results	No action
• T.P.S.I.	Notice of discipline	No action
• W.M.S.I.	Letter of admonition	No action
• T.P.S.I.	Notice of discipline	No action
• T.L.C.	Correspondence	Table pending receipt of additional information
• A.A.L.	Req to take MPJE a 5th time	Approved request
• H.T.L.	Req to take NAPLEX a 6th time	Denied request
• A.H.C.	Req to take NAPLEX a 4th time	Denied request
• R.R.	Accommodations request	Board directed staff to respond by stating the

		individual will need to submit a written request for special accommodations, along with the appropriate documentation from his/her physician.
• G.R.C.	Notice of discipline	No action
• M.R.C.I.	Notice of discipline	No action

Lisa Harris seconded and the Board voted unanimously in favor of the motion.

In regards to GDNA Case #A-17-04, Bill Prather made a motion to summarily suspend the pharmacist license and the facility license. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

In regards to GDNA Case #A-17-04, Laird Miller made a motion to accept the voluntary surrender upon receipt of the original. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 3:57 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, May 10, 2017 at 8:30 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I
Minutes edited by Tanja D. Battle, Executive Director