GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
December 17, 2014
9:00 a.m.

The following Board members were present:
Al McConnell, Chairperson
Laird Miller, Vice-Chairperson
Jim Bracewell
Mike Faulk
Chris Jones
Bill Prather
Bob Warnock

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

Visitors:
Paul Fletcher, Rockwell Medical
Lisa Erhardt, Rockwell Medical
Ken Arthur
Tom Chavers
Moses Henderson
John Sisto, Express Scripts
Melvin Smith, CVS
Jimmy England, Walgreens
Andy Freeman, GPhA
Kallarin Mackey, GHA
Helen Sloat, Kaiser, Hemophilia of Georgia
Scott Biddulph, Target
Todd Tyson, GAMES
Stephen Snow
Mary Ann Langford, Holland & Knight
Teresa Tatum, GAMES
Trish Yeatts, MAG
Mike Grindstaff, Premier Kids Care / ACHC
Josh Belinfante, Robbins Firm
Jose Domingos, ACHC
Joe Cabaleiro, ACHC
Nirmal Patel, Walmart
Mike Chavez, Publix
Chandler Hayden, Petsch Respiratory
David Petsch, Petsch Respiratory
Lynda Chapman
Ben DiMarco, DaVita
R. Scott Lindsay, CAPS
Spencer Tally, Atlanta Vet

Chairperson McConnell established that a quorum was present and called the meeting to order at 9:07 a.m.

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, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Bill Prather and Bob Warnock.

Executive Session

Georgia Drugs and Narcotics Agency – Dennis Troughton

- O.P./L.

Appearances

- R.M.I.
- K.L.A.
- M.T.H.

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

Open Session

Appearances

Appearance by Todd Tyson, Hi-Tech Healthcare, Inc.: Mr. Tyson provided a handout to the Board and thanked the members for allowing him to meet with them. Mr. Tyson stated that he would like to request the Board consider licensure of home medical equipment (HME) and durable medical equipment (DME) in the state of Georgia and stated that the Board has the authority to propose a rule requiring such. He explained that this would protect the health, safety and well-being for Georgia patients and would protect Georgia providers/small business by keeping business local. He stated that neighboring states all currently require licensure for HME/DME. Mr. Tyson stated that the providers in Georgia would fall under the Georgia Board of Pharmacy.

Discussion was held concerning bringing this matter up legislatively along with pursuing funding for such.

Mr. Bracewell asked if the Board would be able to post a rule regarding such with an effective date far enough in the future that the rule could be rescinded should funding not be secured. Ms. Battle responded by stating that the Board could post the rule for consideration and opt not to adopt it if there was no funding appropriated. Discussion was held concerning when the rule would become effective. Ms. Battle commented that the Board has a new license type already and would need ample time to prepare. Mr. Miller agreed that it would be important for Ms. Battle to know what she will have to deal with on an administrative level.

Mr. Tyson asked the Board to consider not requiring a pharmacist to do an inspection on a DME facility as he is aware the Board uses inspectors that are all pharmacists. Ms. Wray responded that a lot of his suggestions are meaningful, but could not be handled by rule. She stated that if he had legislation changed then that would all be appropriate. The law currently requires GDNA inspectors to be used and those would be licensed pharmacists. Mr. Miller requested Mr. Tyson provide any additional information to the Board as soon as possible so that it can take this matter back up in January.

Appearance by Joe Cabaliero and Jose Domingo, Accreditation Commission for Health Care: Mr. Cabaliero thanked the Board for allowing him and Mr. Domingo to meet with them. Mr. Cabaliero

stated that ACHC is requesting to become an approved accreditor for specialty pharmacies in Georgia. He provided a handout and stated that he is simply asking the Board to recognize the program.

Josh Belinfante spoke to the Board and stated he represents Premier Kids Care. Mr. Belinfante stated that he spoke to the Board in 2011 and the Board adopted policy #11, which states the following:

Pursuant to the authority delegated to the Board in O.C.G.A. § 26-4-28(a)(21), and acting as the sole governmental or other authority with the authority to (1) approve or recognize accreditation programs for specialty pharmacy practice, and (2) determine the acceptability of entities which may accredit pharmacies or certify pharmacists in a specialty of pharmacy practice in the State of Georgia, the Board approves and recognizes the URAC Specialty Pharmacy Accreditation Standards, Version 2.0, July 2010 ("URAC Accreditation") as an accreditation program for specialty pharmacy practice.
This policy does not require pharmacists or pharmacies to obtain URAC Accreditation as a prerequisite to specialty or advance pharmacy practice.

