GEORGIA BOARD OF PHARMACY
Conference Call Agenda
2 Peachtree Street, NW, 6th Floor
Atlanta, GA 30303
April 14, 2021
9:00 a.m.

The following Board members were present:
Michael Brinson, President
Dean Stone, Vice-President
Michael Azzolin
Young Chang
Cecil Cordle
Chuck Page
Bill Prather

Staff present:
Eric Lacefield, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst

Visitors:
Diane Sanders
Stephanie Kirkland
Becca Hallum, GHA
Stephen Georgeson

Open Session

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

Mr. Lacefield asked the visitors on the call to send an email via the "Contact Us" portal on the website if he/she would like his/her name reflected as being in attendance in the minutes.

President Brinson welcomed new member, Young Chang.

Approval of Minutes
Vice-President Stone made a motion to approve the March 10, 2021 Public Session and Executive Session Conference Call minutes. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued
Vice-President Stone made a motion to ratify the list of licenses issued. Mr. Cordle seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance
Rule Waiver Petition from etectRx, Inc.: Mr. Prather made a motion to deny the petition. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Hoveround Corporation, PHDME000020: The Board recommended tabling this petition pending further discussion in Executive Session.

Rule Waiver Petition from Jeff Davis Hospital: Vice President Stone made a motion to grant a waiver of Rule 480-10-.12(e). Mr. Page seconded and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Southside Behavioral Lifestyle Enrichment Center, PHOP00010:
Vice-President Stone made a motion to grant the petition. Mr. Cordle seconded and the Board voted unanimously in favor of the motion.

Correspondence from John Finley
The Board considered this correspondence regarding the FDA Memorandum of Understanding. The Board recommended tabling discussion on this matter until its June meeting. President Brinson requested Mr. Greg Reybold, GPhA, who was on the call, to assist with obtaining input from compounding pharmacists. Mr. Reybold responded that he would be happy to assist with such.

Correspondence from Alliance for Pharmacy Compounding
The Board viewed this correspondence for informational purposes only.

Correspondence from Ricky C. Benjamin, Akerman LLP
The Board considered this correspondence regarding a new policy change effective April 1, 2021 implementing Anthem's Designated Specialty Pharmacy Network, which requires specific drugs be provided through Anthem's Specialty Vendor, CVS Pharmacy. President Brinson discussed "white bagging" medication, which means the drug never goes to the patient, but from pharmacy to provider for mixing. He stated that after mixing, the drugs are given to the patient. He added that this process raises many red flags.

Mr. Azzolin commented that Blue Cross Blue Shield offers for the hospital to become a part of the network so they can dispense the drugs themselves. He stated that in accepting that, the reimbursements are changed and reduced. He further stated that many hospitals are either electing to go along with it, take the reduced reimbursement and prepare the drug themselves, or they let the specialty pharmacy provide the drugs. Mr. Azzolin stated if the hospital does that and accepts the drugs from the specialty pharmacy, then those drugs often cannot be fully mixed and prepared by the specialty pharmacy because they are dispensed the day before and shipped to the pharmacy. He stated that the reason they are not mixed and prepared is, many of those drugs often have to be prepared in a cleanroom environment the day the patient arrives for reasons such as the patient needing to be weighed before the actual dose can be determined. He further stated the drugs are being sent from the specialty pharmacy with the labels on them to be prepared by the hospital pharmacy. Mr. Azzolin commented that there are major patient safety issues associated with this situation. He stated that when a medication comes from an outside source, it is a requirement for the hospital to see if the drug has been adulterated in any way, and if they have been adulterated, the medication cannot be used. Mr. Azzolin went on to state that hospitals are being targeted. He added that most hospital oncology clinics are 340B entities and Anthem is getting the savings as opposed to the 340B entities.

Mr. Azzolin discussed O.C.G.A. § 33-64-9.1, which protects covered entities. Mr. Azzolin stated that he never heard of "white bagging" before this matter came up. He asked if unmixed infusions are being sent to be mixed at another pharmacy, does that meet the definition of a filled prescription. He stated that it is an issue that the Board may need to consider in terms of patient safety. President Brinson agreed.

Mr. Azzolin inquired as to whether or not there were any rules that protect against re-dispensation of medications that have not been properly reconstituted by the dispensing pharmacy. Director Troughton responded by stating he is not aware of any rule that would cause that to be an issue if it had been clearly communicated between the physician and the pharmacy that the drug was to be mixed at the physician's office. Director Troughton went on to state that if they dispensed it without reconstituting it and if it went to a patient and a complaint was made, the Board would likely see

that as a misfill; however, if it was clearly communicated in the system as to how to dispense it, he does not see it being a violation if there are records to support it.

After further discussion, Mr. Changus commented that there are many outstanding questions with this situation. He suggested responding to Mr. Benjamin by requesting specific information as to what laws/rules such a policy violates and specific instances where a potential violation may have occurred that can be investigated. The Board agreed.

