

**GEORGIA BOARD OF PHARMACY**  
**Board Meeting**  
**2 Peachtree St., NW, 36<sup>th</sup> Floor**  
**Atlanta, GA 30303**  
**October 16, 2013**  
**9:30 a.m.**

**The following Board members were present:**

Al McConnell, Chairperson  
Tony Moye, Vice-Chairperson  
Mike Faulk  
Chris Jones  
Laird Miller  
Bill Prather

**Staff present:**

Tanja Battle, Executive Director  
Rick Allen, GDNA  
Janet Wray, Senior Assistant Attorney General  
Brandi Howell, Licensure Analyst

**Visitors:**

Katrina Gabriel  
Mike Mizell  
Mary Frances Martin  
James Simmons  
Kerry Lovell  
Acie Harps  
Jim Bartling  
Joe Campanelli  
Brian Morris  
Helen Sloat  
Brad Borum  
Melvin Smith  
Lynda Chapman  
Nirma Patel  
Hal Henderson  
Jignesh Patel  
R. Scott Lindsay

Chairperson McConnell established that a quorum was present and called the meeting to order at 9:33 a.m.

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

**Executive Session**

**Appearances**

- K.J.G.
- J.O.S.
- A.H.
- J.J.C.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

## **Open Session**

Mr. Jignesh Patel and Brian Morris spoke to the Board regarding offsite record storage. Mr. Morris, who is with McKesson Corporation, explained how their system works. Tony Moyer made a motion to request McKesson Corporation submit a written request to the Board to be placed on its next available agenda in order to make its presentation to the Board. Chris Jones seconded and the Board voted unanimously in favor of the motion.

### **Approval of Minutes**

Bill Prather made a motion to approve the Public and Executive Session minutes for the September 18, 2013 full Board meeting. Tony Moyer seconded and the Board voted unanimously in favor of the motion.

### **Ratifications**

Tony Moyer made a motion to ratify the list of issued licenses. Bill Prather seconded and the Board voted unanimously in favor of the motion.

### **Petition for Rule Waiver – Hasmukhkumar G. Patel**

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

### **Petition for Rule Waiver – InTouch Pharmacy, LLC**

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

### **Petition for Rule Variance – InTouch Pharmacy, LLC**

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

### **Petition for Rule Waiver – Philip Mayo**

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

### **Correspondence from Susan M. DelMonico, CVS Caremark**

The Board considered this correspondence and directed staff to send a letter to Ms. DelMonico asking that she appear and do a presentation for the Board regarding the program.

### **Correspondence from Kristan Ryan, Virginia College in Savannah**

The Board considered this correspondence and directed staff to respond to Ms. Ryan requesting additional information and once that information is received, the Board will reconsider the matter.

### **Correspondence from Robert N. Berg**

The Board considered this correspondence and directed staff to respond to Mr. Berg by stating that the Board is currently working on amendments to Rule 480-11-.02 and suggests he resubmit his questions once the rule has been adopted.

### **Georgia Drugs and Narcotics Agency – Rick Allen**

Mr. Allen discussed Rule 480-30 Dispensing of Drugs Under Authority of Job Description or Nurse Protocol. Ms. Wray suggested having a board member review the rules as there have been some changes since it was first adopted.

### **Attorney General’s Report – Janet Wray**

Ms. Wray discussed attorney/client privilege. Whenever the Board requests that she provide something in writing, whether it is concerning a proposed rule or law, that written information has to be provided to the Board in executive session because that information is attorney/client privilege. She further explained that only the client has the authority to waive that privilege.

### **Executive Director’s Report – Tanja Battle**

Ms. Battle reported on the current status of the transition. She stated that right after the transition, pharmacy technician applications were being processed within 40 days and now they are being reviewed within 14 days. She commended staff for a job well done.

She further reported online renewals were just made available for the dental population. The next step is getting online applications functional. She stated that there have been some IT challenges, but is hopeful that online applications will be available soon.

Ms. Battle stated that she sent Mr. Allen and Mr. McConnell an email concerning PointClickCare who has reached out for closure regarding its practice. Chairperson McConnell and Mr. Allen are going to review the information again so that the Board can give them a response.

### **Miscellaneous**

Proposed 2014 Meeting Dates: Bill Prather made a motion to approve the 2014 meeting dates with the changes noted. Chris Jones seconded and the Board voted unanimously in favor of the motion.

The approved meeting dates are as follows:

January 22, 2014  
February 19, 2014  
March 19, 2014  
April 16, 2014  
May 21, 2014  
June 17, 2014  
July 16, 2014  
August 20, 2014  
September 17, 2014  
October 22, 2014  
November 19, 2014  
December 17, 2014

Exam dates and locations are:

January 23<sup>rd</sup> at Mercer University College of Pharmacy, Atlanta  
June 18<sup>th</sup> and 19<sup>th</sup> at University of Georgia College of Pharmacy, Athens  
August 21<sup>st</sup> at South University College of Pharmacy, Savannah

Proposed Rules: Tony Moyer made a motion to post Rules 480-5-.03 Code of Professional Conduct.Amended; 480-13-.04 Absence of Pharmacist; 480-1-.02 Executive Director; 480-10-.20

Required Notifications to the Board; 480-16-.09 Purchase or Receipt of Drugs by a Pharmacy. Laird Miller seconded and the Board voted unanimously in favor of the motion.

**480-5-.03 Code of Professional Conduct. Amended.**

The Board is authorized to take disciplinary action for unprofessional conduct. Consistent with the authority to assure that licensees operate in a professional manner and the Board's responsibility to protect the public health with a safe, dependable and sufficient supply of medication, the Board establishes a Code of Professional Conduct which shall apply to and be observed by all persons engaged in the practice of pharmacy in the State of Georgia.

(a) Ethics. No pharmacist, intern, extern, technician, or pharmacy owner shall engage in any conduct in the practice of pharmacy or in the operation of a pharmacy which tends to reduce the public confidence in the ability and integrity of the profession of pharmacy, or endangers the public health, safety and welfare, or have been guilty of any fraud, misrepresentation, culpable negligence, concealment, dishonest dealings, fix, scheme or device, or breach of trust in the practice of pharmacy or in the conduction of business related to prescriptions, drugs or devices.

(b) Patient Self-Referral. No pharmacist, employee or agent thereof acting on his/her behalf, shall offer, agree to accept, or receive compensation in any form for the referral of professional services to or from another health care provider or entity. This prohibition includes any form of fee division or charging of fees for the referral of patients.

(c) Error or Uncertain Prescriptions. No pharmacist or pharmacy intern/extern shall compound or dispense any prescription, which, in his/her professional opinion, contains any error omission, irregularity or ambiguity. Upon receipt of such prescription, the pharmacist, pharmacy intern/extern shall contact the prescriber and confer with him/her before dispensing the prescription. No pharmacist or intern/extern shall dispense any medication by virtue of a prescription if said pharmacist or intern has any doubt existing in his mind that such prescription is not legitimate.

(d) Betrayal of Confidence. A pharmacist shall not discuss with the patient or representative such matters that should be discussed only with the prescriber.

(e) Diagnosis or Treatment. No pharmacist or employee of a pharmacy shall diagnose, treat, prescribe for, or attempt to do so, any disease, illness, or organic disorder. This limitation shall not be construed to prevent a licensed pharmacist from advising individuals on matters concerning simple ailments, first aid measures, sanitary matters, or the merits and qualities of medicines, nor shall it prevent the full practice of pharmacy as provided in O.C.G.A. Section 26-4-4.

(f) Coded Prescriptions. No pharmacist, pharmacy intern, or extern shall compound or dispense any prescription that is coded. A "coded" prescription is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength and directions for its use, other than normal letters, numbers, words, symbols or other media recognized by the profession of pharmacy as a means for conveying information by prescription. No symbol, word or any other device shall be used in lieu of the name of said preparation.

(g) False or Misleading Advertising. No pharmacist or licensed pharmacy shall disseminate through any communication media any false, misleading or fraudulent advertising.

(h) Changes in Prescriptions. No pharmacist, pharmacy intern or extern shall supply medications or devices which contain an ingredient or article different in any manner from the medication or device that is prescribed upon a prescription unless prior approval has been obtained from the prescriber thereof. Such difference shall immediately be recorded upon said prescription after being approved by said prescriber, showing the date, time and method of ascertaining the said approval.

(i) Prescription Sub-Station. No pharmacist, employer or employee of a licensed pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Board, from which to solicit, accept or dispense prescriptions.

(j) Physician Agreements. No pharmacist or licensed pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with an physician or other practitioner for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement if any kind, whereby in any way a patient's free choice of a pharmacist or licensed pharmacy is or may be limited.

(k) Independent Judgement and Practices. No pharmacist shall offer or engage in professional pharmaceutical services under any terms and conditions that shall tend to interfere with or impair the free and complete exercise of professional judgment and skill of a pharmacist or enter into any agreement that denies the public the right of free choice of pharmacists or pharmacies.

(l) Return of Prescriptions. Except as authorized by Rule 480-10-.17, no pharmacist or employer or employee of a pharmacy may knowingly place in the stock of any pharmacy any part of any prescription dispensed to, or compounded for, any patient of any pharmacy and returned by said patient.