Mr. Belinfante stated that it would be beneficial if there were two accrediting entities.

Mr. Cabaliero gave the Board some background on ACHC. He stated that the ACHC is a nationally-recognized accreditation organization with 28 years of experience. ACHS is known as a national expert in specialty pharmacy accreditation and has CMS Deeming Authority for Home Health, Hospice, and DMEPOS. He stated that ACHC inspects out of state compounding pharmacies for Texas and Florida Boards of Pharmacy. Mr. Miller asked if what ACHC was here for today is for specialty pharmacies. Mr. Cabaliero responded by stating yes. Mr. Belinfante explained that by recognizing ACHC would not impact compounding at all and that instead of recognizing one compounding program you would have two.

Public Hearing

Chairperson McConnell called the public hearing to order at 12:20 p.m.

Rule 480-1-.01 Organization of the Board.Amended.
No comments or written responses were received.

Rule 480-5-.04 Impaired Pharmacists, Interns, and Externs
No comments or written responses were received.

Rule 480-6-.01 Pharmacy Licenses. Amended
No comments or written responses were received.

Rule 480-6-.02 Nonresident Pharmacy Permit
No comments or written responses were received.

Rule 480-7-.01 Manufacturer's Permit
No comments or written responses were received.

Rule 480-7-.04 Researcher's Permit
No comments or written responses were received.

Rule 480-20-.02 Record-Keeping Requirements for Registrants
No comments or written responses were received.

Rule 480-23-.01 Investigations and Hearings
No comments or written responses were received.

Rule 480-25-.12 Enforcement. Amended.
No comments or written responses were received.

Rule 480-38-.04 Communications
No comments or written responses were received.

Rule 480-40-.04 Witness Lists and Respondent Statements
No comments or written responses were received.

The hearing adjourned at 12:24 p.m.

Open Session

Laird Miller made a motion to adopt Rules 480-1-.01 Organization of the Board.Amended., 480-5-.04 Impaired Pharmacists, Interns, and Externs, Rule 480-6-.01 Pharmacy Licenses.Amended, 480-6-.02 Nonresident Pharmacy Permit, 480-7-.01 Manufacturer's Permit, 480-7-.04 Researcher's Permit, 480-20-.02 Record-Keeping Requirements for Registrants, 480-23-.01 Investigations and Hearings, 480-25-.12 Enforcement.Amended, 480-38-.04 Communications, and 480-40-.04 Witness Lists and Respondent Statements. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Approval of Minutes
Laird Miller made a motion to approve the Public Session minutes for the November 19, 2014 meeting. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to approve the Executive Session minutes for the November 19, 2014 meeting. Jim Bracewell 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 – Cubist Pharmaceuticals, U.S.
Chris Jones made a motion to grant the rule waiver petition. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Charlene M. Bunts, GA Hospice and Palliative Care Organization
The Board considered this correspondence regarding hospice nurses not touching medications for destruction after a patient's death. Mike Faulk made a motion to direct staff to respond to Ms. Bunts by stating that the Board is sympathetic to her situation; however, please be advised that it does not have any authority that differs from the federal ruling. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Travis R. Ireland, Walgreens Co. District 207
The Board considered this correspondence requesting clarification on who exactly currently holds prescriptive authority within the state of Georgia. Mr. Ireland is also requesting clarification regarding the security paper requirement for controlled substances. Chris Jones made a motion to direct staff to respond that the Board realizes there are some inconsistencies in the law and that Mr. Ireland can refer to his own legal counsel regarding prescriptive authority within the state of Georgia. Additionally, in

regards to the security paper requirement for controlled substances, he needs to follow the laws of this state. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Steve Georgeson

