GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
October 22, 2014
9:00 a.m.

The following Board members were present:
Al McConnell, Chairperson
Jim Bracewell
Mike Faulk
Chris Jones
Tony Moye
Bill Prather
Bob Warnock

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

Visitors:
Robert Woodall
Jim Bartling
Amy Jones, Advanced Pharma
Shannon Cox, Advanced Pharma
Bourjois Abboud, Advanced Pharma
Brett Smith, Advanced Pharma
Darius Arabghani
Scott Biddulph, Target
Helen Sloat, Hemophilia of GA/Kaiser Permanente
Marilyn Thai
Mike Chavez, Publix
Karen Waters, GHA
Kay Kirkpatrick, Resurgens
Travis Lindley, Resurgens
Lynda Chapman
Melvin Smith, CVS
Robert Stannard, BSL
Keri Conley, GHA
Melissa Price, Eldercare
Vonda Harrison, Eldercare
Karen Nishi, Cubex
Andy Freeman, GPhA
Tracie Lunde, Walgreens
Kallarin Mackey, GHA
Jennifer Bellis, BSL
Stephanie Kozol, Holland Knight
Scott Lindsay, CAPS

Chairperson McConnell established that a quorum was present and called the meeting to order at 9:00 a.m.

Executive Session

Appearance

- R.M.W.

Attorney General's Report – Janet Wray

Ms. Wray discussed the following cases:

- C.P., G.D. and W.E.P.
- M.P.
- P.P.
- R.A.

Appearances

- A.P.
- D.E.A.

Attorney General's Report – Janet Wray

Ms. Wray discussed the following cases:

- A.P.
- B.A.
- B.H.
- K.K.
- C.N.
- S.S.
- F.R.

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

Open Session

Appearance

Appearance by Dr. Kay Kirkpatrick, Resurgens Orthopaedics: Dr. Kirkpatrick stated that they currently have 122 providers. She stated that Resurgens generates many prescriptions and is very interested in solving the problem of overdoses, forgeries and so on. She stated that the issue began when CMS created language for what was required for prescribing through Medicaid and the Board approved EMR paper, but later they were told the paper did not meet the requirements. There have been several attempts to fix this legislatively. Dr. Kirkpatrick stated that the issue is with controlled substances, but now because of the wording of the rule and requiring the electronic signature has become a problem. She stated that schedule II's have always been written on tamper-resistant paper. The written scripts then have to manually be recorded into the EMR or other medical record and a copy of the script scanned in as well. Dr. Kirkpatrick stated that what they need to know from the Board is if their paper is security paper based on CMS guidelines. Dr. Kirkpatrick provided a piece of the actual paper for the Board to look at.

Chris Jones asked Dr. Kirkpatrick why they could not just escribe. Dr. Kirkpatrick responded by stating that is what they mostly do; however, sometimes a patient requests the prescription be printed. She stated that they would much rather escribe, but if the patient requests it, they will print it out.

After reviewing the paper that Dr. Kirkpatrick provided, the Board concluded the security paper she presented did not meet the legal requirements.

Approval of Minutes

Bill Prather made a motion to approve the Public Session minutes for the September 17, 2014 meeting. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to approve the Executive Session minutes for the September 17, 2014 meeting. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Ratifications

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

Petition for Rule Waiver – bioCSL, Inc.

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

Correspondence from Ryan Koenig, Roadrunner Pharmacy

The Board viewed this correspondence for informational purposes only.

Correspondence from Tim Koch, Walmart

The Board considered this correspondence regarding whether or not maintaining e-prescriptions and e-faxed prescriptions solely electronically and being able to print the prescriptions on demand is compliant with Board rules and regulations. The Board directed staff to respond to Mr. Koch by stating that this process is acceptable.

Correspondence from Jennifer Schneider, State Licensing Servicing, Inc.

The Board considered this correspondence from Ms. Schneider regarding whether or not a particular facility needs to be licensed to ship cancer drugs on behalf of the government to hospitals, physicians, and clinical settings in Georgia. Ms. Schneider also asks if the facility would be exempt from licensing. The Board directed staff to respond to Ms. Schneider by stating that the facility is not exempt and would need to obtain a wholesale permit.

Correspondence from Jan Harris, Sharps Compliance, Inc.

The Board considered this correspondence regarding DEA disposal of controlled substance regulations. The Board directed staff to contact Ms. Harris and request additional information.