(m) Evasion of Code of Professional Conduct. No pharmacist, licensed pharmacy or employee or agent thereof, shall act in any way to evade the rules and regulations of the Board and the laws applying to licensed pharmacies and pharmacists, interns, externs and technicians, but may apply methods of their own to enhance compliance with said laws, rules and regulations. Said persons shall be responsible for being acquainted with said laws, rules and regulations, and ignorance of said laws, rules, regulations shall not be a valid defense of the same.

(n) Refusal to Fill Prescription. It shall not be considered unprofessional conduct for any pharmacist to refuse to fill any prescription based on his/her professional judgment or ethical or moral beliefs.

(o) Valid Prescription Drug Orders. Prescription drugs shall be dispensed only pursuant to a valid prescription drug order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription. A pharmacist shall have the same corresponding liability for prescriptions as an issuing practitioner as set forth in 21 C.F.R. as such regulation exists on January 1, 2013. Valid prescription drug orders shall include those issued by a physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state, or of any state or territory of the United States, to prescribe dangerous drugs or controlled substances or both.

(p) Violations of the Code of Professional Conduct. The above set out Code of Professional Conduct is expressly adopted by the Board and shall govern the conduct of all those admitted to practice pharmacy in their capacities as pharmacists, all those issued licenses as a pharmacy in their capacities as licensees and all pharmacy interns/externs in their capacities as pharmacy interns/externs. A license to practice pharmacy or a permit to operate a licensed pharmacy confers to vested right to the holder thereof, but is a conditional privilege revocable for cause. The primary purpose of this Code of Professional Conduct is the protection of the profession of pharmacy and the public health, safety and welfare. It is the responsibility of the Board to purge the profession of those unworthy to practice pharmacy or operate pharmacies in this state. It is the obligation of every licensed pharmacy holder and every licensed pharmacist to give unlimited cooperation and assistance to the Board in the discharge of this responsibility.

Violation of this code may subject the violator to suspension or revocation of any license issued to him/her by the Board and/or public reprimand, fines, probation, letters of concern or other disciplinary actions deemed appropriate by the Board.

#### **480-13-.04 Absence of Pharmacist.**

(1) General. When a licensed pharmacist is not physically present in the hospital and the pharmacy is closed, written policies and procedures shall be prepared in advance by the Director of Pharmacy for the provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and/or by access to the pharmacy. The policies and procedures may include the use of remote order entry pharmacist to ensure that in-patient needs are met at

the hospital when a licensed pharmacist is not physically present. All policies and procedures providing for the use of night cabinets and/or access to the pharmacy when a licensed pharmacist is not physically present shall be made available to the Georgia State Board of Pharmacy, its designee, or a representative of the Georgia Drugs and Narcotics Agency (GDNA), upon request.

(2) A hospital utilizing a remote order entry pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current licensure in the State of Georgia, and the address of each location where the pharmacist will maintain records of remote order entries.

(3) A hospital pharmacy shall be authorized to utilize remote order entry when:

~~(i a)~~ The licensed pharmacist is not physically present in the hospital, the hospital pharmacy is closed, and a licensed pharmacist will be physically present in the hospital pharmacy within ~~46~~ 24 hours; ~~or~~

~~(ii b)~~ When at least one licensed pharmacist is physically present in the hospital pharmacy and at least one other licensed pharmacist is practicing pharmacy in the hospital but not physically present in the hospital pharmacy or;

(c) When it is a weekend and the hospital has a daily census of less than ten acute patients, and the remote licensed pharmacist is physically present in another hospital in this state which is owned or under the same management as the hospital.

(4) Before a hospital may engage in remote order entry as provided in this paragraph, the director of pharmacy of the hospital shall submit to the board written policies and procedures for the use of remote order entry. The required policies and procedures to be submitted to the board shall be in accordance with the American Society of Health-System Pharmacists and shall contain provisions addressing:

~~(i a)~~ quality assurance and safety,

~~(ii b)~~ mechanisms to clarify medication orders,

~~(iii c)~~ processes for reporting medication errors,

~~(iv d)~~ documentation and record keeping,

~~(v e)~~ secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to,

~~(vi f)~~ access to hospital policies and procedures, confidentiality and security, and

~~(vii g)~~ mechanisms for real-time communication with prescribers, nurses, and other care givers responsible for the patient's health care.

(5) Each remote entry record must comply with all recordkeeping requirements and shall ~~entify~~ identify, by name or other unique identifier, the pharmacist involved in the preview and verification of the order. The remote entry pharmacist shall maintain records of any and all records entered for the hospital for a minimum of two (2) years, and such records shall be readily available for inspection, copying by, or production of upon request by the Board, its designee, or a representative for the Georgia Drugs and Narcotics Agency (GDNA), upon request.

(6) If the board concludes that the hospital's actual use of remote order entry does not comply with this rule or paragraph O.C.G.A. 26-4-80, it may issue a cease and desist order after notice and hearing.

(7) Night cabinets. Access to drugs, in the absence of a licensed pharmacist, shall be by locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area to which only specifically authorized personnel as indicated by written policies and procedures may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Director of Pharmacy shall, in conjunction with the appropriate committee of the hospital, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(a) Such drugs are available therein, properly labeled, with drug name, strength, lot number and expiration date;

- (b) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;
- (c) Whenever access to such cabinet(s) has been gained, written practitioner's orders and proofs of use for controlled substances must be provided;
- (d) All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and
- (e) Written policies and procedures are established to implement the requirements of this subsection.

(8) Access to pharmacy. Whenever a drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy pursuant to the practitioner's order and the requirements of this subsection. One nursing supervisor (registered professional nurse or licensed practical nurse) in any given shift may have access to the pharmacy and may remove drugs there from. Such licensed nurse shall be designated in writing by the Director of Pharmacy of the hospital and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training approved by the Director of Pharmacy, in the proper methods of access, removal of drugs, and records and procedures required. The Director of Pharmacy, or designee, shall document the nurse's competence following the education and training. In addition, such licensed nurse accessing a closed pharmacy must receive specific step-by-step instructions in a policy manual, approved by the Director of Pharmacy, before accessing the pharmacy. At any time that a nurse is accessing a closed pharmacy, the Director of Pharmacy must designate a licensed pharmacist, not a remote order entry pharmacist, who is available to the nurse by telephone, and who, in the event of an emergency, is available to come to the hospital. When a nurse accesses drugs directly from the closed pharmacy, the nurse must:

- (a) provide a copy of the order,
- (b) document on a suitable form the name of the drug, the strength and amount of the drug removed, the date and time it was removed, and sign the form.
- (c) The container from which the drug is removed shall then be placed conspicuously to be promptly reviewed and inspected by the next pharmacist coming on duty. The Director of Pharmacy's policies and procedures must provide that the next pharmacist physically coming into the pharmacy must document that they have reviewed the drugs removed and the orders filled.

(9) Emergency kits/crash carts. Drugs may also be provided for use by authorized personnel by emergency kits/crash carts, provided such kits/carts meet the following requirements:

- (a) Emergency kit/crash cart drugs defined. Emergency kit/crash cart drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients;
- (b) Drugs included. The Director of Pharmacy and the medical staff of the hospital shall jointly determine the drugs, by identity and quantity, to be included in the emergency kits/crash carts;
- (c) Storage. Emergency kits/crash carts shall be sealed and stored in limited access areas to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them;
- (d) Labeling — exterior. The exterior of emergency kits/crash carts shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit/crash cart and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by an agent of the Board;
- (e) Labeling — interior. All drugs contained in emergency kits/ crash carts shall be labeled in accordance with such State and Federal Laws and Regulations which pertain thereto; and shall

also be labeled with such other and further information as may be required by the medical staff of the hospital to prevent misunderstanding or risk of harm to the patients;

(f) Removal of drugs. Drugs shall be removed from emergency kits/crash carts only pursuant to a valid practitioner's order, by authorized personnel, or by a pharmacist of the institutional facility;

(g) Notification. Whenever an emergency kit/crash cart is opened, the pharmacy shall be notified; and pharmacy personnel shall restock and re-seal the kit/cart within a reasonable time so as to prevent risk of harm to patients. In the event the kit/cart is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

(h) Inspections. Each emergency kit/crash cart shall be opened and its contents inspected by a pharmacist at least once every ninety (90) days. Upon completion of inspection, the emergency kit/crash cart shall be re-sealed;

(i) Procedures. The Director of Pharmacy shall, in conjunction with the medical staff of the hospital, develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

(10) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be readily available in areas outside the pharmacy where these drugs are stored.

(11) Nothing in this rule shall be construed to relieve the hospital pharmacy of the requirement of having an on-site pharmacist to provide routine pharmacy services within the hospital in order to qualify as a licensed pharmacy.

#### **480-1-.02 Executive Director**

(1) The Board may appoint by a majority vote a person to serve as Executive Director of the Board who shall serve at the pleasure of the Board. Such appointment must be approved by the Board of Community Health.