The Board considered this correspondence requesting clarification regarding section (j) of proposed Rule 480-48-.02 which reads, *"A mail order pharmacy shall make available to the patient or the patient's caregiver contact information of the Board of Pharmacy".* Laird Miller made a motion to direct staff to respond by stating that the intent of the line mentioned is to include the contact information for the Board inside each package. That contact information would include the Board's address and phone number. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Lisa Q. Guo, Ropes & Gray, LLP

The Board considered this correspondence regarding medical device prescriptions. Ms. Guo states that under O.C.G.A. § 26-4-5, a "prescription drug order" means a lawful order of a practitioner for a drug or device and is asking if this means prescriptions for medical devices are subject to the same requirements as prescriptions for prescription drugs (e.g., the requirements in O.C.G.A. § 26-4-80 on filling and refilling of prescriptions). Chris Jones made a motion to direct staff to respond by stating that prescriptions for medical devices are subject to the same requirements as prescriptions for prescription drugs. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from regarding pharmacist licensure requirement for the provision of inspection services

The Board considered this correspondence regarding a firm that provides medications to correctional facilities. The firm serves 12 jails in Mississippi and Louisiana and performs inspections of the facilities, which includes tasks such as checking to ensure proper storage of drugs, proper provision of drugs in emergency carts, and proper recordkeeping procedures for controlled substances. The firm recently won a contract in Georgia and is trying to determine whether or not licensure is required to perform these tasks for the Georgia facility. Chris Jones made a motion to direct staff to respond by stating that the Board suggests he review O.C.G.A. § 26-4-28(a)(19) regarding this matter. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Teresa Melvin, HealthSouth Corporation

The Board considered this correspondence regarding medication dispensing systems and mobile/temporary pharmacies. Laird Miller made a motion to direct staff to respond by stating that, based on the information provided, it does not appear what she proposes would meet the criteria for approval for a pharmacy permit. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jan Harris, Sharps, Inc.

The Board considered this correspondence which had been tabled from the Board's November 19, 2014 meeting. Bill Prather made a motion to table this matter until later in the meeting. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Bernard Ross, Allied Health Resources

The Board considered this correspondence regarding Mr. Ross's request for verification in writing that licensure is not required for his company in the state of Georgia. Chris Jones made a motion to direct staff to respond by stating that the Board suggests he carefully review the law and rules located on the Board's website. Additionally, the Board suggests he download and review the Application for Pharmacy License.

Georgia Drugs and Narcotics Agency – Dennis Troughton
No report.

Attorney General's Report – Janet Wray
No report.

Executive Director's Report – Tanja Battle
Ms. Battle discussed changes in ownership and name changes for facilities and when the facility would be required to submit a new application. Ms. Wray stated that, if the information that was listed on the initial application is changing, then the facility would need to submit a new application. Ms. Battle stated that when the Board goes into executive session it can look at one specifically and discuss the matter further.

Ms. Battle acknowledged GDNA Deputy Director, Dennis Troughton. She expressed her appreciation for his diligence and support in Director Allen's absence.

Miscellaneous
Bill Prather made a motion to post Rule 480-25-.01 Definitions.Amended and Rule 480-25-.08 Equipment.Amended. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Rule 480-25-.01 Definitions. Amended.
Unless a different meaning is required by the context, the following terms as used in these rules and regulations shall have the meaning hereinafter respectively ascribed to them:
(a) "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.
(b) "Board" means the State Board of Pharmacy.
(c) "Compounding of radiopharmaceuticals" means the addition of a radioactive substance to nonradioactive substances or the use of a radioactive substance in preparation for single or multidose dispensation upon the prescription order of a physician who is licensed to use radioactive materials. Compounding of radiopharmaceuticals may include: loading and eluting of radionuclide generators; using manufactured reagents; preparing reagent kits; aliquoting reagents; formulation and quality assurance testing of radiochemicals for use as radiopharmaceuticals, and radiolabeling of compounds or products, including biological products, for use as radiopharmaceuticals.
(d) "Department" means the Department of Human ~~Resources.~~Services.
(e) "Governing Body" or "Management" means the board of directors, trustees, partnership, corporation, association, person or group of persons who maintain and control the operation of the nuclear pharmacy, and who are legally responsible for its operation.
(f) "Internal Test Assessment" means, but is not limited to conducting those tests of a quality assurance necessary to ensure the integrity of the test.
(g) "Licensed Nuclear Pharmacist" means an authorization granted by the Board to a pharmacist to practice as a nuclear pharmacist.
(h) "Manufacturing of radiopharmaceuticals" means the preparation, derivation, or production of a product to which a radioactive substance is or will be added to provide a radiopharmaceutical for sale, resale, redistribution, or reconstitution.
(i) "Nuclear pharmacist" means a pharmacist who compounds and dispenses radiopharmaceuticals in the course of his/her pharmacy practice.
(j) "Nuclear Pharmacy" means a pharmacy providing radiopharmaceutical services.
(k) "Nuclear Pharmacy Permit" means an authorization granted by the Board to the governing body of a facility to operate a nuclear pharmacy.