Correspondence from Zachary Swisher, Counsel for Trinity Medical Pharmacy

The Board considered this correspondence from Mr. Swisher requesting an opinion concerning licensure. The Board directed staff to respond to Mr. Swisher by stating that if the facility is just doing compounding it will need to complete applications for a wholesale pharmacy and a non-resident pharmacy permit. In addition, evidence that the facility is a 503b facility would need to be submitted as well.

Correspondence from Lisa Erhardt, D2 Pharma Consulting, LLC

The Board considered this correspondence regarding virtual manufacturers located in states that do not issue domicile licenses. The Board directed staff to respond to Ms. Erhardt by thanking her for her correspondence and refer her to the laws and rules located on the Board's website.

Correspondence from Mary L. Fleming, Accreditation Commission for Health Care (ACHC)
The Board considered this correspondence regarding ACHC's intent to become an acceptable accreditor for specialty pharmacy services. The Board directed staff to schedule Ms. Fleming for an appearance before the Board to present this information.

Correspondence from Linda M. Stevens, Pipeline Rx
The Board considered this correspondence from Ms. Stevens requesting an appearance before the Board to discuss a pilot project with regards to remote order entry for hospitals only. The Board granted Ms. Stevens' request.

Correspondence from Leonard R. LaRussa, Georgia Board of Podiatry
The Board considered this correspondence regarding compounding pharmacies. The Board directed staff to refer Dr. LaRussa to O.C.G.A. § 43-1B, § 43-1B-4(1) and (7), § 26-4-60(a)(10) and Board Rule 480-5-.03(b) for more information.

Correspondence from Georgia Hospital Association
The Board considered this correspondence regarding hospital pharmacy purchases of compounded drugs from NECC. Keri Conley, representative from GHA, was present at the meeting and stated that she would be happy to answer any additional questions the Board may have regarding this matter. The Board viewed this correspondence for informational purposes only.

Georgia Drugs and Narcotics Agency – Rick Allen
No report.

Attorney General's Report – Janet Wray
Ms. Wray provided the Board with a copy of a report concerning FY2014 Pending Administrative Cases and Attorney Time.

Executive Director's Report – Tanja Battle
Ms. Battle presented the Board with proposed 2015 meeting dates. The Board recommended tabling this matter until the next meeting scheduled for November 19, 2014.

Ms. Battle discussed facility and non-resident applications. Ms. Battle stated that staff has looked at these applications and noticed the language said that the applications instruct applicants as follows *"Any documents submitted as an attachment to the application must also be signed by the owner, partner, or one of the executive officers of the corporation and notarized."* Ms. Battle asked the Board if the certification on the applications can be modified to extend to all attachments sent in support of the application, which would serve the same purpose without requiring notarization and signatures on all attachments. Chris Jones made a motion to amend the applications to require a certification that would extend to all attachments sent in lieu of requiring notarization and signatures on all attachments. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Ms. Battle reported that the Board office has moved to the sixth floor. All meetings will continue to meet on the 36th floor.

Miscellaneous
Bill Prather made a motion to post Rule 480-1-.01 Organization of the Board. Amended., Rule 480-6-.01 Pharmacy Licenses. Amended., Rule 480-6-.02 Nonresident Pharmacy Permit, Rule 480-38-.04 Communications, Rule 480-40-.04 Witness Lists and Respondent Statements, Rule 480-7-.01 Manufacturer's Permits, Rule 480-7-.04 Researcher's Permits, Rule 480-5-.04 Impaired Pharmacists, Interns, and Externs, Rule 480-20-.02 Record-Keeping Requirements for Registrants, 480-25-.12

Enforcement. Amended, and Rule 480-23-.01 Investigations and Hearings. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

480-1-.01 Organization of the Board. Amended

The Georgia State Board of Pharmacy consists of eight (8) members who are commissioned by the Governor. The public may obtain information from the Board, and make submissions and requests to the Board by contacting the Executive Director of the State Board of Pharmacy at ~~T~~the Department of Community Health, 2 Peachtree Street, S.W., ~~3~~6th Floor, Atlanta, Georgia 30303.

480-6-.01 Pharmacy Licenses. Amended

(1) Application for license:

(a) Applications must be filed ~~in duplicate~~ with the Georgia State Board of Pharmacy located at the Department of Community Health, 2 Peachtree Street, ~~3~~6th Floor, Atlanta, GA 30303, along with the required fee.