(2) The Executive Director shall be vested with the following powers:

(a) To hire such personnel as the Board approve and deems necessary to carry out its function, and with Board approval, to appoint professional qualified persons to serve as members of peer review committees;

(b) To issue subpoenas to compel access to documents or other materials related to the fitness of any licensee, registrant, or applicant to practice or where reasonable grounds exist for the belief that a violation of the laws relating to the practice of pharmacy has taken place;

(c) To issue subpoenas for witnesses and documentary evidence, upon approval of the President of the Board, or in his absence, the Vice President.

(d) To issue notices of hearing with the approval of the Board;

(e) With the approval of the Board, enter into contracts as are deemed necessary to carry out this chapter to provide for all services required of the Board;

(f) To act as the custodian of records for the Board; and

(g) To accept service of civil actions and administrative appeals on behalf of the Board.

(3) In the absence of the Executive Director, the Director of the Georgia Drugs and Narcotic Agency shall serve as the Assistant Executive Director and shall have all the powers of the Executive Director.

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

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

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

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

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

(d) "Written notification" shall mean in writing and sent by statutory overnight delivery or by email.

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

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

(b) Change of ownership or location of a licensed pharmacy. Since a pharmacy license cannot be transferable, unless such change has been previously approved by the Board following the submission of the appropriate applications, the existing pharmacy license is void and there is no continuing authority to operate as a pharmacy.

(c) Change in management of a licensed pharmacy.

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

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

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

(g) Disasters or accidents involving the licensed pharmacy.

(h) Thefts or break-ins at the licensed pharmacy.

(i) Theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law.

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

#### **Rule 480-16-.09: Purchase or Receipt of Drugs by a Pharmacy**

All pharmacies are required to purchase or receive dangerous drugs and/or controlled substances from a firm licensed by this state as a drug wholesaler, distributor or manufacturer.

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

In the same motion, the Board voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed and that the formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Chris Jones made a motion to post Rules 480-40-.01 Scope and Application of These Rules; 480-40-.02 Docket; 480-40-.03 Office Hours; 480-40-.04 Communications; 480-40-.05 Date of Filing; 480-40-.06 Computation of Time; 480-40-.07 Extension of Times; 480-40-.08 Signatures; 480-40-.09 Ex-parte Communication; 480-40-.10 Petition for Promulgation, Amendment, or Repeal of Rules; 480-41-.01 Initial Pleading; 480-41-.02 Answer; 480-41-.03 Replies; 480-41-.04 Amendments; 480-42-.01 Motions: Written and Oral; 480-42-.02 More Definite Statement; 480-42-.03 General Procedures; 480-42-.04 Witnesses, Respondent Statements, Witness Statements; 480-42-.05 Pre-Hearing Discover; 480-43-.01 By the Agency; 480-43-.02 Service On All Parties; 480-43-.03 To Party's Attorney; 480-43-.04 Filing of Pleading; 480-44-.01 Substitution of Parties; 480-44-.02 Intervention; 480-45-.01 Evidence on Hearings; 480-45-.02 Evidence on Motions; 480-45-.03 Objections and Exceptions; 480-45-.04 Subpoenas; 480-46-.01 Taking of Testimony by Deposition; 480-46-.02 Conduct of the Deposition; 480-46-.03 Taking of Testimony by Interrogatory; 480-47-.01 Notice of Hearing; 480-47-.02 Conduct of the Hearing; 480-47-.03 Hearing Officers; 480-48-.01 Consolidation; 480-49-.01 Briefs; 480-49-.02 Filing

of Documents Subsequent to Hearing; 480-49-.03 Motion to Reopen Hearing; 480-49-.04 Review of Initial Decision; 480-49-.05 Rehearing; 480-49-.06 Appeals of Final Decisions.

#### **480-40-.01 Scope and Application of These Rules.**

The following Rules govern procedure in "contested cases" as that term is defined in the Georgia Administrative Procedure Act (O.C.G.A. 50-13-2(2)) and which are conducted before the Board of Pharmacy.

#### **480-40-.02 Docket**

(1) The Executive Director shall keep a book known as a docket, which shall be arranged by a sequential numbering system for each case or other matter and shall show for each case of matter, as permitted by law, all proceedings, actions and filings.

(2) The Executive Director shall keep a docket index by both docket number and alphabetical list of the names of the Respondents in all proceedings.

#### **480-40-.03 Office Hours**

The offices of the Board of Pharmacy shall be open from 8:00 a.m. to 5:00 p.m. each weekday except Saturdays, Sundays and legal holidays.

#### **480-40-.04 Communications**

All communications, including correspondence, motions, and pleadings, shall be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, 36<sup>th</sup> Floor, Atlanta, GA 30303. Copies shall be furnished to all parties of record, including the attorney representing the State. An original and one duplicate of all correspondence, motions, and pleadings shall be filed with the Executive Director and shall comply in all respects with Rule 480-41-.04.

#### **480-40-.05 Date of Filing.**

All communications, correspondence, motions and pleadings in any proceedings shall be deemed to be filed or received on the date on which they are actually received by the Executive Director.

#### **480-40-.06 Computation of Time**

Computation of any period of time referred to in these rules shall begin with the first day following that on which the act which initiates such period of time occurs. When the last day of the period so computed is a day on which the office of the Board of Pharmacy is closed, the period shall run until the end of the following business day. When such period of time, with the intervening Saturdays, Sundays and legal holidays counted, is seven (7) days or less, the said Saturdays, Sundays and legal holidays shall be excluded from the computation; or otherwise such days shall be included in the computation.

#### **480-40-.07 Extension of Times**

It shall be within the discretion of the presiding officer to extend, for good cause shown, any time limit prescribed or allowed by these rules. All requests for an extension should be made by a motion in accordance with 480-40-.01 and shall indicate therein whether all parties concur. The presiding officer shall notify all parties of its action upon the motion. Extension shall be granted only when the presiding officer is satisfied that good cause has been shown and not otherwise.

#### **480-40-.08 Signatures**

Every notice, pleading, petition, motion or other document filed by a party, represented by an attorney, shall be signed by at least one attorney of record in his individual name and his address and telephone number shall be stated. A party who is not represented by an attorney shall sign his pleading and state his address and telephone number. Except when otherwise specifically provided by rule or statute, pleadings need not be verified or accompanied by affidavit. The signature of an attorney constitutes a certificate by him that he has read the pleading, and that it is not interposed for delay.

#### **480-40-.09 Ex-parte Communication**

No person not employed by the Board of Pharmacy shall communicate *ex-parte* with the presiding officer, any member of the Board of Pharmacy or any employee of the Board of Pharmacy involved in the decisional process with respect to the merits of a contested case. If any *ex-parte* communication is directed to any person in violation of these rules, the presiding officer and all other parties shall be immediately informed of the substance of the communication and the circumstances of its receipt; provided, that a request for information with respect to the status of a proceeding shall not be prohibited by this section.

#### **480-40-.10 Petition for Promulgation, Amendment, or Repeal of Rules**

(1) Form of Petition. Each petition for promulgation, amendment or repeal of rules made pursuant to the Georgia Administration Procedure Act shall be filed with the Board of Pharmacy. The petition shall be in writing and shall state:

(a) The name and address of the petitioner;

(b) The full text of the rule requested to be amended or repealed, or the full text of the rule desired to be promulgated;

(c) A statement of the reason such rule should be amended, repealed, or promulgated including a statement of all pertinent existing facts which relate to petitioner's interest in the matter;

(d) Citations of legal authority, if any, which authorize, support, or require the action requested by petition. The petition shall be verified under oath by or in proper behalf of; the petitioner.

(2) Proceeding on Petition. Upon receipt of the petition, the Board of Pharmacy shall decide upon the action to be taken. Within thirty days after receipt of the petition, the Board either shall deny the petition in writing (stating its reasons for the denial) or shall initiate rule-making or rule-changing proceedings in accordance with Section 4 of the Georgia Administrative Procedure Act.

#### **480-41-.01 Initial Pleading**

(1) The hearing in a contested case shall be commenced by the Agency's filing of a notice of hearing directed to the respondent, or respondents.

(2) Every pleading or other paper submitted for filing in a contested case, to the extent possible, shall contain the following:

(a) A title which indicates the nature of the proceeding and the parties involved therein;

(b) The name of the Agency;

(c) A short and plain statement of the nature of the pleading (e.g. Answer, Motion for Continuance, etc.);

(d) In addition, the notice of hearing shall, to the extent possible, contain the following:

1. A short and plain statement of the matters asserted or the issues involved;

2. A clear and concise statement of the laws involved;

3. A notice of the rights of the person to whom the notice of hearing is directed;

4. A statement that an answer to the matters asserted is required;

5. Any other information required by law or deemed appropriate by the Agency.

#### **480-41-.02 Answer**

The party to whom a notice of hearing is directed must file with the Agency an answer within fourteen (14) days after service of the notice of hearing. All allegations contained in the notice of hearing which are not specifically admitted are deemed denied.

#### **480-41-.03 Replies**

A reply to the answer shall not be permitted and any new matters asserted in the answer shall be deemed denied.