(l) "Pharmacist" means an individual who is currently licensed to practice pharmacy under the provisions of O.C.G.A. Title 26, Chapter 4, Article 3.
(m) "Pharmacy Intern" means an individual who is currently licensed to practice as a pharmacy intern under the provisions of O.C.G.A. Title 26, Chapter 4, Article 3.
(n) "Physician" means an individual who is currently licensed to practice medicine under the provisions of O.C.G.A. Title 43, Chapter 34.
(o) "Radiopharmaceutical" means radioactive drugs and chemical products used for diagnostic and therapeutic purposes and includes the terms radioactive pharmaceuticals, radioisotopes, and radioactive tracers.
(p) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on radiopharmaceuticals and their component materials and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.
(q) "Radiopharmaceutical service" means, but is not limited to, the compounding, dispensing, labeling, and delivering of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization review; the
maintenance of radiopharmaceutical quality assurance; and the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy.
(r) "Unit dose transport container" (a/k/a "lead pig") means a lead lined container designed to transport doses of radiopharmaceutical agents and prevent the emission of radiation or radioactive materials during the process. The terms "unit dose transport container" and "lead pig" may be used interchangeably.

480-25-.08 Equipment. Amended.
(1) In addition to other articles and equipment required by the Board for all pharmacies in the State, the nuclear pharmacy shall have:
(a) dose calibrator;
(b) vertical laminar flow hood;
(c) single or multiple channel scintillation analyzer;
(d) microscope and hemocytometer;
(e) adequate glassware, utensils, and gloves;
(f) calculator;
(g) laboratory incubator;
(h) water or oil bath;
~~(i) ultrasonic bath;~~
~~(j)~~(i) aluminum ion test kit; and
~~(k)~~(j) adequate apparatus and supplies for performing chromatography.
(2) Nuclear pharmacies shall also have equipment required for the safe handling and storage of radioactive materials, as required by the Department's Rules and Regulations for radioactive materials.
(3) Each nuclear pharmacy shall utilize unit dose transport containers, a/k/a lead pigs,
(a) Unit dose transport containers, a/k/a lead pigs, for radioactive doses shall include:
1. an effective tamper-evident seal;
2. an effective mechanism to avoid radioactive contamination; and
3. an effective system to prevent contamination of the transport container with blood, bodily fluids, or other biohazardous substances.
(b) No nuclear pharmacist or nuclear pharmacy shall re-use a unit dose transport container or lead pig that has been contaminated with blood, bodily fluids, or other hazardous substances.
(c) Any unit dose transport container or lead pig returned to a nuclear pharmacy with the tamper-evident seal broken and containing an exposed unit dose syringe shall be considered contaminated.

(d) Section 3 of this Rule shall not apply to:
1. an individual prescriber preparing radiopharmaceuticals for administration to his or her own patients;
2. transfer of radioactive material, not intended for use as a drug, to other legally authorized persons; and
3. the occasional transfer of bulk radiopharmaceuticals to other authorized entities or persons to meet shortages.
(e) Biohazardous prevention systems containing a barrier that if used properly eliminates or substantially reduces the potential for contamination of the unit dose transport container, or lead pig, would meet the requirements of these regulations. Improper use of such system resulting in ineffective sanitation of the unit dose transport container, or lead pig, would require that such containers be effectively sanitized prior to subsequent use or discarding of that container.