(b) Application for the licensing of a pharmacy will be considered on the basis of the application filed and an approval letter received from the ~~d~~Director of the Georgia Drugs and Narcotics Agency certifying the pharmacy possesses the necessary facilities and equipment for a license. (c) The application fee shall NOT be refundable.

(2) Every pharmacy shall be under the direct charge of a registered pharmacist whose name shall appear on the license. In the event such pharmacist whose name shall appear on said license shall no longer be in charge of a pharmacy, the Board shall be notified immediately and shall be notified, at the same time, of the successor registered pharmacist.

(3) Licenses shall not be transferable. Licenses become null and void upon the sale, or change of mode of operation of the business.

(4) Licenses shall be renewed every two years and expire on June 30th of each odd year and may be renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st of the odd year, the license shall lapse and shall not be renewable except by application for a new license.

480-6-.02 Nonresident Pharmacy Permit

(1) Effective 01/01/2015, it shall be unlawful for any person, pharmacy, or facility located outside this state to ship, mail, or deliver prescription drugs orders into this state or to advertise its services, personally or through an in-state third party, unless such person, pharmacy or facility holds a pharmacy license pursuant to O.C.G.A. Section 26-4-110.1, or holds a nonresident pharmacy permit pursuant to O.C.G.A. Section 26-4-114.1, or is otherwise exempt from Georgia registration as a matter of Georgia law.

(2) Application for a non-resident pharmacy permit:

(a) Applications must be filed ~~in duplicate~~ with the Georgia State Board of Pharmacy located at 2 Peachtree Street, NW, ~~3~~6th Floor, Atlanta, Georgia 30303, along with the required fee.

(b) The Board requires information from each applicant for a nonresident pharmacy permit on its application, including but not limited to, the following:

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 each facility used by the applicant for the records, storage, handling, and distribution of prescription drugs into this state;

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 receives and dispenses prescription drug orders;
9. The names and license numbers of the pharmacist-in-charge of each facility involved in dispensing drugs to residents of this state and evidence that the pharmacist(s) 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 in is 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 that is no older than two (2) years 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 an owner or pharmacist of a felony involving the practice of pharmacy 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 if 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 a completed 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 not paid before September 1st of the odd-numbered year, the permit shall lapse and shall not be renewed, and an application for a new permit shall be required.
(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 the state in which they are located and licensed for all prescriptions shipped, mailed or delivered to patients or practitioners in the State of Georgia, but shall be maintained a minimum of two (2) years. 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 within fifteen (15) business days, upon written request.

(10) In addition to labeling requirements required by the state where the nonresident pharmacy is located, the permit holders shall label the drugs dispensed with the following minimum information:

(a) The name and address of the dispenser;

(b) The serial number and date of the prescription or of its filling; (c) The name of the prescriber;

(d) The name of the patient;

(e) The name of the drug dispensed;

(f) The direction for use and cautionary statements; and

(g) Identification of the pharmacist filling the prescription.

(11) Nonresident pharmacy permit holders shall comply with the Board's rules and regulations on delivery of prescriptions by mail in Board Chapter 480-48.

(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 federal compounding laws as required in Board Chapter 480-11.

(14) 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.

(15) Nonresident pharmacy permit holders must notify the Board within five (5) business 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.

(16) Within 72 hours, nonresident permit holders must update the Board of any change in pharmacist-in-charge of shipping into Georgia by completing forms provided by the Board and including such pharmacist licensure information and criminal history. Where a criminal background check cannot be completed within the seventy-two (72 hours) contemplated by this section, nonresident pharmacy permit holders must still update the Board of any change in pharmacist-in-charge of shipping into Georgia by completing forms provided by the Board and including such pharmacist licensure information, but shall have up to fifteen (15) business days to provide criminal history information.

(17) 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 holder's compounding practices. The permit holder shall respond within ten (10) business 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.

(18) 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.

