

**GEORGIA BOARD OF PHARMACY**  
**2 MLK Jr. Drive, SE, 11<sup>th</sup> Floor, East Tower**  
**Atlanta, GA 30334**  
**July 19, 2023**  
**9:00 a.m.**

**The following Board members were present:**

Michael Azzolin, President  
Jim Bracewell  
Michael Brinson (via Teams)  
Young Chang  
Cecil Cordle  
Michael Farmer (via Teams)  
Dean Stone

**Staff present:**

Eric Lacefield, Executive Director  
Dennis Troughton, Director, GDNA  
Michael Karnbach, Deputy Director, GDNA  
Emily Lobeck, Special Agent, GDNA  
Max Changus, Senior Assistant Attorney General  
Clint Joiner, Attorney  
Brandi Howell, Business Support Analyst I

**Visitors:**

Stephanie Kirkland, ElderCare  
Rahul Bali, WABE News  
Dawn Sasine  
Diane Sanders, Kaiser Permanente  
Zohaib Laklani, Northside Hospital  
Merrilee Gober, Medical Association of Georgia  
Jennifer Duckett, Walgreens  
Lisa Pinkney, Trulieve GA  
Travis Clark, CAPS Pharmacy Norcross  
Becca Hallum, GHA  
Jordan Khail, UGA  
Ben Cowart, Georgia Retailers  
Stephen Georgeson  
Matthew Frey, J.L. Morgan  
Erin J. Searles, Cardinal Health, Inc.  
Amit Jain, Publix  
Brandon Brooks, Publix  
Heather Hughes, Publix  
Andrew Wilson, PCOM  
Jonathan G. Marquess, GPhA  
Shea Ross-Smith, Kaiser Permanente  
Olivia Buckner, Nelson Mullins  
Georgia Ray, Nelson Mullins  
Emily Yona, Impact Public Affairs  
Deborah Olayemi  
Mary Kate Snead, Guardian Atlanta  
Lisa Harris, Trulieve GA  
Beth Jarrett, Walmart

**Open Session**

President Azzolin established that a quorum was present and called the meeting to order at 9:01 a.m.

### **Approval of Minutes**

Mr. Cordle made a motion to approve the February 15, 2023, Low THC Committee minutes and the Public and Executive Session Pharmacy Board minutes from the June 14, 2023, meeting. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

### **Report of Licenses Issued**

Mr. Stone made a motion to ratify the list of licenses issued. Mr. Bracewell seconded, and the Board voted unanimously in favor of the motion.

### **Correspondences**

**Correspondence from Donelle Humphrey-Franklin, Georgia Department of Public Health, Division of Medical and Clinical Services:** The Board considered this correspondence regarding the Georgia Department of Health's Opioid and Substance Abuse Misuse Response Program's request for a letter of support from the Georgia Board of Pharmacy concerning its application to the Bureau of Justice Assistance's Harold Rogers Prescription Drug Monitoring Program funding opportunity. Mr. Lacefield commented that a letter was drafted in response to the request. Mr. Stone made a motion to direct staff to send the letter on behalf of the Board supporting this request. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

**Correspondence from Ben Cowart, Georgia Retailers:** The Board considered this correspondence regarding suggested amendments to Rule 480-36-.07 Notification to Patients and Rule 480-36-.01 Definitions. Mr. Stone stated that he felt Mr. Cowart made some valid points and appreciated the input from the Georgia Retailers. He suggested the Board add this matter to its next scheduled workshop agenda.

Mr. Cowart was present and spoke to the Board regarding the request. He stated that the first suggestion was regarding Rule 480-36-.07 Notification to Patients. He explained that the Georgia Retailers felt that the new rule, which requires the signage notification to be posted in letters at least three (3) inches in size, is inconsistent with the existing rule dealing with central fill notification, which only requires the signage be "clearly visible to and readable by the public."

Mr. Cowart stated that the second suggestion was regarding Rule 480-36-.01 Definitions, which requires there only be one (1) secondary remote entry pharmacist to assist the primary dispensing pharmacist with remote prescription drug order processing per prescription. He explained that the Georgia Retailers felt that limiting a prescription to only one remote pharmacist and one dispensing pharmacist diminishes patient care and patient experience.