Correspondence from Melissa Russell, Dexcom

The Board considered this correspondence regarding whether or not a permit is needed to manufacture continuous glucose monitoring devices for Type 1 Diabetes. Vice-President Stone made a motion to direct staff to respond to Ms. Russell by stating that a permit would not be required for this device as it falls under the O.C.G.A. § 26-4-51(g)(8) exemption. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Correspondence from Aaron Lopez, Political Capital LLC

The Board viewed this correspondence for informational purposes only.

Correspondence from Melissa R. Osborne, Advanced Pharmaceutical Consultants, Inc.

The Board considered this correspondence requesting the Board mandate a human trafficking continuing education course. In response, the Board directed staff to respond to Ms. Osborne by suggesting she contact the various associations to see if they would be interested in offering the course for free.

Correspondence from Stephen Georgeson, Pharmacy Council of the Georgia Retail Association

The Board considered this correspondence requesting the Board amend language under Rule 480-10A-.05(4) to clarify that the requirement for writing "Central Fill" on the face of any hard copy prescription applies only to controlled substance prescriptions. Ms. Emm commented that when the Board originally drafted the Central Fill regulations, the Board did discuss why it was requiring the same requirements for controlled substances and dangerous drugs. She added that the Board came to the decision that it did not see any reason to make the requirements different. Director Troughton commented that GDNA would encourage the Board to keep the rule as is. He stated that the information on each prescription is there, which makes it more efficient and better for investigators. President Brinson asked if there were any further comments. There were none.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA has conducted 2056 inspections and 286 investigations for FY2021.

Director Troughton welcomed Mr. Chang to the Board. He stated that Mr. Chang, and any other board members were welcome to visit GDNA to see what they do.

Attorney General's Report – Max Changus

Mr. Changus introduced himself to Mr. Chang and explained his role with the Board.

Executive Director's Report – Eric Lacefield

Renewals: Mr. Lacefield reported that facilities and pharmacy technicians are currently renewing. He requested the Board and guests to encourage people to not wait until the last minute as the expiration date is June 30th.

Renewal Fee for Durable Medical Equipment Suppliers: Mr. Lacefield reported that Durable Medical Equipment Suppliers are the newest license type and it is time for them to renew. He requested the Board determine a renewal fee and late renewal fee. He stated that the application fee is $750. Mr. Page made a motion to set the renewal fee to $600 and the late renewal fee to $900. Mr. Cordle seconded and the Board voted unanimously in favor of the motion.

Continuing Education Report: Report presented. Vice-President Stone made a motion to ratify the below continuing education program approved since the previous meeting. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
05/21/2021-12/01/2021	4	The Medical Center, Navicent Health	2021 USP 797 Aseptic Work Practices Competency	2021-0003

Delegate for NABP Annual Meeting: Mr. Lacefield reported that the NABP Annual Meeting will be held virtually in May and the Board will need to vote on a delegate and an alternate. Mr. Chang made a motion to serve as the delegate with Vice-President Stone as the alternate. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

Legal Services – Kimberly Emm

No report.

Miscellaneous

President Brinson thanked Ms. Emm for all of her hard work on the rules that were on the agenda for consideration. Ms. Emm responded by stating that the rules being presented for consideration were previously discussed by the Board at its meeting in February. She further stated that all requested changes have been made to the rules and if the Board is in agreement with the amendments, it can proceed with voting to post and then the rule amendments will be sent to Mr. Changus to review for authority.

Mr. Page made a motion to post Rule 480-27-.01 Definitions, Rule 480-27-.09 Patient Records, Rule 480-31-.01 Patient Counseling, Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders, Rule 480-37-.03 Minimum Requirements, Rule 480-10-.01 Controlled Substances and Dangerous Drugs, Rule 480-13-.06 Drug Distribution Control, Rule 480-48-.01 Definitions, Rule 480-10-.06 Licensure, Applications, and Display of License and Renewal Certificate, and Rule 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances. Vice-President Stone seconded. Discussion was held by Mr. Azzolin. Mr. Azzolin requested clarification regarding the status of the rules that contained the "null/void" language for a change of location. Ms. Emm responded that Mr. Azzolin was referencing an email on Sharepoint that lists all of the rules that will need to be amended if the Board chooses to remove the "null/void" language for a change of location. She continued by stating that the Board has not voted to make those changes yet. Ms. Emm explained that a request for a change of location would still require a new application, an inspection by GDNA, etc. She stated that it does not necessarily change the license number. Ms. Emm stated that if the Board wished to make those changes, the rules that would be impacted are Rule 480-6-.02, Rule 480-7-.01, Rule 480-7-.03, Rule 480-7-.04, Rule 480-7A-.04, Rule 480-7B-.02, Rule 480-8-.02, Rule 480-13-.02, Rule 480-18-.02, and Rule 480-33-.02. Mr. Azzolin asked if the Board does vote to amend the rules that would be impacted, would that allow the facilities to change locations without being issued a new license number. Ms. Emm affirmed that was correct. Mr. Azzolin inquired about Rule 480-10-.06. Ms. Emm responded by stating that the Board addressed that rule in February. Mr. Azzolin suggested the Board address

the impacted rules as soon as possible. With no further discussion, the Board voted unanimously in favor of the motion.