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

480-38-.04 Communications
All communications, including correspondence, motions, and pleadings, shall be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, ~~3~~6th Floor, Atlanta, GA 30303. Copies shall be furnished to all parties of record, including the attorney representing the State. An original 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-.04 Witness Lists and Respondent Statements
(1) Should a party seek a list of the names of witnesses, including experts, whom another party expects to call or may call on its behalf, the party seeking the list must communicate the request in writing (by mail, personal service, or electronically) to the other party at least fourteen (14) days prior to the hearing. Such a request must also be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, ~~3~~6th Floor, Atlanta, GA 30303. The party of whom the information is requested shall, within a reasonable time prior to the commencement of the hearing but at least ten (10) days prior to the hearing, provide such a list to the requester.
(2) The parties may 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. Upon request, the parties shall make available to each other for inspection, copying, testing or sampling any tangible item intended to be introduced as evidence, within a reasonable period of time prior to the hearing. Where a party seeks documents or other evidence already in the possession of the other party which are intended to be introduced as evidence at the hearing, the party seeking the documents must communicate a request for the evidence in writing (by mail, personal service, or electronically) to the other party at least fourteen (14) days prior to the hearing. Such a request must also be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, ~~3~~6th Floor, Atlanta, GA 30303. The party of whom the information is requested shall, within a reasonable time prior to the commencement of the hearing but at least ten (10) days prior to the hearing, provide such evidence to the requester or file a motion seeking an order to quash the request.
(3) If a licensee makes a general or specific written request to the Board for exculpatory, favorable, or arguably favorable evidence that is relative to pending allegations concerning the licensee, the Board must furnish the requested information, indicate that no such information exists, or refuse to furnish the information requested prior to a hearing.
(a) The Board is not required to furnish information made confidential by state or federal law, until such requested information has been determined to be exculpatory, favorable, or arguably favorable pursuant to the *in camera* procedure specified in part (b) of this subsection.
(b) Once the Board has furnished exculpatory, favorable, or arguably favorable information, has indicated that no such information exists, or has refused to furnish such information, a licensee may request a prehearing *in camera* inspection of the remainder of the investigative file by the Board or its designee. The Board or its designee shall furnish the licensee with all material that would aid in the licensee's defense that is exculpatory, favorable, or arguably favorable. The Board or its designee shall seal a copy of the entire investigative file in order to preserve it in the event of an appeal.
(4) If a party refuses to or neglects to produce documents, evidence, witness lists or statements in accordance with a request pursuant to 480-40-.04(1) or 480-40-.04(2), the Board or its designee may issue an order compelling production by motion of the requester or on its own motion. Where the party of whom information is requested has filed a motion to quash the request for production pursuant to

480-40-.01 and 480-40-.04(2), the Board or its designee may issue an order to quash the request for production upon good cause shown by the party requesting such an order. If a party subsequently refuses to or neglects to produce the requested materials in spite of an order compelling it to do so, the Board or its designee shall have the same rights and powers given the court under the Georgia Civil Practice Act. The Board or its designee may certify the facts to the Superior Court of Fulton County or any county where the offense is committed for appropriate action, including a finding of contempt. The Board or its designee shall have the power to issue writs of *fieri facias* in order to collect fines imposed for violation of a lawful order of the Board or its designee.
(5) 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 Board or its designee, upon its 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.

480-7-.01 Manufacturer's Permit.
(1) Applications for registration for a manufacturer's permit must be filed with the Office of the Georgia State Board of Pharmacy ("Board") ~~in duplicate~~ with the required fee.
(2) Registration of a manufacturer will be considered on the basis of the application filed, fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a permit.
(3) Application fees shall NOT be refundable.
(4) Permits shall not be transferable. Permits become null and void upon the sale, or change of mode of operation of the business, or location of business.
(5) Licenses are renewed for two years and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st of the odd numbered year, the license shall lapse and shall not be renewable except by application for a new license.
(6) Upon request by the Board or its designee, any manufacturer holding a permit issued by the Board that causes a dangerous drug or controlled substance product to be marketed or distributed in this state shall provide, at no cost to this state, a quantity of one gram or more of the pure compound of each such product to the Georgia Drugs and Narcotics Agency. Such quantities of pure compound will only be used for testing and analysis purposes.
(a) All quantities of a pure compound provided to the Georgia Drugs and Narcotics Agency will be accounted for using a perpetual inventory system, and a copy of each product inventory will be available for review by the manufacturer providing the compound upon written request to the Board.
(b) As the manufacturer is required by this subsection to submit the dangerous drug or controlled substance for analysis, the results of any chemical analysis shall be considered a trade secret within the meaning of Code Section 50-18-72(b)(1).