President Azzolin thanked Mr. Cowart and stated that the Board would take this matter into consideration.

**Correspondence from Lori Duke, Assistant Dean for Experience Programs, UGA College of Pharmacy:** The Board considered this correspondence regarding a continuing education requirement on emergency preparedness. President Azzolin commented that he was not personally familiar with what Ms. Duke was referring to. He inquired if this was a one-time requirement. Mr. Lacefield responded by stating that his understanding was that it was a one-time issue that was a requirement for that particular time. He stated that he was not aware of any current requirements for such.

Director Troughton stated that, in his research, he found that it was a one-time requirement for every pharmacist in 2010 that was not repeated. The Board directed staff to respond to Ms. Duke by stating that the Board does not have a continuing education requirement for emergency preparedness.

**Correspondence from Tracy Robertson, Boehringer Ingelheim Animal Health USA, Inc., PHWH004870 and PHWH004684:** The Board considered this correspondence requesting written

permission to export the following materials to customers outside the United States of America and its territories:

- FDA approved NADA 042-633 Tresaderm (thiabendazole, dexamethasone, neomycin sulfate solution) to countries that accept the U.S. approved product, such as Aruba, Bahamas, Barbados.

Mr. Cordle made a motion to approve the request. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

**Correspondence from Scott B. Smith, South Georgia Medical Center:** The Board discussed this correspondence regarding South Georgia Medical Center transitioning from a Hospital Authority Governed entity to a 501c3 incorporated entity and requesting to retain the same license numbers. President Azzolin explained that this change will cover several locations. He continued by stating that the Board is currently working on a rule relative to this topic and will be discussing it later in the meeting. He added that since the Board is able to modify the rule to impact maintaining license numbers, it seems the rule could be waived; however, they did not submit a rule waiver request.

Mr. Lacefield commented that the Board could choose to reissue the same license number as that is something that has been done previously by the Board in a situation like this where only the structure is changing and not ownership. He stated that they are also making a second request regarding their ambulatory surgery center. He explained that they would like to surrender the license of the ambulatory surgery center and bring that department under the central hospital pharmacy license for provision of oversight and management of medications. President Azzolin inquired if it had a different physical address. Director Troughton responded by stating that GDNA would need to conduct an inspection.

After further discussion, the Board directed staff to respond by stating that South Georgia Medical Center would need to submit a rule petition in order to retain the same license numbers. GDNA will conduct an inspection and report back to the Board regarding the request concerning the ambulatory surgery center.

#### **Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton**

Director Troughton introduced Special Agent Emily Lobeck to the Board.

Director Troughton reported that GDNA conducted 2952 inspections and received 489 complaints for FY2023.

Director Troughton reported that a vendor has been chosen for GDNA's database. He stated that old information will not be able to be incorporated into the new database as that costs more money to do so. He further stated that the database will allow GDNA to maintain better statistical information for the Board that they are unable to provide now. He explained that the database will be implemented in three (3) phases. He stated that the inspection portion will be implemented first, followed by the application portion, and then investigations. Director Troughton stated that he hopes to have everything in place by next July.

Mr. Bracewell inquired as to what will happen with the historical data. Director Troughton responded by stating that GDNA will have to maintain it and keep it. He explained that as far as criminal investigations, that information must be maintained for evidence. He continued by stating that, due to the opioid litigation, GDNA cannot destroy anything in any paper or electronic format, including cell phones. Director Troughton stated that GDNA will request more funds to incorporate the old data if it can.

#### **Attorney General's Report – Mr. Max Changus**

No report.

**Executive Director's Report – Mr. Eric Lacefield**

**Continuing Education Report:** No report for July.

**Application for Low THC Pharmacy Dispensary Specialty Permit/Application/Fees:** Mr. Lacefield discussed the Low-THC Pharmacy Dispensary Specialty Permit application. He stated that if the Board has reviewed the application staff had questions regarding changes that dispensaries will be able to make as it relates to ownership and location. Based on the law and rules, he inquired if staff are to interpret the ownership for the predicate pharmacy and the ownership for specialty low THC dispensary permit must be the same? President Azzolin responded by stating that since the license for the low THC permit is tied to the license of the predicate pharmacy, he does not see how it could not be the same.