#### **480-41-.04 Amendments**

Any party, including the Agency, may amend any pleading or notice without leave until the eighth day prior to the date set for the hearing on the matter. Thereafter a party may amend his pleadings only by

leave of the Board or its designee and leave shall be freely given when justice so requires. If an amendment is made to a notice of hearing, the answer to said amended notice shall be filed within seven (7) days after service of the amended notice, unless otherwise ordered by the presiding officer.

#### **480-42-.01 Motions: Written and Oral**

(1) An application to the Agency for an order to take any action or to enter any order shall be made by motion which, unless made during the hearing, shall be made in writing, shall state specifically the grounds therefor, and shall set forth the action or order sought. A copy of all written motions shall be served upon the parties in accordance with Chapter 480-41.

(2) A motion for a continuance or an extension of time shall be ruled upon by the presiding officer forthwith. All other motions shall be ruled upon by the presiding officer at the outset of the hearing, after an opportunity for argument by the parties; provided, however, that when the presiding officer is a duly appointed hearing officer, the presiding officer may establish a hearing schedule and dispose of motions at his discretion. The presiding officer may request briefs in support of or in opposition to any motion.

#### **480-42-.02 More Definite Statement**

A motion for more definite statement shall be filed and ruled upon pursuant to 480-40-.01.

#### **480-42-.03 General Procedures.**

Proceedings before the Agency shall be conducted as expeditiously as possible, with due regard to the rights of the parties. In contested cases before the Board of Pharmacy upon issuance of a notice of hearing, the procedures set forth in this chapter and Chapters 480-38 through Chapter 480-47 shall enable the parties to obtain relevant information needed for preparation of the case, to the extent that such disclosure is authorized by law.

#### **480-42-.04 Witnesses, Respondent Statements, Witness Statements.**

(1) The parties shall within a reasonable time prior to the commencement of the hearing but at least ten (10) days prior to the hearing, exchange lists of the names, addresses, and phone numbers of witnesses, including experts, whom each party expects to call or may call on its behalf.

(2) The parties shall also, within a reasonable period of time prior to the hearing, exchange copies of documents, and designate documents already in the possession of the other party which are intended to be introduced as evidence at the hearing. The parties shall similarly, upon request, make available to each other for inspection, copying, testing or sampling any tangible item intended to be introduced as evidence.

(3) Respondent shall be furnished, within a reasonable time prior to the commencement of the hearing but at least ten (10) days prior to the hearing, any written statements or other record memorializing oral statements made by the Respondent during the course of the investigation.

(4) The parties shall be required to confer either in person or by telephone, in reasonable advance of a scheduled hearing date but at least seven (7) days prior to the hearing, in a good-faith attempt to reach an agreement as to the admissibility of any documents or tangible items intended to be offered in evidence for either side. The parties may stipulate as to any matter of fact and such stipulation will satisfy a party's burden of proving the fact alleged. The parties shall be encouraged to reach pre-hearing stipulations which could facilitate adjudication of the case. The hearing officer, upon his or her own motion or upon the request of either party, may schedule a pre-hearing conference to hear and rule on motions or other preliminary matters, or otherwise facilitate adjudication of the case.

#### **480-42-.05 Pre-Hearing Discovery**

Except as may be expressly authorized by these rules or by statute, no other forms of prehearing discovery shall be authorized or permitted including, but not limited to the following: interrogatories; requests for production of documents and things; requests for physical or mental examination; and requests for admission.

**480-43-.01 By the Agency**

Service of the notice of hearing, initial decision and final order shall be by personal delivery or certified mail to the licensee or applicant, in addition to counsel of record. All other notices, pleadings, orders, motions and other documents shall be served by hand delivery or first class mail.

**480-43-.02 Service On All Parties.**

A copy of the answer and all other pleadings, notices, motions, briefs, memoranda and other documents filed by any party with the Executive Director shall be served upon all other parties to the proceeding, including counsel for the Agency, by personal delivery or by first-class mail.

**480-43-.03 To Party's Attorney**

Service upon a party's attorney shall be deemed service upon the party, except as provided in 480-41-.01.

**480-43-.04 Filing of Pleading**

A pleading subsequent to the Notice of Hearing shall not be entitled to filing unless accompanied by an Acknowledgement of Service required hereunder or a certificate that the service required hereunder has been made. In addition, a pleading shall not be entitled to filing unless it is stamped or otherwise marked in the upper left hand corner on the first page of the document as "original", and a duplicate copy is simultaneously submitted which is stamped or otherwise marked as "duplicate" in the upper left hand corner on the first page.

**480-44-.01 Substitution of Parties**

The presiding officer may upon motion, at any time during the course of the proceeding, permit such substitution of parties as justice may require.

**480-44-.02 Intervention**

Any person desiring to intervene pursuant to Section 14 of the Georgia Administrative Procedure Act (O.C.G.A. 50-12-14) shall file a motion in accordance with Rule 480-41-.04, which motion shall state therein the specific grounds for seeking intervention. The Agency and any other parties shall have fourteen (14) days from the date of service to file a response to such request.

**480-45-.01 Evidence on Hearings**

In all hearings, the testimony of witnesses shall be taken orally before the Agency or hearing officer, unless otherwise provided by these rules.

**480-45-.02 Evidence on Motions**

When a motion is based on facts not appearing of record, the presiding officer may hear the matter on affidavits presented by the respective parties, but the presiding officer may direct that the matter by heard wholly or partly on oral testimony.

**480-45-.03 Objections and Exceptions**

Formal exceptions to rulings on evidence are unnecessary. It is sufficient that a party, at the time that a ruling of the presiding officer is made or sought, makes known to the presiding officer the action which he desires taken or his objections to such action and his grounds therefor.

**480-45-.04 Subpoenas.**

(1) In contested cases, subpoenas shall be issued without discrimination between public and private parties. At any time after issuance of the Notice of Hearing, and prior to the scheduled date for the hearing, the parties may request the issuance of subpoenas by filing a written request with the Executive Director, in accordance with Rule 480-38-.04, with appropriate service on the opposing party or counsel. Subpoena requests shall state the name and complete address of the person to whom it is directed.

(2) Subpoenas issued pursuant to a request in accordance with Rule 480-38-.04(1) shall not be issued in blank. Every subpoena issued by the Executive Director shall state the name of the Board of Pharmacy and the title of the action, and shall command each person to whom it is directed to attend and give testimony at the hearing at a time and place therein specified, or to produce documents for examination at the hearing, or both. If such a subpoena is directed to any member, investigator, employee, or other agent or representative of the Agency, including experts retained by the Agency for purposes of the particular case, production of documentary evidence from the Agency or investigative file of the applicant or licensee and the taking of testimony at the hearing from such person or persons shall be governed by applicable provisions in the Pharmacy Practice Act, and by O.C.G.A. 43-1-19(h)(2).

(3) The party requesting the issuance of the subpoena shall be responsible for serving the same and paying the cost of securing the attendance of witnesses, in the same manner as prescribed by law in civil cases in Superior Court.

#### **480-46-.01 Taking of Testimony by Deposition**

(1) At anytime during the course of the proceeding, the presiding officer may, in his discretion, permit the testimony of a witness to be taken by deposition. Application to take testimony by deposition shall be made in writing and shall be filed with the Executive Director of the Board and served upon all parties to the proceedings, including counsel for the Agency.

(2) The application shall state the name and address of the witness, the subject matter concerning which the witness is expected to testify, the date, time and place of the proposed deposition, and the reason why the witness cannot appear and testify before the Agency. The presiding officer may, in his discretion, allow the application where the circumstances are such that the witness to be deposed cannot appear before the Agency without substantial hardship to the deponent or to the parties to the case or that testimony by any other method will unduly delay expeditious completion of the proceedings. An application for the taking of testimony by deposition shall not be allowed if the deposition would result in any undue burden to another party or any undue delay of the proceedings. If the application is allowed, the presiding officer should give notice of the taking of the testimony by deposition to all parties.

#### **480-46-.02 Conduct of the Deposition**

(1) Examination and cross-examination of the witness shall proceed as would be permitted at the hearing and under those rules of evidence applicable to proceedings conducted pursuant to the Georgia Administrative Procedure Act. The officer before whom the deposition is to be taken shall put the witness on oath and shall personally record the testimony of the witness. The testimony shall be taken stenographically and shall be transcribed. All objections made at the time of examination to the qualifications of the officer taking the deposition, or to the manner of taking it, or to the evidence presented, or to the conduct of any party, and any other objections to the proceedings, shall be noted by the officer upon the deposition. Evidence objected to shall be taken subject to the objection.

(2) All errors and irregularities in the notice of taking testimony by deposition shall be deemed waived unless written objection thereto is served upon the Board prior to the deposition. Objections to taking testimony by depositions because of disqualification of the officer before whom it is to be taken shall be deemed waived unless made before the deposition begins or as soon thereafter as the disqualification becomes known or could be discovered with reasonable diligence.

(3) Objections to the competency of a witness are not waived by failure to make them before or during the deposition, unless the ground of the objection is one which might have been obviated or removed if presented at that time. Errors and irregularities occurring at the taking of the testimony in the manner of taking the deposition, in the form that the questions are answered, in the oath of affirmation, or in the conduct of the parties, and errors of any kind which might be obviated, removed or cured if properly presented, shall be deemed waived unless reasonable objection thereto is made at the deposition.