A motion was made by Chris Jones, seconded by Bill Prather, and the Board voted that the formulation and adoption of this amendment does 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 this rule will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Mr. Prather asked Ms. Battle what the status was on renewals. Ms. Battle responded that staff are processing renewals as quickly as possible. She stated that the Affidavit Regarding Citizenship has to be submitted for this one time only and after this renewal, it should not have to be submitted again. Ms. Wray added that the affidavit would not need to be resubmitted as long as the licensee is a U.S. citizen.

Ms. Foreman presented the Board with a draft records retention schedule and executive summary of the draft schedule. Jim Bracewell made a motion to accept the records retention schedule and the executive summary. Chris Jones seconded and the Board voted unanimously in favor of the motion.

The Board discussed a suggested statement of intent regarding Rule 480-48-.01 Definitions. Bill Prather made a motion to table this matter and revisit at a future date. Chris Jones seconded and the Board voted unanimously in favor of the motion. Ms. Battle stated that if a board member would like to work on the language and send it to her, she will have Ms. Foreman draft it and have ready for posting at the January meeting.

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, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Bill Prather and Bob Warnock.

Executive Session

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- A.P.
- C.P.
- K.

- B.L.
- R.A.
- A.J.S.
- C.P.

Georgia Drugs and Narcotics Agency – Dennis Troughton

- Compounding/Wholesale Distributors

Mr. Troughton discussed the following individuals:

- J.W.
- M.G.
- B.H.
- B.H.

Applications

- E.N.S.
- M.L.M.
- R.L.T.
- O.A.M.
- P.M.A.

Cognizant's Report – Laird Miller

- GDNA Case #A-14-30
- GDNA Case #T-31300
- GDNA Case #T-31292
- GDNA Case #A-14-43
- GDNA Case #A-14-44
- GDNA Case #T-31341
- GDNA Case #A-14-46
- GDNA Case #B-31132
- GDNA Case #A-31265
- GDNA Case #B-31238
- GDNA Case #A-14-30

Executive Director's Report – Tanja Battle

- J.G.W.
- W.C.

Applications

- A.E.R.
- G.L.C.
- J.S.R.
- C.S.S.
- R.L.E.
- C.R.M.
- C.L.
- H.S.C.
- A.P.

- A.M.P.
- A.R.
- I.S.L.
- M.P.
- M.S.P.
- R.P.
- A.H.C.
- O.P.S.
- T.A.P.
- V.F.I.
- C.P.
- C.P.
- C.P.
- R.P.I.
- M.H.P.
- B.
- U.S.C.
- R.S.
- R.S.
- R.S.
- C.C.S.I.S.
- R.S.
- R.S.
- B.
- R.I.
- B.
- A.A.
- C.L.
- R.M.C.
- R.M.C.
- R.M.C.
- R.M.C.
- H.C.
- R.M.C.
- R.M.C.
- R.M.C.
- R.M.C.
- H.H.S.
- U.G.P.S.D.

Correspondences/Requests

- D.T.H.S.
- M.R.M.C.
- F.D.
- S.P.I.
- C.A.P.
- P.M.B.
- T.E.D.

- J.L.P.
- J.H.

Miscellaneous

- Accreditation
- Eric Lacefield, Deputy Director, discussed the upcoming January examination with the Board.

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

Open Session

Chairperson McConnell stated that the Board needs to nominate officers for the upcoming year. Bill Prather made a motion to nominate Laird Miller as President. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Chris Jones made a motion to nominate Mike Faulk as Cognizant and Vice-Chairperson. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to post Rule 480-6-.02 Nonresident Pharmacy Permit and Rule 480-16-.03 Return of Previously Dispensed Drugs or Devices. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Rule 480-6-.02 Nonresident Pharmacy Permit

(1) Effective ~~01/01/2015~~April 1, 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 with the Georgia State Board of Pharmacy located at 2 Peachtree Street, NW, 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.