480-7-.04 Researcher's Permit.
(1) Applications for registration must be filed with the Office of the Georgia State Board of Pharmacy ("Board")~~, in duplicate~~ with the required fees.
(2) Registration of a Researcher will be considered on the basis of the application filed and a report from the director of the GDNA certifying the applicant possesses the necessary qualifications for a permit.
(3) Application fees shall NOT be refundable.
(4) Permits shall not be transferable. Permits become null and void upon the change of mode, operation and/or location of the permit-holder.

(5) Permits are renewable every two (2) years and expire on June 30th of the even- numbered years. Permits may be renewed upon the payment of the required renewal fee and the filing of the renewal application form. If the application is not made and the fee not paid before September 1st of the even-numbered year, the permit shall lapse and shall not be renewable except by application for a new permit.
(6) Minimum Qualifications:
(a) The Board will consider the following factors in determining eligibility for persons or entities applying for permits to engage in research.
1. Any convictions of the applicant under any Federal, State, or local laws related to dangerous drugs or controlled substances;
2. Any felony convictions of the applicant under any Federal, State, or local laws;
3. The applicant's past experience in research related to dangerous drugs including controlled substances;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug research;
5. Suspension or revocation by Federal, State or local government of any permit currently or previously held by the applicant for drug research;
6. Compliance with the requirements under previously granted permits or licenses, if any;
7. Compliance with requirements to maintain and/or make available to the State licensing or permitting authority or to Federal, State or local law enforcement officials those records required to be maintained by researchers;
8. Any other factors or qualifications such as age, education, training, etc. the Board considers relevant to be inconsistent with the public health and safety; and
9. Having a Peace Officer Certification suspended or revoked by the Georgia Peace Officers Standard and Training (POST) or other professional licensing authority.
(b) The Board reserves the right to deny a permit to any applicant if it determines that the granting of such a permit would not be in the public interest.
(7) Storage and Security:
(a) All drugs including dangerous drugs and controlled substances shall be stored at appropriate temperatures and under appropriate conditions in accordance with labeled requirements or those published in the current edition of an official compendium, such as the United States Pharmacopoeia (USP) Compendiums;
(b) All facilities used for storage of drugs including dangerous drugs and controlled substances shall be of suitable size and construction to facilitate cleaning, maintenance and proper operations; and shall provide security from unauthorized entry as approved by the Board or GDNA.
1. All such facilities will be located in an appropriately zoned district, such as a college, school, university, law enforcement office, or commercial area. No permit will be issued to any researcher whose facility is located in a residential area, dwelling, or location. The Board may choose to grant an exception to this rule upon receipt of a written request from such applicant stating the reason for such an exemption.
(8) Record Keeping and Accountability:
(a) Researchers shall establish and maintain records of all transactions regarding receipt, distribution or other disposition of dangerous drugs or controlled substances.
(b) All records required by these regulations shall be retained for a minimum period of two (2) years following any disposition of any drugs received.
(c) Such records shall be kept at the storage site or shall be immediately retrievable by computers or other electronic means for authorized inspection during the retention period. (9) Sanctions and Penalties:
(a) The Board under these regulations shall have the power to suspend or revoke any permit issued or to reprimand or to fine, not to exceed $500 per violation, the holder of such permit when such holder shall have:
1. Become unfit or incompetent;
2. Been convicted of a felony or any other crime involving moral turpitude;
3. Violated any Pharmacy laws or rules or regulations promulgated by the Board, or violated any other state, federal, or local laws and rules related to drugs.

4. The Board may refuse to grant a permit or renewal to any person, firm, corporation, agency, department or other entity for any of the grounds set forth in O.C.G.A. Section 26-4-49 and/or 26-4-60 of the Georgia Pharmacy Practice Act.

480-5-.04 Impa~~r~~ired Pharmacists, Interns and Externs.

Pursuant to O.C.G.A. T.26, Ch. 4 and O.C.G.A. Section 43-1-19, whenever a pharmacist, intern or extern becomes unfit to practice pharmacy with reasonable skill and safety by reason of a mental or physical condition including impairment due to the use of alcohol, narcotics, stimulants, or other habit-forming drugs, the Board has the duty and authority to place appropriate conditions or limitations on that person's license, including conditions or limitations on that person's license, including suspension or revocation.