(4) Errors and irregularities in the manner in which the testimony is transcribed or the deposition is prepared, certified, sealed, endorsed, transmitted, filed, or otherwise dealt with by the officer taking the

testimony are waived unless a motion to suppress the deposition or some part thereof is made with reasonable promptness after such defect is, or with due diligence might have been, ascertained.

(5) The deposition shall be sealed and filed with the Board of Pharmacy.

#### **480-46-.03 Taking of Testimony by Interrogatory**

Application to take testimony by interrogatory shall be made and allowed in the same manner as prescribed in Rule 480-44-.01.

#### **480-47-.01 Notice of Hearing**

The Agency shall notify all parties of the date, time and place of the hearing.

#### **480-47-.02 Conduct of the Hearing**

(1) The hearing shall be conducted by the Board of an administrative law judge (ALJ) appointed by the Office of State Administrative Hearings (OSAH).

(2) Duties of the Presiding Officer. The Board shall have the authority to do the following: to administer oaths and affirmations; rule upon offers of proofs; regulate the course of the hearing; set the time and place for continued hearings; fix the time for filing briefs and memoranda; dispose of motions; and reprimand or exclude from the hearing any person for any indecorous or improper conduct committed in the presence of the presiding officer.

(3) Sworn Testimony. All testimony given at the hearing shall be under oath administered by the Board or any person designated by the Board.

(4) Order of Presentation. The State, or in a proper case a moving or complaining party, shall present its evidence or testimony first. Where there is more than one moving or complaining party, the order of presentation shall be at the discretion of the Board. After all of the evidence and testimony of the State, or the moving or complaining party, has been received, all other parties shall be allowed to present their evidence or testimony. All parties, other than the party introducing the testimony, shall be allowed to cross-examine any witness immediately after his testimony has been received. The State, or the moving or complaining party, shall be allowed to present rebuttal testimony or evidence if it so desires.

#### **480-47-.03 Hearing Officers**

The Board or the Chairman or president of the Board may appoint a hearing officer to act as the presiding officer in the proceeding.

#### **480-48-.01 Consolidation**

The presiding officer upon his own motion, or upon motion by a party or other person joined in the proceeding, may order proceedings involving a common question of law or fact to be consolidated for hearing on any or all of the matters at issue in such proceedings.

#### **480-49-.01 Briefs**

Briefs may be filed by a party or any interested person either before or during the course of the hearing, or within such time thereafter as the Board or its designee shall designate. Failure to file a brief shall in no way prejudice the rights of any party.

#### **480-49-.02 Filing of Documents Subsequent to Hearing**

(1) Upon request, the Board or its designee may, for good cause shown, allow the parties to file evidentiary documents of any kind, or exhibits, at a time subsequent to the completion of the hearing, such time to be determined by the Board or its designee. If a request for such subsequent filing is granted, the requesting party shall, on or before the date set for filing, send copies of all documents or exhibits which are the subject of the request to all other parties.

(2) Prior to the admission into evidence of any documents or exhibits filed subsequent to the hearing, the opposing party shall have ten (10) days from the date of service of copies of such proposed documents or exhibits to file any objections to the admission of such evidence.

### **480-49-.03 Motion to Reopen Hearing**

A party may, at any time prior to the rendering of a final decision by the Agency, move that the hearing be reopened for the purpose of receiving new evidence. Such motions shall be filed in accordance with the provisions of Rule 480-40-.01 and shall be granted only for good cause shown. The Agency shall notify all parties of its action upon the motion. Notwithstanding the above, the Agency may at any time prior to the rendering of a decision, reopen the hearing on its own motion.

### **480-49-.04 Review of Initial Decision**

(1) Either the Respondent or the Board may seek review of the initial decision of the hearing officer pursuant to O.C.G.A. 50-13-17(a). If the Respondent files a timely motion for review of the initial decision of the hearing officer, the Respondent may include therein a statement of the reasons for seeking review and alleged errors made by the hearing officer in the initial decision. If the Board files a timely order for review of the initial decision on its own motion, it may include in its order the issues to be considered by the Board at the review hearing.

(2) Upon the filing of a timely motion by Respondent seeking review of the initial decision of the hearing officer, or upon the filing of a timely order for review of an initial decision by the Board on its own motion, notice of the date and time for the review shall be served on Respondent or counsel for Respondent and counsel for the Agency.

(3) The Board may appoint a hearing officer for review, other than the hearing officer who entered the initial decision, who shall preside over the review proceedings and control the conduct of the review hearing. In acting as presiding officer, the hearing officer for review shall rule on all procedural and evidentiary questions that arise during the course of the review. At the direction of the Board, the hearing officer for review shall draft the final decision for the Board.

(4) On review, the Board shall have all the powers it would have in making the initial decision, and in its discretion shall have the power to take additional testimony or remand the case to the original hearing officer for such purpose, as provided in the Administrative Procedure Act, O.C.G.A. 50-13-17 and in accordance with this Rule. Motions, including motions to present additional evidence, shall be filed in accordance with the time periods for such motions set forth in the Order scheduling the review.

(a) Motions to present additional evidence or to remand the case to the original hearing officer for such purpose shall be granted only if the additional evidence is material, and there was good cause for failing to present such evidence before the original hearing officer. All motions, including motions for the presentation of additional evidence, shall be ruled on by the Board, prior to oral arguments during the review hearing.

(5) Oral argument up to 30 minutes per side is permitted in the review hearing. Additional time for argument must be requested in writing and docketed at least fourteen (14) days before the date set for the review hearing.

(6) Once the review hearing is concluded, the Board shall deliberate as to the final decision. Neither the hearing officer for review nor the parties nor their counsel shall be present during or participate in the deliberations or voting on the final decision. Provided, however, that during the course of the deliberations the Board may seek or obtain legal advice of its counsel or make an inquiry on the record concerning either procedure or the merits of the case in the presence of all parties.

(a) At the conclusion of the deliberations, the vote and decision of the Board shall be announced in open session, unless the sanction imposed by the decision is made confidential by statute, in which case it shall be announced *in camera* to the Respondent and counsel for the parties. The Board may take the matter under advisement and continue the deliberations until a date certain if deemed necessary due to the Board's agenda or the complexity of the issues.

### **480-49-.05 Rehearing**

Any party may file a motion for rehearing of a final decision of the Board within ten (10) days after the date of actual service of such final decision on the Respondent or Respondent's counsel. Such motion shall be in accordance with Rule 480-40-.01 and, in addition, shall include a statement of all matters alleged to have been erroneously decided and, if applicable, a statement as to any newly discovered

matters or circumstances that have arisen subsequent to the final decision. The filing of said motion shall not operate as a stay of the final decision of the Agency unless so ordered by the Board.

#### **480-49-.06 Appeals of Final Decisions**

All appeals shall be filed in accordance with the Georgia Administrative Procedure Act and must be filed in the Superior Court of Fulton County, the court of domicile of the Board.

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

In the same motion, the Board voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed and that the formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

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 the Assistant Attorney General's report. Voting in favor of the motion were those present who included Al McConnell, Tony Moye, Mike Faulk, Chris Jones, Laird Miller and Bill Prather.

#### **Executive Session**

#### **Attorney General's Report – Janet Wray**

Ms. Wray shared a memo of legal advice with the Board.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

#### **Open Session**

Laird Miller made a motion to post Rule 480-11-.02 Compounded Drug Preparations. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

#### **480-11-.02 Compounded Drug Preparations**

(1) Compounded drug preparations –Pharmacist/Patient/Prescriber Relationship.

(a) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations that are ~~commercially or~~ not commercially available in the marketplace. Dispensing of pharmaceutical products shall be consistent with the provisions of O.C.G.A. T. 16, Ch. 13 and T. 26, Ch. 4 relating to the issuance of prescriptions and the dispensing of drugs.

(b) Pharmacists shall receive, store, or use ~~drugs~~ pharmaceuticals that have been made in a FDA-approved facility. Pharmacists shall also receive, store, or use ~~drugs~~ pharmaceuticals in compounding prescriptions that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.

(c) Pharmacists may compound ~~drugs~~ pharmaceuticals prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such preparations compounded at the pharmacy. Pharmaceuticals compounded in anticipation of a

valid prescription drug order shall be properly labeled to include the name of the compounded pharmaceutical, date of compounding, and beyond-use date. The distribution of compounded products, for office use by a practitioner, shall not exceed 5% of production of compounded product in a calendar year by that pharmacy. Amounts produced greater than 5% shall be considered manufacturing and will require separate licensure as a manufacturer. Pharmacists must maintain a separate compounding log for each product that includes the quantity and amount of each product that is compounded. The compounding of inordinate amounts of drugs, relative to the practice site, in anticipation of receiving prescriptions without any historical basis is considered manufacturing which requires a manufacturer's license.