Rule 480-16-.03 Return of Previously Dispensed Drugs or Devices.
(1) It shall be unlawful, and a violation of these rules, for any licensed pharmacist or pharmacy licensed under O.C.G.A. 26-4 to accept for refund purposes, or otherwise, any unused portion of a drug which has been previously dispensed via a prescription drug order and delivered to the patient or patient's caregiver.
(a) Such receipt is deemed detrimental to the public health due to the likelihood that such drugs, once out of the control of the pharmacy, could have been tampered with, been adulterated, or become contaminated with communicable diseases and/or contagious diseases under the holder thereof;
(b) In addition, such receipt would tend to create a health problem if placed in stock and could be reused by any licensed pharmacist or pharmacy;
(c) Nothing in this Rule shall be meant to be in conflict with Board Rule 480-10-. 17, which allow a pharmacy to receive unused, manufacturer's unit-dose packaged drugs from a Medicaid patient residing in a long term care facility.
(d) Nothing in this Rule shall prohibit a facility that is approved by the Drug Enforcement Administration (DEA) from operating the Take-Back program.

A motion was made by Mike Faulk, seconded by Jim Bracewell, and the Board voted that the formulation and adoption of this amendment does 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 this rule will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

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

Georgia Drugs and Narcotics Agency – Dennis Troughton

- O.P./L. Wholesaler Pharmacy Refer to the Attorney General's office

Appearances

- R.M.I. Wholesaler Pharmacy Tabled pending receipt of additional information
- K.L.A. Pharmacist Reinstatement Approve with public consent order
- M.T.H. Pharmacist Intern Approved application

Attorney General's Report – Janet Wray
Ms. Wray presented the following consent orders:

- A.P. Private consent order accepted
- Corner Pharmacy Public consent order accepted
- K. Private consent order accepted
- B.L. Private consent order accepted
- R.A. Private consent order accepted
- A.J.S. Private consent order accepted
- C.P. Private consent order accepted

Georgia Drugs and Narcotics Agency – Dennis Troughton

- The Board received advice from Ms. Wray regarding compounding/wholesale distributors.

Mr. Troughton discussed the following individuals:

- J.W. Accept inactive status application upon receipt
- M.G. No action taken
- B.H. Accept Interim Consent Order for Assessment
- B.H. Accept Voluntary Surrender

Applications

• E.N.S.	Pharmacy Technician	Overturn denial and approve upon receipt of additional information
• M.L.M.	Pharmacy Technician	Denied registration
• Regina L. Thomas	Pharmacy Technician	Approved registration
• O.A.M.	Pharmacy Technician	Denied registration
• Precious M. Allen	Pharmacy Technician	Approved registration

Cognizant's Report – Laird Miller

• GDNA Case #A-14-30	Accept Private Interim Consent Order
• GDNA Case #T-31300	Revoke technician registration
• GDNA Case #T-31292	Revoke technician registration
• GDNA Case #A-14-43	Accept Private Interim Consent Order
• GDNA Case #A-14-44	Accept Interim Consent Order for Assessment
• GDNA Case #T-31341	Accept Voluntary Surrender
• GDNA Case #A-14-46	Accept Voluntary Surrender
• GDNA Case #B-31132	Refer to the Attorney General's office
• GDNA Case #A-31265	Refer to the Attorney General's office
• GDNA Case #B-31238	Refer to the Attorney General's office and schedule for an investigative interview
• GDNA Case #A-14-30	Refer to the Attorney General's office and schedule for an investigative interview

Executive Director's Report – Tanja Battle

- Joseph G. Washington Pharmacist Renewal Approved
- W.C.: Direct staff to respond by stating if there is no change to the ownership information as it is currently listed on an application, a letter advising the Board of the corporate restructuring suffices. If there is a change to the ownership information as it is currently listed on an application, a new application for change in ownership would be required.