Whenever such pharmacist, intern or extern is impaired or has otherwise endangered the public health and welfare while engaged in the practice of pharmacy, and any other Board licensee is aware of such impairment he/she has the obligation and duty to notify the Board of such impaired persons and their actions.

480-20-.02 Record-Keeping Requirements For Registrants.

(1) Each registrant shall maintain records of unusual orders of controlled substances received by the registrant and shall inform the Office of the Director of the Georgia Drugs and Narcotics Agency (GDNA) of unusual orders when discovered by the registrant. For purposes of this section, an unusual order shall include orders of greatly increased quantity, orders deviating substantially from a normal pattern, and orders of highly abnormal frequency.

(2) Before distributing or transferring any controlled substance and/or a dangerous drug, without a prescription drug order, to any customer, a registrant must ensure such customer is properly licensed or registered to purchase, receive, or possess such drug(s) by maintaining, on file, a copy of the current license or registration for any and all such customers. Any transfer, sale, distribution of a drug to an unlicensed or unregistered customer shall be deemed to be in violation of O.C.G.A. 26-4-115, 16-13-30 and/or 16-13-72.

480-25-.12 Enforcement. Amended.

The enforcement and administration of these Rules and Regulations shall be as prescribed in the Georgia Administrative Procedure Act, O.C.G.A., Title 50, Chapter 13, Title 26, Chapter 4, and Title 43, Chapter 1.

480-23-.01 ~~Procedural Rules. Amended.~~ Investigations and Hearings

~~(1) The Georgia State Board of Pharmacy (Board) hereby adopts by reference as its permanent rules Chapters 295-3 through 295-13, and any future amendments thereto, Rules and Regulations of the Office of the Division Director of the Professional Licensing Boards Division of the Office of the Secretary of State.~~

~~(2)~~ (1) Proceedings by the Board in the exercise of its authority to cancel, suspend, sanction, or revoke any license issued by the Board shall be conducted in accordance with O.C.G.A. Tit le 50 Chapter 13, the "Georgia Administrative Procedure Act." In all such proceedings, the Board shall have the authority to compel the attendance of witnesses and production of any book, writing, or document upon the issuance of a subpoena thereafter signed by the ~~Division Director, formerly known as the Joint Secretary~~ Executive Director for the Board or the Director of the Georgia Drugs and Narcotics Agency (GDNA).

~~(3)~~ (2) The Board shall have the authority to conduct investigative interviews or board hearing, with or without the necessity of utilizing the Office of the State Administrative Hearings, in respect thereto.

~~(4)~~ (3) The Vice President of the Board will be known as the investigative member of the Board and shall have the following duties:

(a) Serve as the contact member, or liaison member, between the Board and the GDNA;

(b) Receive findings from GDNA case reports and other investigations regarding possible violations of law and report same to the Board;
(c) Conduct investigative interviews on behalf of the Board; and
(d) Make various presentments, recommendations, and findings from investigative interviews and other miscellaneous sources to the Board.
A motion was made by Chris Jones, seconded by Mike Faulk, and the Board voted that the formulation and adoption of these amendments 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 at O.C.G.A§ 50-13-9 16 5 9 4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

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

Executive Session

Attorney General's Report – Janet Wray
Ms. Wray discussed the following:

- Letter from J.S.R.

Ms. Wray presented the following consent orders:

- B.C.H.
- D.M.C.
- E.A.
- M.F.
- M.R.
- S.R.M.
- P.H.
- P.H.H.
- S.G. and J.P.C.
- M.Z.

Georgia Drugs and Narcotics Agency – Rick Allen
Mr. Allen discussed the following:

- NABP Forum
- Pharmacy Technicians being sent to patient rooms to take medication histories
- Same chain store to chain store transfers

Cognizant's Report – Mike Faulk

- GDNA Case #A-14-35
- GDNA Case #T-31257
- GDNA Case #T-31145
- GDNA Case #T-31226
- GDNA Case #31259
- GDNA Case #31165
- GDNA Case #B-31114
- GDNA Case #B-31152
- GDNA Case #A-31190
- GDNA Case B-31185
- GDNA Case B-31180
- GDNA Case #B-31181
- GDNA Case #B-31135
- GDNA Case #B-31133
- GDNA Case #B-31183
- GDNA Case #B-31184
- GDNA Case #B-31149
- GDNA Case #B-31191
- GDNA Case #B-31186
- GDNA Case #B-31222
- GDNA Case #A14-36
- Correspondence regarding W.P.I. and P.P.I.