Rule 480-27-.01. Definitions

For purposes of these Rules and Regulations, the following definitions apply:

(a) Authentication. Any process by which the identities of the parties sending and receiving electronic prescription data are verified.

(b) Automated Electronic Data Processing System. A system utilizing computer software and hardware for the purpose of record-keeping and/or receiving prescription drug orders. Any and all such systems that are compatible and capable of interacting with, and electronically transferring prescription drug data with any other system must be in compliance with the rules of the Board for use in electronic prescription monitoring.

(c) Board. The Georgia State Board of Pharmacy.

(d) Computer. Programmable electronic device capable of multifunctions including but not limited to storage, retrieval, and processing of information.

(e) Controlled Substances. Those drug items regulated by federal law and/or the Georgia Controlled Substances Act.

(f) Dangerous Drugs. Those drug items and devices regulated by the Georgia Dangerous Drug Act.

(g) Digital ID. An authenticated identifiable signature than can be attached to an electronic e-mail and is tamper proof.

(h) Downtime. That period of time when a computer is not operable.

(i) Electronic Means. An electronic device used to send, receive, and/or store prescription drug order information, including computers, facsimile machines, etc.

(j) Electronic Signature. An electronically reproduced visual image signature or an electronic data signature of a practitioner, which appears on, is attached to, or is logically associated with an electronic prescription drug order.

(k) Facsimile. A hard copy prescription drug order sent via a facsimile machine.

(l) Hard Copy. A fileable prescription drug order which is written or printed via electronic means.

(m) Hardware. The fixed component parts of a computer.

(n) HIPPA. The Health Insurance and Portability and Accountability Act and the associated security standards for the protection of electronic protected health information.

(o) Intervening Electronic Formatter. An entity that is not prohibited under O.C.G.A. Section 26-4-80(c)(1) and (5), and that provides the infrastructure that connects a computer or automated electronic data processing system or other electronic device used by a prescribing practitioner with a computer or automated electronic data processing system or another electronic device used by the pharmacy to facilitate the secure transmission of:

1. An electronic prescription drug order;
2. A refill authorization request;
3. A communication; and
4. Other patient care information between a practitioner and pharmacy.

(p) NPI. National Provider Standard Identifier.

~~(q) Practitioner Drug Order. A drug order written in an institutional practice/setting in a patient's chart for a specific patient. It is not necessary to reduce to writing as required for a prescription drug order.~~

~~(r)~~(q) Prescriber. A practitioner authorized to prescribe and acting within the scope of this authorization.

~~(s)~~(r) Prescription Drug Order. A lawful order from a practitioner, acting within the scope of his or her license to practice, for a drug or device for a specific patient. Such order includes a written order from the practitioner, a telephone order reduced to writing by the pharmacist, and electronic image prescription drug order and an electronic data prescription drug order.

~~(t)~~(s) Print-out. A hard copy document generated by computer or other electronic means that is readable without the aid of any special device.

~~(u)~~(t) Regulatory Agency. Any federal or state agency charged with enforcement of pharmacy or drug laws and regulations, i.e., the Georgia Drugs and Narcotics Agency (GDNA), the Drug Enforcement Administration (DEA), or the Georgia Department of Medical Assistance (Medicaid).

~~(v)~~(u) Security Paper. Paper with security features on which the electronic visual image prescription drug order of a practitioner is printed and presented to a patient so as to ensure that a prescription drug order is not subject to any form of copying, reproduction, or alteration, and may include a watermark produced by the electronic digital process when a prescription is printed that clearly shows if a prescription has been reproduced or copied in an unauthorized manner. Such security paper shall include, at a minimum, but not limited to, the following security features:

1. A latent, repetitive pattern shall be visible across the entire front of the prescription blank if the prescription is scanned or photocopied; and
2. A chemical void protection that prevents alteration by chemical washing.

~~(w)~~(v) Software. Programs, procedures, and systems for receipt and/or storage of required information data.

~~(x)~~(w) Stop Date. In institutional settings, the practitioner normally indicates on his/her drug order, the length of time to administer the medication. In absence of such a notation, a committee will have determined by policy, the length of time to administer the medication by category.

Rule 480-27-.09. Patient Records

(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for filling or dispensing. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:
   (a) Full name of the patient for whom the drug is intended;
   (b) Street address and telephone number of the patient;
   (c) Patient's age or date of birth;
   (d) The patient's gender;
   (e) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug, prescription number, name and strength of the drug, the quantity and date received, and the name of the practitioner; and
   (f) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs or devices currently being used by the patient which may relate to prospective drug review.

(3) A patient record shall be maintained for a period of not less than ~~five~~ two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

Rule 480-31-.01. Patient Counseling

Purpose: The purpose of the regulations issued in this part is to comply with the requirements of the Omnibus Budget Reconciliation Act of 1990 and to enhance the public health and welfare by

providing that pharmacists shall offer consultation to patients regarding their medications and various conditions which could affect or be affected by the use of those medications.