~~(d) The distribution of compounded preparations without a prescriber/patient/pharmacist relationship is considered manufacturing.~~ Pharmacists shall label all compounded pharmaceutical products that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. T. 16, Ch. 13 and O.C.G.A. T. 26, Chs. 3 and 4, and Board rules and regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

~~(e) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order, pharmacists may compound, in reasonable quantities, drug products that are commercially or not commercially available in the marketplace. All pharmaceutical products compounded and labeled in accordance with Board rules and regulations regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of O.C.G.A. T. 16, Ch. 13, and T. 26, Chs. 3 and 4.~~

~~(f) Pharmacists shall not offer compounded drugs to other state licensed persons or commercial entities for subsequent resale.~~

~~(g) Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable state laws and rules regulating the practice of pharmacy.~~

(2) Compounded drug preparations –Pharmacist for Distribution to Practitioner

(a) Only a pharmacy licensed or registered by the Board may distribute compounded products to practitioners licensed in this state for administration to their patients in the course of their professional practice, either personally or by an authorized person under their direct and immediate supervision.

(b) A practitioner shall make a request to the pharmacy for a compounded pharmaceutical in the same manner as ordering pharmaceuticals from a wholesale pharmaceutical distributor or manufacturer and not by using a prescription drug order.

(c) A pharmacy receiving an order from a practitioner for a compounded pharmaceutical shall maintain such order with its compounding rules as required in Rule 480-11-.08 and other rules and regulations of the Board.

(d) Pharmacists shall label all compounded pharmaceutical products distributed to practitioners for administration to their patients with the following:

1. “By purchase order, Not by prescription”.

2. “For Office Use Administration Only – Not for resale”.

3. The name of the active ingredients and strengths contained in the compounded pharmaceutical,

4. The lot number or identification of the compounded pharmaceutical,

5. The pharmacy's name, address and telephone number,

6. The initials of the pharmacist verifying the finished product and the date verified,

7. The quantity, amount, size, or weight of the compounded pharmaceutical in the container,

8. An appropriate beyond-use (expiration) date of the compounded pharmaceutical as determined by the pharmacist in compliance with Board rule and USP-NF standards for pharmacy compounding, and

9. Appropriate ancillary instructions such as storage instructions or cautionary statements, and where appropriate, hazardous drug warning labels.

(e) Pharmacists shall enter into a written agreement with a practitioner for the practitioner's use of the compounded pharmaceutical before providing any compounded pharmaceutical to the practitioner. The written agreement shall provide the following information:

1. The name and address of the practitioner, license number and contact information.

2. An agreement by the practitioner that the compounded pharmaceutical may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity.
3. An agreement by the practitioner to include on the patient's chart, or medication administration record the lot number and beyond-use date of the compounded pharmaceutical administered to the patient.
4. The procedures for a patient to report an adverse reaction or to submit a complaint about a compounded pharmaceutical.
5. The procedure to be used when the pharmacy has to recall a batch of compounded pharmaceuticals.
  - (f) When pharmacists are compounding sterile pharmaceuticals to be provided to practitioners for use in patient care or when pharmacists are altering or repackaging such pharmaceuticals for practitioners to use in patient care in the practitioner's office, the sterile compounding shall be conducted as allowed by applicable federal law and Board rules and shall be in compliance with USP-NF standards for sterile compounding.
  - (g) Sterile compounded pharmaceuticals may be dispensed to practitioners in quantities no more than 100 individual dosage containers and must have a beyond-use date no less than one week.
  - (h) Pharmacist may not compound Schedule II, III, IV or V controlled substances, as defined in Article 2 of Chapter 13 of Title 16 without a patient specific prescription drug order.
  - (i) Prior to any pharmacy engaging in the practice of compounding pharmaceuticals for use in the practitioner's office, the pharmacy must notify the Georgia Drugs and Narcotic Agency ("GDNA") of its practice, and must maintain on file the written acknowledgement of receipt of the notice from GDNA.
  - (j) Nothing in this paragraph shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners employed by an institution or its affiliated entities; provided, however, pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to the other rules and regulations of the Board governing the compounding of pharmaceuticals.
- (3) Pharmacists must maintain documentation of proof that the beyond-use date on compounded pharmaceuticals is valid.
- (4) Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final verification check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.
- (5) Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.
- (6) Pharmacists may use prescription bulk substances in compounding when such bulk substances:
  - (a) Comply with the standards of an applicable USP-NF monograph, if such monograph exists, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-91) and the Board rules on pharmaceutical compounding; or are substances that are components of pharmaceuticals approved by the FDA for use in the United States; or otherwise approved by the FDA;
  - (b) Are manufactured by an establishment that is registered by the FDA; and
  - (c) Are distributed by a wholesale distributor licensed by the Board and are distributed by a supplier approved by the FDA to distribute bulk substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.
- (7) Pharmacists shall maintain records of all compounded pharmaceutical products. Pharmacist shall maintain a complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail when such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.
- (8) Pharmacists engaged in the compounding of pharmaceuticals shall operate in conformance with USP 795 and applicable state laws regarding the practice of pharmacy. (2) If low or ; medium risk preparations are being compounded, they must be compounded in accordance with USP 795 and

applicable laws and rules. If, and/or high risk sterile preparations are being compounded, they must be in accordance with USP 797 and/or Georgia laws and regulations.

~~(3)~~(9) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.

~~(4)~~(10) Special precaution preparations. If drug preparations with special precautions for contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

~~(5)~~(11) Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved.

(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet or an appropriate barrier isolator. Other preparations should not be compounded in this cabinet.

(b) Personnel compounding cytotoxic drugs shall wear protective apparel as outlined in the National Institute of Occupation Hazards (NIOSH.) in addition to appropriate compounding attire as described in USP 797.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations.

(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and delivered in a manner to minimize the risk of accidental rupture of the primary container.

(g) Disposal of cytotoxic and/or hazardous wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of cytotoxic and/or infectious waste in a manner so as not to endanger the public health.

(12) Pharmacists shall not engage in the following:

(a) The compounding for human use of a pharmaceutical product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe.

(b) The compounding of any pharmaceutical products that are essentially copies of commercially available pharmaceutical products. However, this prohibition shall not include:

1. The compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,

2. The compounding of a commercially available manufactured pharmaceutical during times when the product is not available from the manufacturer or wholesale distributor,

3. The compounding of a commercially manufactured pharmaceutical whose manufacturer has notified the FDA that the pharmaceutical is unavailable due to a current drug shortage,

4. The compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or

5. The mixing of two or more commercially available products of which the end product is a commercially available product.

(13) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. Section 26-4-130 shall comply with all the provisions of this rule and other applicable Board laws, rules and regulations.

Chris Jones made a motion to post Rule 480-39-.01 Definitions and Rule 480-39-.02 Conditions for use of Delivery by Mail.

#### 480-39-.01 Definitions

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

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

~~(a-b) “Delivery by Mail” or “delivered by mail” shall mean delivery to a patient by the United States postal service or a commercial common carrier. Mail order is when a patient requests that a pharmacy licensed by the board to sell, distribute, dispense, or deliver a filled prescription drug order by use of the U.S. Postal Service or a common commercial carrier. And when such filled prescription drug is taken from a pharmacy and kept overnight in a storage facility or vehicle and not delivered on the same day to the patient. (1) It is not considered to be delivery by mail order when a pharmacy uses its own employees or employs a local courier service to deliver filled prescriptions in the same day from the pharmacy to a patient. Such method of delivery can be made without the patient having to request delivery for their filled prescriptions.~~

~~(2) A patient's guardian or caregiver or a physician or physician acting as the patient's agent for whom the prescription drug was prescribed can request on behalf of the patient that a pharmacy use mail order to deliver the patient's filled prescription drug.~~

(c) “Pharmacy” means a pharmacy holding a current Board issued license or permit to operate a pharmacy in Georgia and shall include pharmacy benefit managers licensed pursuant to O.C.G.A. Section 26-4-110 and 26-4-110.1.

~~(b d) “Regularly employ”ing or “regularly use”. Regularly employing means when a pharmacy which routinely, on a monthly or quarterly basis, employs or uses the U.S. Postal Service or a common commercial carrier to deliver an entire prescribed quantity of a filled prescription to a single patient as requested by the patient.~~

#### 480-39-.02 Conditions for use of Delivery by Mail Order.

~~(1 a) Any pharmacy can regularly employ the U.S. Postal Service or a common commercial carrier to sell, distribute, dispense, or deliver a drug which requires a prescription in a manner in which the drug is kept overnight in a storage facility or vehicle and not taken the same day from the pharmacy to a patient only after the patient has requested that a pharmacy use this ese method of delivery for his/her ~~their~~ filled prescription drugs.~~

~~(2 4) A pharmacy must document in writing ~~the manner in which~~ a patient's request for delivery by mail order ~~delivery~~ of their ~~his/her~~ filled prescription drugs. Such documentation must be maintained for at least two years after the last delivery by mail.~~

~~(3 b) Any pharmacy regularly using delivery by mail ~~the U.S. Post Service or common commeree carriers~~ to deliver dispensed prescription drugs ~~pursuant to this rule~~ shall comply with the following conditions:~~

~~(a 4) The pharmacy shall provide an electronic, telephonic, or written communications mechanism which provides a proof of delivery which records when the medications delivered by mail ~~the U.S. Postal Service or common commercial carrier~~ were received by the patient or their designee.~~

~~(b) The pharmacy shall ensure that the mail service will not leave medications ~~which cannot be delivered will not be left unattended~~ and will hold the medications ~~must be held~~ for pickup by the patient or ~~their~~ his/her designee.~~

~~(c 2) A pharmacy that regularly employs delivery by mail must provide a pharmacist or pharmacy intern acting under the direct supervision of the pharmacy ~~who employs mail order~~ must provide a manner method, including a local or toll-free telephone number, for the patient to call and speak with a pharmacist at the pharmacy if the patient has any questions regarding their medication and to allow the pharmacist or pharmacy intern under the supervision of the pharmacist to offer counseling~~

on each filled prescription drug in accordance with and obligated by Code Section 26-4-85, unless the patient refuses such consultation or counseling and such refusal is documented.