Mr. Lacefield inquired if the low the dispensary specialty permit would only be allowed at the location of the predicate pharmacy. The Board responded affirmatively.

Mr. Lacefield stated that the application contains the additional information required by the rule. He further stated that the Board would need to determine the application and renewal fee. Mr. Cordle made a motion to set the application fee to \$300. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

Mr. Cordle made a motion to set the renewal fee to \$150. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

Mr. Farmer inquired about the location restrictions and local zoning. He stated that he was assuming Director Troughton does not want the impetus to be on the GDNA agents to determine the legality of those location boundaries. He continued by stating that that the two (2) items under number four (4) on the application come from the language in the law that states that no dispensing licensee may operate in any location within a 1,000 foot radius of schools, churches, daycares, etc. He stated that if he was reading that correctly, the applicant would be required to provide proof at the point of inspection of having a variance from the local zoning board if the location falls within the 1,000 foot radius of the locations mentioned. He inquired if the first item was stating that the pharmacist can supply a statement that the proposed location would comply with the location restrictions. Mr. Stone responded by stating that the applicant would be attesting that the location was in compliance with the law. He stated that the Board could take action against the licensee if they were not truthful. He added that he does not feel that GDNA should start measuring the boundaries.

Director Troughton explained that GDNA will not receive the application until the applicant provides either item (I) or (II). He stated that GDNA is the last part of the application process. He further stated that once the applicant has met all the requirements, the applicant would contact GDNA to schedule an inspection. He continued by stating that when GDNA inspects the facility, it will not look up local ordinances. Director Troughton stated that the agents will ask questions like they do as part of an inspection for a new facility and if the agents see anything that is not in compliance, it will be brought back to the Board for consideration. He added that part of the inspection would not be looking at churches, schools, daycares, etc.

Mr. Farmer inquired about application processing time. He stated that the application has language stating to allow for a minimum of sixty (60) business days for processing of the application. He inquired if that includes time for the inspection. Mr. Lacefield responded by stating that processing times fluctuate. He explained that typically the initial application review is done within 30-45 days, but if there is a deficiency, it is on the applicant to provide that information back to board staff. Mr. Lacefield continued by stating that once the application is complete, it will be forwarded to GDNA.

Director Troughton commented that when GDNA receives the application, they may see something and have to request additional information from the applicant and that is where the biggest hold up happens. He stated after that, it seems to run smoothly. He further stated that the inspection is based on when the applicant wants the facility to be inspected. He stated that from GDNA's side, the average time is 2-3 weeks once they receive the application.

Mr. Stone reminded the members of the public that the low THC rules have not been approved by the Governor's office and are not in effect currently. He stated that the Board is only approving the application at this time in order to be prepared. Mr. Lacefield commented that the application will not be posted on the Board's website until after the rules become effective.

Mr. Cordle commended Mr. Lacefield and board staff on how they process applications and all the work they do. He stated that 98% of the time when he receives an inquiry, it is the applicant that is holding the application up because Mr. Lacefield and his staff are good about processing applications in a timely manner. Mr. Brinson agreed.

Mr. Lacefield commented that the renewal cycle for technicians and facilities was just completed and that is the Board's largest population. He stated that between March 1<sup>st</sup> and June 30<sup>th</sup> there were over 35,000 transactions on the website and there were issues. He explained a new vendor for merchant services was obtained last year and this was the first big test. Mr. Lacefield continued by stating that when they were reconciling at the end of the month staff found some transactions that were not going through. He explained that the licensee made the renewal fee payment online but the information was not transmitted to the board office, and as a result the office was not aware of the renewal until they reconciled or by the licensee calling the board office inquiring about the renewal. He added that the renewals, for the most part, should be automatic. Mr. Lacefield explained that unless the licensee answered a question that requires him/her to submit additional information to the office, the renewal should be automatic after the system updates every hour. He stated that there were about 2% of those renewals staff were not aware they received until they reconciled. He further stated that staff contacted the licensee and most of those issues have now been resolved.