(a) Patient Records.

1. A patient record system shall be maintained by all pharmacies for patients for whom Prescription Drug Orders are dispensed. For purposes of the regulations under this part, “Prescription Drug Order" is defined to mean the lawful order of a Practitioner for a Drug or Device for a specific patient. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The Pharmacist or his designee shall make a reasonable effort to obtain, record, and maintain the following information:

(i) full name of the patient for whom the Drug is intended.
(ii) address and telephone number of the patient;
(iii) date of birth; and
(iv) patients gender.

2. The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs, or devices currently being used by the patient which may relate to Prospective Drug Review unless the patient or the patient's agent refuses such information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

(i) A list of all Prescription Drug Orders obtained by the patient at the Pharmacy where the Prescription Drug Order is being filled within the preceding two years, showing prescription number, name and strength of the Drug, the quantity and date dispensed, the name of the Practitioner; and
(ii) comments from the Pharmacist relevant to the individual's drug therapy, including any other information peculiar to the specific patient or Drug.

3. A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(b) Prospective Drug Review.

1. A pharmacist shall review the patient record and each Prescription presented for Dispensing for purposes of promoting therapeutic appropriateness by identifying:

(i) over-utilization or under-utilization;
(ii) therapeutic duplications;
(iii) drug-disease contraindications;
(iv) Drug-Drug interactions;
(v) incorrect Drug dosage or duration of Drug treatment;
(vi) Drug-allergy interactions;
(vii) clinical abuse/misuse.

2. Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(c) Patient Counseling.

1. Upon receipt of a Prescription Drug Order and following a review of the patient's record, the dispensing Pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. <u>If the prescription is being delivered, then the personal offer to counsel may be made verbally or in written format. A written offer must provide a telephone number and business hours during which the dispensing pharmacist can be reached.</u> Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling,

based on the professional judgment of the pharmacist. Such elements may include but are not limited to the following:

(i) the name and description of the Drug;
(ii) the dosage form, dose, route of Administration, and duration of drug therapy;
(iii) intended use of the Drug and expected action;
(iv) special directions and precautions for preparation, Administration, and use by the patient;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(vi) techniques for self-monitoring drug therapy;
(vii) proper storage;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

2. Additional forms of patient information shall be used to supplement Patient Counseling when appropriate.

3. Patient Counseling, as described above and defined in the Act, shall not be required for:

(i) in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).
(ii) inmates of correctional institutions where pharmacy services are provided by the Georgia Department of Corrections or by county or municipal political subdivisions either directly or by a subcontractor of the above; or
(iii) patients receiving drugs from the Georgia Department of Human Resources Division of Public Health; provided however, that pharmacists who provide medications to patients in accordance with Section 43-34-26.1 of the Official Code of Georgia Annotated shall include in all dispensing procedures a written process whereby the patient or the caregiver of such patient is provided with the information contained in Chapter 480-31 of the Rules of the Georgia State Board of Pharmacy.
(iv) refills of prescription drug orders for which, in the professional judgment of the Pharmacist, appropriate counseling has taken place or has been declined. The need for counseling on refills resides in the professional judgment of the dispensing Pharmacist.

4. A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

5. These rules will become effective January 1, 1993.

(d) Nothing in these rules shall be interpreted so as to prohibit the pharmacist from being remunerated for said professional services.

Rule 480-22-.07. Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders

(1) A pharmacist or pharmacy intern/extern may dispense Schedule III, IV and V Controlled Substances (C-III, IV, V), as defined by O.C.G.A. §§ 16-13-27, 16-13-28, and 16-13-29, pursuant to:

(a) A written prescription drug order bearing the signature of a practitioner as permitted by this rule;
(b) A facsimile of a written, signed prescription drug order transmitted directly to the pharmacy with the requirements contained in O.C.G.A. § 26-4-80, by the practitioner of the practitioner's agent;
(c) An oral prescription drug order made by an individual practitioner and promptly reduced to writing by the pharmacist or pharmacy intern/extern to a hard copy; and

(d) A written prescription drug order transmitted via electronic means other than a facsimile, if it meets the requirements and limitations for electronically transmitted prescription drug orders set forth in O.C.G.A. § 26-4-80, and Rules as set forth by the Board. Such electronically received prescription drug orders must be promptly reduced to hard copy, except as follows:

(2) Permanent records of electronic prescriptions do not have to be reduced to hard copy provided the following requirements are met:

~~A).~~(a) Electronic prescription data must be maintained in the original format received for a minimum of two years; and

~~B).~~(b) Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1hr UL approved) container, stored in a secured offsite location or backed up to a documented offsite secure storage device within 48 hours following each work day.

(3) A pharmacy must ~~either~~ file or maintain the original prescription drug order, hard copy or electronically transmitted ~~or generate a hard copy prescription drug order to be filled,~~ both of which are required to contain all of the information required by this chapter.