~~(3) A pharmacy shall not utilize mail order to deliver Schedule II controlled substance medications, medications which require refrigeration, chemotherapy medications deemed by the federal Environmental Protection Agency as dangerous, medications in suppository form, and other medications which, in the professional opinion of the dispensing pharmacist, may be clinically compromised by distribution and delivery through the U.S. Postal Service or a common commercial carrier;~~

~~— (i) The State Board of Pharmacy may promulgate a list of other medications which may not be delivered by the U.S. Postal Service or a common commercial carrier.~~

(d 4) The pharmacy shall utilize, in accordance with standards of the manufacturer, United States Pharmacopeia and National Formulary, Federal Drug Administration and other standards, adopted by the State Board of Pharmacy, temperature tags, time temperature strips, insulated packaging, or a combination of these which protect the integrity of and indicate when the integrity of any drug which has been delivered by mail order has been compromised.

(e 5) The pharmacy shall provide information to the patient shall receive information from the pharmacy indicating on the procedure the patient should follow what he or she should do if any prescription drug does not arrive in a timely manner, or if the integrity of the packaging or medication has been compromised during shipment and delivery by mail. Order

(f) ; and what action the Any pharmacy utilizing delivery by mail shall immediately replace any prescriptions drugs that are compromised during shipment and delivery by mail or that do not arrive in a timely manner. take to ensure the patient's compromised drugs are replaced.

(i) Each pharmacy utilizing mail order shall establish policies and procedures to address instances in which any drug delivered by mail order does not arrive in a timely manner or in which the drug has been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs.

(g) A pharmacy using delivery by mail shall document in its records when the prescription drug was sent to the patient and received by the patient or his/her designee, and such records shall be maintained for the same time period and in the same method as when a patient is delivered the medication in person or by courier.

(h) A pharmacy using delivery by mail shall document instances when prescription drugs have been compromised during shipment and delivery by mail or when drugs do not arrive in a timely manner, and shall maintain such documentation for two (2) years.

(4) The following drugs may not be delivered by mail:

- (a) Schedule II controlled substances;
- (b) Prescription drugs that require refrigeration;
- (c) Chemotherapy drugs deemed by the federal Environmental Protection Agency as dangerous;
- and
- (d) Medications in suppository form.

(5) Quantity of C3-C4 30 day supply or 180 tabs

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

Bill Prather made a motion to post Rule 480-6-.02 Nonresident Pharmacy Permit. Tony Moye seconded and the Board voted unanimously in favor of the motion.

#### **480-6-.02. Nonresident Pharmacy Permit.**

(1) Effective 05/01/2014, every pharmacy located out of the State of Georgia that ships, mails or delivers dispensed drugs into the State of Georgia must hold a permit issued by the Georgia State Board of Pharmacy in accordance with the laws and regulations of this State before shipping, mailing or delivering prescription drugs or offering to ship, mail or deliver prescription drugs into this State.

(2) Nonresident pharmacies that intend to ship, mail or deliver prescription drugs into this state must file an application for a Nonresident Pharmacy permit as follows:

(a) Applications must be filed in duplicate with the Georgia State Board of Pharmacy located at 2 Peachtree Street, SW, 36<sup>th</sup> Floor, Atlanta, Georgia 30303.

(b) The Board requires the following information from each applicant for a nonresident pharmacy permit as part of the initial licensing procedure and as part of any renewal of such permit.

1. The name, full business address, and telephone number of the applicant;
2. All trade or business names used by the applicant;
3. Address, telephone numbers, and the names of contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;
4. Address, telephone number and name of agent of service for the applicant;
5. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship);
6. The name(s) of the owner and/or operator of the pharmacy, including:
  - (i) If a person, the name of the person;
  - (ii) If a partnership, the name of each partner, and the name of the partnership;
  - (iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the incorporation; and the name of the parent company, if any; or
  - (iv) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.
7. Where operations are conducted at more than one location by a single pharmacy, each such location shall be permitted by the Board;
8. Proof of a valid, unexpired license, permit, or registration to operate a pharmacy in the compliance with the laws and rules of each state in which the applicant received and dispenses prescription drug orders;
9. The names and license numbers of each pharmacist and pharmacy technician involved in dispensing drugs to residents of this state and evidence that the pharmacist(s) and pharmacy technicians are licensed and in good standing in the state where they are located;
10. Information necessary to demonstrate compliance with O.C.G.A. T. 50, Ch. 36;
11. Evidence satisfactory to the Board that the applicant is in compliance with all laws and investigations from each regulatory or licensing agency in which the applicant holds a license; and
12. If dispensing sterile or nonsterile compounding for practitioners to use in patient care in the practitioner's office, a copy of the most recent inspection report which is no older than six months before the date of application was submitted and which is from an inspection conducted by the regulatory or licensing agencies of the jurisdiction in which the applicant is located that indicates compliance with the Board's rules and regulations and compliance with USP-NF standards for pharmacies performing sterile and nonsterile compounding, or another inspection approved by or conducted by the Board.

- (3) Registration of a nonresident pharmacy permit will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the GDNA certifying the applicant possesses the necessary qualifications for a permit.
- (4) Application fees and renewal fees shall be set by the Board in a fee schedule, and shall not be refundable.
- (5) Permits may be denied for failure to comply with rules of the Board, for failure to meet the minimum qualifications for a permit, for the conviction by a owner or pharmacist of a felony involving the practice of practice or the distribution of drugs, for false representations on an application, and for any other good cause related to evidence of misfeasance or malfeasance by the applicant.
- (6) Permits become null and void upon the sale, transfer or change of mode of operation or location of the business. Prior to the sale, transfer or change in mode of operation or the location of the business, the nonresident pharmacy may apply for such change by submitting a Board approved application to the Board, and paying a fee. The permits of nonresident pharmacies will not become void of proper application is made and approved prior to the change.
- (7) Permits are issued for two years and expire on June 30th of each odd numbered Year, and may be renewed for two years upon the payment of the required fee for each place of business and the filing of an application for renewal. Applicants for renewal must submit such evidence as requested by the Board including, but not limited to evidence of certain inspection reports on compounding and the status of the licenses of the pharmacy and pharmacists in the state of location. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the permit shall lapse and shall not be renewed except by application for a new permit.
- (8) The denial of a nonresident pharmacy permit and the denial of the renewal of a nonresident pharmacy permit shall not be considered a contested case under the provisions of O.C.G.A. T. 50, Ch. 13, but the applicant shall be entitled to an appearance before the Board.
- (9) Nonresident pharmacy permit holders shall comply with all the recordkeeping requirements of Rule 480-10 and Rule 480-27 for all prescriptions shipped, mailed or delivered to patients or practitioners in the State of Georgia. Nonresident pharmacy permit holders shall notify the Board of each location where the required records are being maintained and such records must be readily retrievable and produced to the Board immediately, upon written request. Records shall be maintained for a minimum of two (2) years.
- (10) Nonresident pharmacy permit holders shall comply with the minimum labeling requirements required by O.C.G.A. Section 26-3-8 and other Board laws, rules and regulations.
- (11) Nonresident pharmacy permit holders shall comply with the Board's rules and regulations on delivery of prescriptions by mail in Board Chapter 480-39.
- (12) Nonresident pharmacy permit holders shall comply with the laws and rules and regulations of the state where such pharmacies are located.
- (13) Nonresident pharmacy permit holders who compound drugs must comply with the Board's rules on compounding found in Board Chapter 480-11.
- (14) Nonresident pharmacy permit holders shall comply with the patient counseling laws and rules for all prescriptions shipped, mailed or delivered into this State.

(15) Nonresident pharmacy permit holders shall maintain a toll-free telephone number operational during the permit holder's regular hours of operation, but not less than six days per week for a minimum of 60 hours per week in order to provide patient counseling. Such toll-free number shall be capable of receiving inbound call from patients to the permit holder and such number shall be on file with Board and shall be included on the label affixed to each container of all dispensed and distributed drugs sent into the State of Georgia.