**NABP-MPJE Review Delegate:** Mr. Lacefield stated that the Board would need to determine a delegate. Deputy Director Karnbach stated that two (2) delegates are needed. After further discussion, the Board stated it would follow up with Mr. Lacefield.

**August Meeting:** Mr. Lacefield reminded the Board and the members of the public that the August meeting will be held at the Philadelphia College of Osteopathic Medicine (PCOM).

### **Legal Services – Mr. Clint Joiner**

**Rules with Amendments to Correct Spelling, Grammar, or Format:** Mr. Joiner stated that at the April meeting he mentioned several rules that required amendments to correct spelling, grammar, or format. He further stated that those corrections had been made and were available on Sharepoint for the Board to review. Mr. Stone made a motion to post Rule 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes, Rule 480-3-.03 Continuing Pharmacy Education, Rule 480-33-.01 Definitions, Rule 480-5-.04 Impaired Pharmacists, Interns and Externs, Rule 480-7-.05 Reverse Distributors, and Rule 480-7A-.03 Restriction on the Distribution of Listed Chemicals. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

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

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

- (a) However, pharmacies electronically sharing a real-time, online computerized database may transfer the prescription drug order information as many times as there are authorized refills, up to the maximum of five (5) times, if it is within six (6) months from the date of issuance.
- (2) A transfer is considered a communication between two licensed pharmacists and/or pharmacy interns/externs. Transfers are subject to the following requirements:
  - (a) The transferring pharmacist or pharmacy intern/extern shall record the following information in either real time or at the first opportunity after the transfer:
    - 1. The word "VOID" must be written on the face of the original, hard copy, invalidated prescription drug order;
    - 2. The following must be written on the back of the original, invalidated prescription drug order: the name, address, telephone number, and DEA number of the pharmacy to which it is transferred, and the name of the pharmacist receiving the prescription information; and
    - 3. The date of the transfer and the name of the pharmacist transferring the information must be recorded on the back of the prescription drug order.
  - (b) The pharmacist or pharmacy intern/extern receiving the transferred prescription drug order information shall reduce it to writing and record the following information:
    - 1. The word "TRANSFER" shall be written on the face of the transferred prescription drug order hard-copy;
    - 2. All information required to be recorded on a ~~prescription~~ prescription drug order pursuant to this chapter, which shall include:
      - (i) Date the prescription drug order was originally issued by the prescribing practitioner;
      - (ii) The number of refills authorized on the original prescription drug order.
  - (c) Date the prescription drug order was originally dispensed by the transferring pharmacy; (d) Number of valid refills remaining, and date(s) and pharmacy location(s) where any previous refills were dispensed;
  - (e) The pharmacy's name, address, telephone number, DEA number, and prescription serial number from which the prescription information was transferred; and
  - (f) The name of the pharmacist who transferred the prescription drug order.
- (3) The original and transferred prescription(s) must be maintained for a period of two ~~years from~~ years from the date of the last refill.
- (4) Pharmacies electronically transferring a prescription drug order for the purpose of refills must maintain the same information and record keeping requirements as do pharmacies with manual, non-electronic record keeping systems.

**Rule 480-3-.03. Continuing Pharmacy Education**

- (1) The Georgia State Board of Pharmacy has the statutory responsibility and authority for the requirement of continuing education as prerequisite for a license renewal.
- (2) The purpose of continuing education for pharmacists is to maintain and enhance the professional competency of pharmacists licensed to practice in Georgia for the protection of the health, safety and welfare of the people of the State of Georgia.
- (3) As a requirement for the biennial renewal of his/her license, a pharmacist must complete not less than thirty (30) hours of approved continuing education.
- (4) One hour of C.E. is defined as 0.1 C.E.U. Each pharmacist in the State of Georgia must obtain 30 hours of continuing education or 3.0 C.E.U.'s per biennium for license renewal.
  - (a) Certificates documenting that 30 hours of approved continuing education or 3.0 C.E.U.'s must be completed and dated within the biennium.
- (5) A pharmacist licensed before or during the first six (6) months of the biennium (January 1,

Year-One to June 30, Year-One), shall be required to obtain 30 hours of C.E. A pharmacist licensed during the following twelve (12) months (~~June July-1, Year-One~~ to ~~July~~ June 30, Year-Two) shall be required to obtain 15 hours of C.E. A pharmacist licensed during the last six (6) months of the biennium (July 1, Year-Two to December 31, Year-Two) shall be exempt from continuing education for that biennium only.