(4) Upon dispensing a C-III, IV, or V controlled substance, the dispensing pharmacist shall ensure that his or her initials, the dispensing date, and the prescription serial number appear on the face of or the rear of each such prescription. Nothing shall prohibit the use of a computer-generated label to fulfill the requirements of this paragraph and/or the requirements of this Rule.

(a) All such information shall be placed on the prescription drug order in such a manner that it does not cover or veil any information required by this chapter or any other rule or law to appear on such prescription.

(5) Prescription drug orders for schedule C-III, IV, or V controlled substances shall be maintained either in a separate prescription drug order file for such C-III, IV, or V drug orders only or in such a form that they are readily retrievable from the other prescription drug orders of the pharmacy.

(a) A prescription drug order will be deemed readily retrievable if, at the time it is initially filled, the face of the prescription drug order is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed in the usual consecutively numbered prescription drug order file for dangerous drugs; or

(b) A pharmacy which utilizes a computerized record keeping system for prescription drug orders which permits identification of prescription drug orders by serial number and retrieval of documents by prescriber's name, patient's name, drug dispensed, and date filled, then there is no requirement to mark hard copy prescriptions with a red "C".

Rule 480-37-.03. Minimum Requirements

Minimum Requirements. A pharmacy may use a RAMS provided that:

(a) The pharmacy has a policy and procedure manual at the skilled nursing facility or hospice that includes:

1) The type or name of each RAMS including a serial number or other identifying nomenclature.

2) A method to ensure security of a RAMS to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.

3) A process of filling and stocking a RAMS with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.

4) Documentation of inventory procedures including removal of any discontinued/out-dated medications.

5) Compliance with a Continuous Quality Improvement Program.
6) A method to ensure that patient confidentiality is maintained.

(b) No more than a 30-day supply of each individual medication may be stocked in a RAMS at one time.

(c) All drugs in a RAMS must inventoried no less than once every 30 days and documentation must be maintained of the inventories including the removal of any discontinued/out of date medications.

(d) All the registered pharmacists, licensed pharmacy interns or registered pharmacy technicians involved in the process of stocking, entering information into RAMS, or inventorying the RAMS must be identified. No person shall be permitted to perform a function related to the machine that they are not authorized to do in the pharmacy. Specifically, where direct supervision is required in the pharmacy, such supervision must occur in duties related to the RAMS.

(e) Patient confidentiality must be maintained.

(f) The PIC, or a pharmacist designated by the PIC, must be ablet to revoke, add, or change access to RAMS at any time.

(g) Only a Georgia registered nurse~~s~~ or a Georgia licensed practical nurse may be assigned to access ~~to~~ and remove dangerous drugs from a RAMS.

(h) Only a Georgia registered nurse may access and remove ~~a~~ controlled substances from a RAMS.

(i) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.

(j) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, or registered pharmacy technicians involved in the processing of the prescription order.

(k) A RAMS shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(l) The stocking or restocking of a dangerous drug or controlled substances shall ~~only~~ be completed by ~~a Georgia pharmacist or a pharmacy intern/extern under the direct on-site supervision of a Georgia licensed pharmacist.~~:

1) A Georgia licensed pharmacist,
2) A Georgia licensed pharmacy intern/extern under the direct ~~on-site~~ supervision of a Georgia licensed pharmacist, or
3) A Georgia registered pharmacy technician only under the following circumstances:
    a. If the remote automated medication system utilizes radio frequency identification or bar coding in the filling process, the pharmacy shall retain an electronic record of the filling activities of the pharmacy technician; or
    b. If the remote automated medication system does not utilize radio frequency identification or bar coding in the filling process, a pharmacist shall supervise continuously the filling activities of the pharmacy technician through a two-way audiovisual system.

(m) A RAMS must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from a RAMS.

(o) All medication shall be packaged and labeled in compliance with Board rules and laws for patient specific labeled medication and/or unit of use medication.

(p) The licensed pharmacist responsible for filling, verifying, or loading the RAMS shall be responsible for their individual action.

(q) A prescription drug dispensed by the RAM pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

(r) A licensed pharmacist may remove discontinued and/or out-dated medications from the RAMS and return such medications to the licensed pharmacy for proper disposition. A registered or licensed practical nurse may remove discontinued and/or out-dated medications and place them in the designated secured return bin in a RAMS.

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.

(b) It shall be the responsibility of the pharmacist on duty to sign the invoice for all controlled substances upon receipt.

(2) All controlled substances and/or dangerous drugs shall be kept in 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) 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 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.

(b) At the conclusion of an inspection, the GDNA personnel examining said drugs and/or records shall have the responsibility of providing to such retail pharmacy a copy of an 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 480-13-.06. Drug Distribution 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) All invoices for controlled substances must be signed for by a pharmacist upon receipt and verification;

(~~c~~d) 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~~e) 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 non-controlled 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 in-patients. 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).

Rule 480-48-.01. Definitions

For purposes of this chapter of the Rules and Regulations, the following definitions apply:

(a) "Board" shall mean the Georgia Board of Pharmacy.