(16) Nonresident pharmacy permit holders shall maintain the following information and shall provide such information to the Board, upon request:

(a) Normal delivery protocols and times;

(b) The procedure to be followed if the a patient's prescription drug is not available from the nonresident pharmacy or if the delivery will be delayed beyond the normal delivery time;

(c) The procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the nonresident pharmacy permit holder at the earliest possible time so that the patient does not miss a scheduled dose; and

(d) The procedure to be followed when the nonresident permit holder is advised that the patient's medication has not been received within the normal delivery time and the patient is out of medication and requires interim dosages until the medication becomes available or delivery by mail.

(17) Nonresident pharmacy permit holders must comply with all the USP and FDA requirement for the storage, packaging and shipping of prescription drugs and devices.

(18) Nonresident pharmacy permit holders must notify the Board within five (5) days of the receipt of any final order or decision by any other licensing board or federal agency of the imposition of disciplinary action or restriction by such other licensing board or federal agency. A final order or decision includes a consent order or agreement and is any decision, regardless whether there still exists an appellate right to the state or federal courts. Any revocation or suspension of a state or federal license or permit will result in the immediate suspension of the nonresident pharmacy permit pending a final decision by the Board.

(19) Nonresident pharmacy permit holders shall cooperate with the Board in any investigation involving prescription drugs distributed by such permit holder into this state or related to the permit holders compounding practices. The permit holder shall respond within ten (10) calendar days to all communications from the Board or its designee. Failure to respond or cooperate with the Board shall be grounds for the immediate suspension of the nonresident pharmacy permit, pending a hearing on further disciplinary action by the Board. Failure to cooperate with the Board is grounds for disciplinary action by the Board.

(20) Notices to nonresident pharmacy permit holders shall be made on the agent of record with the Board. If notices are returned as undeliverable or unclaimed, service shall be made on the Executive Director and any disciplinary proceedings shall proceed, or if a final decision, the decision shall become effective.

(21) If, in the course of investigation of a nonresident pharmacy permit holder, an onsite inspection by the Board or its designee is required, the permit holder shall be responsible for the cost of such onsite inspection.

(22) A nonresident pharmacy permit may be revoked or suspended or otherwise disciplined for any reason that a permit may be denied, for failure to comply with this rule, for disciplinary action by other

states and federal agencies, for conduct causing bodily or psychological injuries to a resident of this state, and for failure to comply with Board laws and other applicable rules.

(23) This rule shall not apply to nonresident pharmacies, facilities or entities licensed under Title 33, and shall not apply to pharmacies licensed pursuant to O.C.G.A. Section 26-4-110.1.

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

In the same motion, the Board voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed and that the formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

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

## **Executive Session**

### **Georgia Drugs and Narcotics Agency – Rick Allen**

Discussed latest PDMP reports.

### **Executive Director's Report – Tanja Battle**

- J.J.C.

### **Cognizant's Report – Tony Moye**

- GDNA Case #A-30063E
- GDNA Case #A-30650
- GDNA Case #B-30819
- GDNA Case #B-30799
- GDNA Case #A13-58
- GDNA Case #B-30830
- GDNA Case #B-30877
- GDNA Case #B-30900
- GDNA Case #B-30793
- GDNA Case #B-30790
- GDNA Case #A30818
- GDNA Case #A-30510-10
- GDNA Case #A-30510-21
- GDNA Case #A-30510-22
- GDNA Case #A-30510-23
- GDNA Case #A-30510-24
- GDNA Case #A-30510-25
- GDNA Case #A-30510-28
- GDNA Case #A-30510-29

- GDNA Case #A-30510-30
- GDNA Case #A-30510
- GDNA Case #A-30510-85
- GDNA Case #A-30510-91
- GDNA Case #A-30510-92
- GDNA Case #A-30510-94
- GDNA Case #A-30510-95
- GDNA Case #A-30510-96
- GDNA Case #A-30510-97
- GDNA Case #A-30490

**Attorney General's Report – Janet Wray**

Ms. Wray presented the following consent orders for acceptance:

- J.L.D.
- G.L.H.

**Applications**

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

- R.K.D.
- T.A.S.
- A.P.F.
- A.S.B.
- F.P.M.
- H.E.B.
- J.N.G.
- T.S.J.
- P.M.
- A.G.W.

**Correspondences/Requests**

- H.S.A.H.
- T.P.A.
- P.M.
- W.L.
- S.B.F.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

**Open Session**

Bill Prather made a motion to approve all recommendations based on deliberations in Executive Session as follows:

**Appearances**

- K.J.G. Approve with private consent order
- J.O.S. Deny request for reinstatement
- A.H. Approve with private consent order
- J.J.C. Uphold denial of pharmacist application

**Georgia Drugs and Narcotics Agency – Rick Allen**

- Discussion of PDMP reports. No action taken.

**Executive Director’s Report – Tanja Battle**

- J.J.C. Approve pharmacy technician application pending receipt of additional information.

**Cognizant’s Report – Tony Moye**

- GDNA Case #A-30063E Refer to the Attorney General’s office for discipline
- GDNA Case #A-30650 Refer to the Attorney General’s office for discipline
- GDNA Case #B-30819 Close with no action
- GDNA Case #B-30799 Refer to the Attorney General’s office for discipline
- GDNA Case #A13-58 Accept private Consent Order upon receipt
- GDNA Case #B-30830 Close with no action
- GDNA Case #B-30877 Close with no action
- GDNA Case #B-30900 Close with no action
- GDNA Case #B-30793 Close with no action
- GDNA Case #B-30790 Close with no action

- GDNA Case #A30818 Close with a letter of concern
- GDNA Case #A-30510-10 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-21 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-22 Close with a letter of concern
- GDNA Case #A-30510-23 Close with a letter of concern
- GDNA Case #A-30510-24 Close with a letter of concern
- GDNA Case #A-30510-25 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-28 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-29 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-30 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510 Close with a letter of concern
- GDNA Case #A-30510-85 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-91 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-92 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-94 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-95 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-96 Refer to the Attorney General's office for discipline
- GDNA Case #A-30510-97 Refer to the Attorney General's office for discipline
- GDNA Case #A-30490 Refer to the Attorney General's office for discipline

**Attorney General's Report – Janet Wray**

Ms. Wray presented the following consent orders for acceptance:

- J.L.D. Private Consent Order accepted
- G.L.H. Private Consent Order accepted

**Applications**

- D.G.G. Pharmacy Technician Approved renewal
- B.X.C. Pharmacy Technician Approved renewal
- R.M.R. Pharmacy Technician Approved for registration
- T.D. Pharmacy Technician Table pending receipt of additional information
- T.W. Pharmacy Technician Denied registration
- T.M. Pharmacy Technician Table pending receipt of additional information
- B.A. Pharmacy Technician Approved for registration
- D.M. Pharmacy Technician Denied registration
- Y.C. Pharmacy Technician Approved renewal
- M.K. Pharmacy Technician Denied registration
- S.L. Pharmacist Reinstatement Denied application
- D.R.D. Pharmacist Reciprocity Table pending receipt of additional information
- D.G.T. Pharmacist Reciprocity Table pending receipt of additional information
- J.N.B. Pharmacist Reciprocity Denied application
- J.A.L. Pharmacist Reciprocity Denied application
- L.M.W. Pharmacist Reinstatement Denied application
- M.E.R. Pharmacist Reciprocity Table pending receipt of additional information
- M.A.E. Pharmacist Reciprocity Table pending receipt of additional information
- Y.A.A. Pharmacist Reciprocity Table pending receipt of additional information
- R.G.M. Pharmacist Approved to take MPJE a fourth time
- A.M.C. Pharmacist Reinstatement Approved application
- D.Y.W. Pharmacist Reciprocity Denied application

- J.J.C. Pharmacist Reinstatement Approved application
- M.S.W. Pharmacist Reinstatement Table and place on November agenda for consideration
  
- Q.P. Wholesaler Pharmacy Approved renewal
- P.S.I. Wholesaler Pharmacy Request denied
- A.H.G.I. Retail Pharmacy Table pending receipt of additional information
- J.F.J. Pharmacist Intern Approved application
- J.M.A. Pharmacist Intern Approved application
- K.T.P. Pharmacist Intern Approved application
- R.L.W. Pharmacist Intern Approved application
- R.K.D. Pharmacist Intern Table and place on November agenda for consideration
  
- T.A.S. Pharmacist Intern Approved application
- A.P.F. Pharmacist Intern Approved application
- A.S.B. Pharmacist Intern Refer to the Attorney General's office for discipline
- F.P.M. Pharmacist Intern Approved application
- H.E.B. Pharmacist Intern Approved application
- J.N.G. Pharmacist Intern Approved application
- T.S.J. Pharmacist Intern Approved application
- P.M. RAMS Table pending receipt of additional information
- A.G.W. Pharmacist DTM Cert Approved

**Correspondences/Requests**

- H.S.A.H. Wholesaler Pharmacy Table pending receipt of additional information
- T.P.A. Appearance request Approved request
- P.M. Retail Pharmacy No action taken
- W.L. Request to lift direct supervision requirement Approved request
- S.B.F. Request for the Board to waive waiting period to take NAPLEX Deny request

Tony Moye seconded and the Board voted unanimously in favor of the motion.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, November 13, 2013, at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 6:01 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist  
 Minutes edited by Tanja D. Battle, Executive Director