Applications

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

Correspondences/Requests

- J.L.K.
- M.A.R.
- M.I.
- A.K.
- J.L.P.
- L.J.
- L.B.G.
- E.P.B.
- R.K.H.
- R.M.B.
- B.W.M.
- N.D.Y.
- D.J.
- T.L.

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

Open Session

Bob Warnock made a motion for the Board to take the following actions:

Appearance

- R.M.W. Approved request to terminate probation

Attorney General's Report – Janet Wray

Ms. Wray discussed the following cases:

- C.P., G.D. and W.E.P. Accept Voluntary Surrender
- M.P. Refer to Attorney General's office
- P.P. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- R.A. Private Consent Order accepted

Appearances

- A.P. Denial overturned and table pending receipt of additional information
- D.E.A. Denial overturned and application approved

Attorney General's Report – Janet Wray

Ms. Wray discussed the following cases:

- A.P. Change disposition to a letter of concern
- B.A. Proceed with disciplinary action if renewal is initiated
- B.H. Close with letter of concern
- K.K. Close with no action
- C.N. Close with no action
- S.S. Close with letter of concern

- F.R. Close case on N.S. with a letter of concern and proceed against F.R.

Attorney General's Report – Janet Wray

Ms. Wray discussed the following:

- Letter from J.S.R. Refer to GDNA to investigate. No action taken on P.P.

Ms. Wray presented the following consent orders:

- B.C.H. Private Consent Order accepted. Close case on K.L. with a Letter of Concern.
- D.M.C. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- E.A. Private Consent Order accepted
- M.F. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- M.R. Private Consent Order accepted. Close case on M.C.
- S.R.M. Private Consent Order accepted
- P.H. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- P.H.H. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- S.G. and J.C. Private Consent Order accepted. Close case on J.C.
- M.Z. Private Consent Order accepted

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen discussed the following:

- NABP Forum: No action taken
- Pharmacy Technicians being sent to patient rooms to take medication histories: Ms. Wray indicated that a medical history may be taken by any employee designated to do so by the doctor's office.
- Same chain store to chain store transfers: Mr. Allen will draft a rule for the Board's consideration regarding this matter.

Cognizant's Report – Mike Faulk

- GDNA Case #A-14-35 Accept Interim Consent Order
- GDNA Case #T-31257 Accept Voluntary Surrender. Requested GDNA investigate PIC and pharmacy
- GDNA Case #T-31145 Revoke technician registration
- GDNA Case #T-31226 Revoke technician registration
- GDNA Case #31259 Revoke technician registration
- GDNA Case #31165 Accept Voluntary Surrender
- GDNA Case #B-31114 Refer to the Attorney General's office for discipline
- GDNA Case #B-31152 Close with letter of concern
- GDNA Case #A-31190 Refer to the Attorney General's office for discipline
- GDNA Case B-31185 Close with no action
- GDNA Case B-31180 Close with no action
- GDNA Case #B-31181 Close with letter of concern
- GDNA Case #B-31135 Close with no action

- GDNA Case #B-31133 Close with no action
- GDNA Case #B-31183 Close with letter of concern
- GDNA Case #B-31184 Close with no action
- GDNA Case #B-31149 Close with no action
- GDNA Case #B-31191 Close with no action
- GDNA Case #B-31186 Close with letter of concern
- GDNA Case #B-31222 Close with letter of concern
- GDNA Case #A14-36 Accept Interim Consent Order
- Correspondence regarding W.P.I. and P.P.I.