(b) "Delivery by Mail" or "delivered by mail" or "delivery by mail" shall mean delivery to a patient or the patient's designee by the United States Postal Service or by a commercial common carrier from the pharmacy which fills the prescription.

(c) "Delivery by Pharmacy" shall mean delivery directly to a patient or patient's designee from the pharmacy by contract or private carrier or by an employee of the pharmacy.

(d) "Mail order pharmacy" shall mean a pharmacy that uses delivery by mail as a means of delivery of a prescription drug to a patient or the patient's designee.

(e) "Pharmacy" means a pharmacy holding a current Board issued license to operate a pharmacy in Georgia~~, including pharmacy benefit managers required to be licensed pursuant under O.C.G.A. 26-4-110.1,~~ and nonresident pharmacy permit holders.

Rule 480-10-.06. Licensure, Applications, and Display of License and Renewal Certificate

(1) Licensure and Applications

(a) Every retail pharmacy must be licensed by the Board in accordance with the laws and regulations of this State. As used in these rules, a "retail pharmacy" shall mean all pharmacies, except hospital, clinic, prison, and specialty pharmacies, located in this state where pharmacy is practiced as defined in O.C.G.A. §§ 26-4-4 and 26-4-5~~, and shall mean every pharmacy benefit manager, as defined in O.C.G.A. § 26-4-110.1, providing services or benefits in this State that constitute the practice of pharmacy as defined in O.C.G.A. § 26-4-4~~.

(b) All retail pharmacies shall renew biennially by June 30th of the odd-numbered years with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those retail pharmacies who comply with this rule.

(c) Certificates of registration shall be issued only to those retail pharmacies who meet the following requirements:

1. Submission of an application with the following information:

i. The name, full business address, and telephone number of the licensee;

ii. All trade or business names used by the licensee;

iii. Address, telephone number, and the name of the Pharmacist in Charge;

iv. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship); and

v. The name(s) of the owner and/or operator of the licensee, including:

(I) If a person, the name of the person;

(II) If a partnership, the name of the partnership and the name of each partner;

(III) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; or

(IV) If a corporation, the corporate name, the name and title of each corporate officer and director, the state of incorporation; and the name of the parent company, if any.

vi. Where operations are conducted at more than one location by a single retail pharmacy, each such location shall be licensed by the Board.

2. Payment of an application fee. Application fees shall not be refundable.

3. Filing a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.

~~(c)~~(d) Licenses become null and void upon the sale, transfer or change of mode of operation ~~or location of the business~~.

~~(d)~~(e) Licenses are renewed for two year periods and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed except by application for a new license.

~~(e)~~(f) Changes in any information in this rule shall be submitted to the Board prior to such change.

~~(f)~~(g) The Board will consider the following factors in determining eligibility for licensure of applicants in charge of the facility who are applying for a retail pharmacy license:

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

2. Any felony convictions of the applicant under Federal, State, or local laws;

3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

4. Suspension or revocation by Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;

5. Compliance with licensing requirements under previously granted licenses, if any;

6. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by retail pharmacies; and

7. Other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

~~(g)~~(h) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

(2) The pharmacist's wall certificate issued by the Georgia State Board of Pharmacy (Board), along with the current renewal license of each full-time Pharmacist, employed at the pharmacy, shall be displayed in a conspicuous place, near the prescription department where such pharmacist is actively engaged in the practice of Pharmacy;

(a) While employed in a pharmacy on a full-time basis, if a pharmacist has not yet received their Board issued Pharmacist Wall Certificate, in its place such pharmacist shall post a copy of their current Board issued pocket license card;

(b) Any pharmacist employed on a part-time basis at a pharmacy shall post a copy of their current Board issued pocket license instead of posting their Pharmacist Wall Certificate; and

(c) Any pharmacist employed as a relief or "prn" pharmacist need not post any type of Board issued license, but such pharmacist must maintain and present upon request their current Board issued pocket license.

(3) Any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from this, or any other rule, must be posted and/or displayed next to the current Board of Pharmacy renewal permit; and

(4) No pharmacist or intern/extern shall display his or her license in any pharmacy where he or she is not employed or engaged in the practice of pharmacy, and shall not knowingly permit any other person to use his or her license for the purpose of misleading anyone to believe that such person is the holder or recipient of said license or intern certificate.

~~(5) Every pharmacy benefit manager providing services or benefits in this state which constitutes the practice of pharmacy as defined in Code Section 26-4-4 shall be licensed as a retail pharmacy in this state and shall comply with the provisions of 26-4-110 as required under 26-4-110.1(b).~~

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

(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~~ Georgia Drugs and Narcotics Agency (GDNA), as well as the Drug Enforcement Administration (DEA) if quantified as significant by DEA standards.

(2) A written report must be made and sent to GDNA regarding any theft, loss or unaccounted for controlled substances. If the theft, loss or unaccounted for controlled substances is significant by DEA standards, then notification must be made by completing a DEA Form 106. If DEA form 106 is used:
   (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.