Applications

• Azza El-Remessy	Pharmacist Reinstatement	Approved application and request for reduction of the reinstatement fee
• Gara L. Coffey	Pharmacist Renewal	Approved
• Joyce S. Rimmer	Pharmacist Renewal	Approved
• Christina S. Stepp	Pharmacist Renewal	Approved
• R.L.E.	Pharmacist Renewal	Table pending receipt of additional information
• Chinwendu R. Mbonu	Pharmacist Renewal	Approved

• Christopher Laguerre	Renewal Pending	Approved
• Hyoung S. Choi	Renewal Pending	Approved
• ACS Pharmacy	Non-Resident Pharmacy	Approved
• Advantage Medical Pharm	Non-Resident Pharmacy	Approved
• Assured RX, LLC	Non-Resident Pharmacy	Approved
• IV Solutions of Lubbock	Non-Resident Pharmacy	Approved
• Maxor Pharmacies	Non-Resident Pharmacy	Approved
• Medimix Specialty Pharmacy	Non-Resident Pharmacy	Approved
• RX3 Pharmacy	Non-Resident Pharmacy	Approved
• AnazaoHealth Corporation	Non-Resident Pharmacy	Approved
• Orchard Pharmaceutical Serv	Non-Resident Pharmacy	Approved
• The Alliance Pharmacy	Non-Resident Pharmacy	Approved
• V.F.I.	Non-Resident Pharmacy	Denied application
• Costco Pharmacy #581	Non-Resident Pharmacy	Approved
• Costco Pharmacy #562	Non-Resident Pharmacy	Approved
• Costco Pharmacy #570	Non-Resident Pharmacy	Approved
• Roadrunner Pharmacy, Inc.	Non-Resident Pharmacy	Approved
• Med 4 Home Pharmacy	Non-Resident Pharmacy	Approved
• Biocure, LLC	Non-Resident Pharmacy	Approved
• U.S.C.	Non-Resident Pharmacy	Approved with letter of concern
• R.S.	Non-Resident Pharmacy	Approved with letter of concern
• R.S.	Non-Resident Pharmacy	Approved with letter of concern
• R.S.	Non-Resident Pharmacy	Approved with letter of concern
• Coram CVS/Spec Infusion	Non-Resident Pharmacy	Approved
• R.S.	Non-Resident Pharmacy	Approved with letter of concern
• R.S.	Non-Resident Pharmacy	Approved with letter of concern
• Biologics, Inc.	Non-Resident Pharmacy	Approved
• R.I.	Non-Resident Pharmacy	Approved with letter of concern
• B.	Non-Resident Pharmacy	Refer to the Attorney General's office
• A.A.	Non-Resident Pharmacy	Table pending receipt of additional information
• C.L.	Manufacturing Pharmacy	Refer to the Attorney General's office
• ResMed Corp	Manufacturing Pharmacy	Approved
• ResMed Corp	Manufacturing Pharmacy	Approved
• ResMed Corp	Manufacturing Pharmacy	Approved
• ResMed Corp	Manufacturing Pharmacy	Approved
• Haemonetics Corporation	Wholesaler Pharmacy	Approved
• ResMed Corp	Wholesaler Pharmacy	Approved
• ResMed Corp	Wholesaler Pharmacy	Approved
• ResMed Corp	Wholesaler Pharmacy	Approved
• ResMed Corp	Wholesaler Pharmacy	Approved
• Heather H. Seibert	Pharmacist Cert of DTM	Approved
• University of GA/Poultry Science Department	Researcher Pharmacy	Approved for reinstatement and waiver of the reinstatement fee

Correspondences/Requests

• D.T.H.S.	Correspondence	Viewed this correspondence for informational purposes only.
• M.R.M.C.	Remote Order Entry	Denied
• F.D.	Request to retake E&O and/or temporary licensure	Request denied
• S.P.I.	Records request	Request denied
• C.A.P.	Appearance request	Request denied
• P.M.B.	Request regarding supervised practice	Request approved
• T.E.D.	Appearance request	Request approved
• J.L.P.	Request for reduction of the reinstatement fee	Request approved
• J.H.	Correspondence	Directed staff to respond that the Board is currently working to amend its rule regarding the matter

Miscellaneous

- Accreditation: Table and revisit at a future date.
- Eric Lacefield, Deputy Director, discussed the upcoming January examination with the Board. No action taken.

Laird Miller seconded and the Board voted in favor of the motion, with the exception of Chris Jones, who abstained from the vote regarding W.C., and Al McConnell, who abstained from the vote regarding GDNA Case #B-31132.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, January 21, 2015 at 8:00 a.m. at Mercer University College of Pharmacy, 3001 Mercer University Drive, Atlanta, GA 30341.

The Board meeting adjourned at 5:02 p.m.

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