Applications

• D.J.W.	Pharmacy Technician	Tabled until November 19, 2014 meeting
• C.B.	Pharmacy Technician	Denied registration
• J.B.P.	Pharmacy Technician	Denied registration
• Ruby Lira	Pharmacy Technician	Approved registration
• Kamaria A. Willis	Pharmacy Technician	Approved registration
• R.G.W.	Pharmacy Technician	Denied registration
• Q.A.	Pharmacy Technician	Tabled until November 19, 2014 meeting
• L.H.	Pharmacy Technician	Tabled until November 19, 2014 meeting
• C.J.O.	Pharmacist Renewal	Table pending receipt of additional information
• D.N.G.	Pharmacist	Denied application
• E.A.C.	Pharmacist Reciprocity	Approved application
• M.E.V.	Pharmacist Renewal	Approved for renewal
• K.A.L.	Pharmacist Renewal	Approved for renewal
• B.M.	Pharmacist Intern	Approved application with letter of concern
• B.A.E.	Pharmacist Intern	Approved application with letter of concern
• J.W.	Pharmacist Intern	Approved application with letter of concern
• K.T.N.	Pharmacist Intern	Approved application with letter of concern
• L.N.G.	Pharmacist Intern	Approved application with letter of concern
• Matthew A. Stone	Pharmacist Intern	Approved application
• M.T.J.H.	Pharmacist Intern	Schedule for an appearance with the Board
• T.G.M.	Pharmacist Intern	Approved application with letter of concern
• T.Y.H.	Pharmacist Intern	Approved application with letter of concern

Correspondences/Requests

• J.L.K.	Correspondence	Refer individual to appropriate code sections
• M.A.R.	Request for extension of intern license	Approved one year extension
• M.I.	Notice of discipline	Board viewed as informational purposes only
• A.K.	Request to be allowed to take NAPLEX	Request denied
• J.L.P.	Requesting the Board reinstate reinstate license	Advise individual that he/she must submit a reinstatement application
• L.J.	Request for telephonic appearance	Request denied
• L.B.G.	Remote Order Entry	Request denied

• E.P.B.	OMPE results	Private Consent Order to be accepted and signed with express permission upon receipt of the original
• R.K.H.	Requesting to be considered for reinstatement, plus a reduction of the fee	Accept fee minus renewal fee already paid
• R.M.B.	Correspondence	Directed staff to respond to individual by stating that based on the information submitted, the Board has determined only one license is required.
• B.W.M.	Correspondence	Board viewed as informational purposes only
• N.D.Y.	Request for extension of intern license	Request denied
• D.J.	Request to remove supervised practice restriction	Request approved
• T.L.	Correspondence	Board needs to confirm that two licenses are required

Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Bob Warnock made a motion to adopt the following policy regarding labeling of prescriptions:

In response to numerous inquiries about the proper labeling of prescriptions drugs, the Georgia State Board of Pharmacy has examined the issue in light of state law. O.C.G.A. Section 26-4-80(k) expressly provides:

All out-patient prescription drug orders which are dispensed shall be appropriately labeled in accordance with the rules and regulations promulgated by the board as follows:

(1) Before an out-patient prescription drug is released from the dispensing area, the prescription drug shall bear a label containing the name and address of the pharmacy, a prescription number, the name of the prescriber, the name of the patient, directions for taking the medication, the date of the filling or refilling of the prescription, the initials or identifying code of the dispensing pharmacist, and any other information which is necessary, required, or, in the pharmacist's professional judgment, appropriate; and

(2) The pharmacist who fills an out-patient prescription drug order shall indicate the identity of the dispensing pharmacist on the label of the prescription drug. Identification may be made by placing initials on the label of the dispensed drug. The label shall be affixed to the outside of the container of the dispensed drug by means of adhesive or tape or any other means which will assure that the label remains attached to the container.

Board Rule 480-27-.05 is consistent with this rule in regards to recordkeeping. However, it appears that O.C.G.A. Section 16-13-73 currently requires that whenever a pharmacist dispenses a dangerous drug, the pharmacist shall place a label upon each container that has the name of the "physician" prescribing the drug. Since persons other than physicians are authorized to prescribe dangerous drugs under Georgia law, see, e.g., O.C.G.A. Section 16-13-78.1 and 16-13-70.1, the Board plans to ask the General Assembly to pass legislation during the 2015 Session to make Code section 16-13-72 consistent with the other statutory provisions and to eliminate any confusion in this area.

Until such time as the law can be changed, the Board will consider compliance with O.C.G.A. Section 26-4-80(k) and its rules regarding labeling to be compliance with the laws and rules for purposes of any disciplinary action. That means that pharmacists may use the name of the prescribing or ordering practitioner on the label. A practitioner is a physician, dentist, podiatrist, physician's assistant, advanced practice registered nurse, or other person licensed, registered, or otherwise authorized under the laws of this state to prescribe or order dangerous drugs or controlled substances.

Mike Faulk 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 19, 2014, at 9:00 a.m. at Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 4:07 p.m.

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