(3) The report shall include the following information:
   (a) Full name and address of the pharmacy;(e) List of cost codes, or identification symbols on package stolen; and
   (b) Pharmacy DEA registration number;
   (c) Date of theft, loss, or discovery of missing controlled substance;
   (d) Type of incident, i.e. theft, loss, etc.;
   (e) List of cost codes, or identification symbols on package stolen; and
   (f) List of the controlled substances missing.

A motion was made by Vice-President Stone, seconded by Mr. Page, and the Board voted that the formulation and adoption of these rule amendments does not impose excessive regulatory cost on any licensee and any cost to comply with the rule 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 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.

Miscellaneous

President Brinson discussed House Bill 316, which increases the technician ration from three (3) to four (4) and removes the intern/extern limit. He stated this is a subject the Board needs to consider and suggested discussing it further at the Board's June meeting.

President Brinson stated that the unsung heroes during the pandemic are the hospitals. He commented that the hospitals have done a tremendous job during this difficult time.

Vice-President Stone made a motion and Mr. Azzolin 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 Michael Azzolin, Michael Brinson, Young Chang, Cecil Cordle, Chuck Page, Bill Prather, and Dean Stone.

Executive Session

Miscellaneous

- S.C.

Appearances

- J.R.A.
- W.C.M.

Georgia Drugs and Narcotics Agency – Dennis Troughton

- J.R.
- GDNA Case #A33552
- R.P.

Cognizant's Report – Dean Stone

- GDNA Case # A33521
- GDNA Case # B33605
- GDNA Case # A33606
- GDNA Case # A33612
- GDNA Case # B33563
- GDNA Case # B33597
- GDNA Case # B33622
- GDNA Case # T33659
- GDNA Case # A33590
- GDNA Case # B33538
- GDNA Case # B33568
- GDNA Case # B33614
- GDNA Case # B33658
- GDNA Case # B33396

Attorney General's Report – Max Changus

Mr. Changus discussed board member recusal from applications/investigative matters.

Mr. Changus discussed the following cases:

- J.A.S.
- H.P.U.S.A.
- J.Q.H.
- U.O.U.

Mr. Changus presented the following consent orders for acceptance:

- O.B.I.
- M.V.A.
- F.K.A.
- D.H.

- W.
- B.D.R.
- C.R.R.
- C.J.B.W.
- K.A.O.
- C.V.S.
- M.M.
- G.M.S.

Executive Director's Report – Eric Lacefield

- A.B.W.C.

Legal Services – Kimberly Emm

The Board received legal advice regarding O.C.G.A. § 50-18-70.

Applications

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

Correspondences/Requests

- A.P.S.
- T.A.P.
- T.A.P.
- M.D.I.
- M.D.I.
- K.C.P.
- T.P.
- I.C.S.
- K.P.W.M.O.P.
- K.P.S.A.R.C.
- K.P.P.
- K.P.P.
- A.E.P.
- A.E.P.

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

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

Open Session

Petition for Rule Waiver or Variance

Rule Waiver Petition from Hoveround Corporation, PHDME000020: Mr. Page made a motion to grant the petition in conjunction with the decision made in Executive Session. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

Miscellaneous

Vice-President Stone made a motion for the Board to direct Ms. Emm to review the "null/void" language found in Rule 480-6-.02, Rule 480-7-.01, Rule 480-7-.03, Rule 480-7-.04, Rule 480-7A-.04, Rule 480-7B-.02, Rule 480-8-.02, Rule 480-13-.02, Rule 480-18-.02, and Rule 480-33-.02 and report back to the Board with suggested amendments. Mr. Page seconded and the Board voted unanimously in favor of the motion.

President Brinson inquired as to when the Board may resume in-person meetings. Mr. Lacefield responded by stating that the Department of Community Health (DCH) continues to reaffirm the guidance to work remotely to help mitigate the spread of the virus. President Brinson responded by suggesting the Board meet in-person for when appearances are scheduled, and possibly meet virtually when there are not any appearances scheduled to come before the Board. Mr. Lacefield stated that in-person meetings would be permissible as soon as DCH allows for such.

Vice-President Stone made a motion for the Board to take the following actions:

Miscellaneous

• S.C.	Denied Pharmacist Renewal	Overturn denial and approved application

Appearances

• J.R.A.	Pharmacist Reinstatement	Refer to the Department of Law
• W.C.M.	Pharmacist Reinstatement	Refer to the Department of Law

Georgia Drugs and Narcotics Agency – Dennis Troughton

• J.R.	Nuclear Pharmacy	Board directed GDNA to respond that a rule petition is not required per 480-25-.04(4).
• GDNA Case #A33552	Request regarding Inactive Status	Accept Application for Inactive Status upon receipt
• R.P.	Request regarding drive thru plans	Approved request

Cognizant's Report – Dean Stone

• GDNA Case # A33521	PIC-Letter of Concern Facility-Refer to the Department of Law
• GDNA Case # B33605	Misfill Policy #1
• GDNA Case # A33606	Refer to the Department of Law
• GDNA Case # A33612	Refer to the Department of Law
• GDNA Case # B33563	Close with a letter of concern
• GDNA Case # B33597	Close with no action
• GDNA Case # B33622	Close with a letter of concern
• GDNA Case # T33659	Revoke Technician Registration
• GDNA Case # A33590	Close case and null & void permit
• GDNA Case # B33538	Close with no action
• GDNA Case # B33568	Close with no action
• GDNA Case # B33614	Close with no action
• GDNA Case # B33658	Close with no action
• GDNA Case # B33396	Close with no action

Attorney General's Report – Max Changus

Mr. Changus discussed board member recusal from applications/investigative matters.

Mr. Changus discussed the following cases:

• J.A.S.	Denied counterproposal
• H.P.U.S.A.	Denied counterproposal
• J.Q.H.	Denied counterproposal
• U.O.U.	Update provided

Mr. Changus presented the following consent orders for acceptance:

• O.B.I.	Public Consent Order accepted
• M.V.A.	Public Consent Order accepted
• D.H.	Private Consent Order accepted
• W.	Public Consent Order accepted
• B.D.R.	Private Consent Order accepted
• C.R.R.	Public Consent Order accepted
• C.J.B.W.	Private Consent Order to be accepted and signed with express permission upon receipt of the original.
• K.A.O.	Public Consent Order to be accepted and signed with express permission upon receipt of the original.
• C.V.S.	Public Consent Order accepted

- M.M. Private Consent Order accepted
- G.M.S. Public Consent Order accepted

Mr. Changus presented the following consent order for ratification:

- F.K.A. Public Consent Order

Executive Director's Report – Eric Lacefield

- A.B.W.C. Request for waiver of renewal fee Approved request

Legal Services – Kimberly Emm

The Board received legal advice regarding O.C.G.A. § 50-18-70.

Applications

- N.J.H. Pharmacy Technician Denied registration
- T.D.T. Pharmacy Technician Approved for registration
- J.D.D. Pharmacy Technician Approved for registration
- C.C.R. Pharmacy Technician Denied registration
- T.L. Pharmacy Technician Approved for registration
- S.B. Pharmacy Technician Denied registration
- D.J.H. Pharmacy Technician Approved for registration
- N.T.W. Pharmacy Technician Denied registration
- C.A.M. Pharmacy Technician Approved for registration
- D.S.D. Pharmacy Technician Approved for registration
- A.D.V. Pharmacist Reciprocity Approved application
- D.T. Pharmacist Reciprocity Approved application
- K.A.M. Pharmacist Reciprocity Approved application
- L.S.E. Pharmacist Reciprocity Approved application
- K.M.E. Nuclear Pharmacist Approved application
- J.R.B. Pharmacist Examination Denied application
- A.J.S. Pharmacist Reinstatement Approved application

Correspondences/Requests

- A.P.S. Notice of Discipline No action
- T.A.P. Notice of Discipline No action
- T.A.P. Notice of Discipline No action
- M.D.I. Notice of Discipline No action
- M.D.I. Notice of Discipline No action
- K.C.P. Notice of Discipline No action
- T.P. Notice of Discipline No action
- I.C.S. Notice of Discipline No action
- K.P.W.M.O.P. Notice of Discipline No action
- K.P.S.A.R.C. Notice of Discipline No action
- K.P.P. Notice of Discipline No action
- K.P.P. Notice of Discipline No action
- A.E.P. Notice of Discipline No action
- A.E.P. Notice of Discipline No action
- O.R. Notice of Discipline No action
- Y.M.A.I. Notice of Discipline No action
- Y.M.A. Notice of Discipline No action

• C.P.	Notice of Discipline	No action
• C.D.	Notice of Discipline	No action
• H.F.P.A.S.	Notice of Discipline	No action
• B.H.S.	Appearance Request	Approved request
• C.C.R.	Correspondence	The Board viewed this correspondence for informational purposes only.
• C.C.R.	Correspondence	Table pending receipt of additional information.
• A.S.I.	Correspondence	Board directed staff to respond by stating a wholesale pharmacy license would be required.
• J.D.F.	Correspondence	Board directed staff to respond by stating that the individual may submit an application for reinstatement to be considered by the Board.
• B.L.A.	Request for 4th attempt at MPJE	Approved request
• C.J.I.	Request for 4th attempt at NAPLEX	Denied request
• G.S.R.	Request for 4th attempt at NAPLEX	Denied request
• H.R.	Request for extension of intern license	Approved extension through 12/2024
• A.W.T.	Request to terminate probation	Approved request effective 05/12/2021
• P.E.H.	Request to terminate probation	Approved request effective 04/23/2021
• J.C.H.	Appealing the Board's denial of request for reinstatement	Denial upheld
• R.A.F.	Request to lift supervised practice restriction	Approved request

Mr. Page seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 4:58 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, May 19, 2021 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6th floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I
Minutes edited by Eric Lacefield, Executive Director