- (6) In the event of an audit and a pharmacist fails to submit certificates, which document his/her required continuing education credits, the Board will not process his/her request to renew the license until the continuing education requirements are provided to the Board.
  - (a) The pharmacist may not carry over continuing education credits from one licensing period to the next.
  - (b) Nothing is meant to prohibit representatives from the Georgia Drugs and Narcotics Agency (GDNA) from assisting, auditing, or verifying a pharmacist's continuing education certificates as needed.
  - (c) Each licensed pharmacist shall maintain these certificates of attendance at continuing education meetings for a period of two (2) years from the date of the preceding renewal period.
- (7) The staff of the Georgia Board of Pharmacy may audit, or otherwise select randomly, the continuing education of a percentage of licensees as determined by the Board.
- (8) The Board may accept continuing education approved by other Boards of Pharmacy where such continuing education meets the requirements established by the Board.
- (9) Approval of providers and sponsors shall be as follows:
  - (a) All providers and sponsors of continuing education must be approved by the Board.
  - (b) American Council on Pharmaceutical Education (A.C.P.E.) approved providers shall submit documentation to the Board of such approval every two (2) years and have blanket approval.
  - (c) All other providers shall request approval of programs as a provider on the program approval form each time a program is presented. Nothing in these rules ~~are~~ is meant to prohibit the Board and/or GDNA from establishing a program or programs which can be granted special program approval(s) by the Board, and which may be utilized on more than one occasion or whenever such program or programs are presented by the Board or GDNA during a biennium.
- (10) The following criteria for quality shall be used for the approval of providers:
  - (a) There shall be an administrative authority charged with the responsibility of maintaining the criteria for quality in continuing education programming for each provider.
  - (b) The administration shall be stable and an established procedure shall exist that ~~insures~~ ensures an orderly transfer of responsibilities in the event there is a change in administration.
  - (c) Providers shall present a program or activity based on the needs of the target audience or the timeliness of the topic.
  - (d) Program objectives and rationale shall be stated.
  - (e) Providers shall give adequate, advanced promotional information, material about target audience, goals and objectives, program content, faculty credentials and fees.
  - (f) Each approved provider of continuing education in the State of Georgia shall provide a means of registration of the participants at each program and a record of attendance shall be maintained for a period of five (5) years. The provider shall also furnish to each participant, adequate documentation of his successful completion of the program.
  - (g) There shall be a method of program evaluation established and a statement of the evaluation process planned shall accompany each application. (The Board may supply sample forms.)
- (11) Providers shall furnish each participant with adequate documentation of this or her participation in the program. Information shall include:
  - (a) Name and license number in each state of participant;
  - (b) Name of provider;

- (c) Name of program;
  - (d) Hours/C.E.U. completed;
  - (e) Date of completion;
  - (f) Authorized signature.
- (12) The provider shall develop policies and procedures for the management of grievances. (This does not have to be submitted to the Board.)
- (13) The facility shall be appropriate and adequately equipped to support the delivery of the program.
- (14) Approval of programs shall be as follows:
- (a) Acceptable forms of continuing education shall be as follows:
    - 1. Institutes, seminars;
    - 2. Lectures, conferences, workshops;
    - 3. Correspondence and electronically delivered courses that are A.C.P.E. approved.
  - (b) The following are not acceptable as continuing education programs: welcoming remarks, business sessions, unstructured demonstrations, degree programs, or medical continuing education programs which are not A.C.P.E. or Georgia Board approved.
- (15) All continuing education providers seeking approval of the continuing education program by the Georgia Board shall submit a program approval form for each program presented. These forms should be submitted sixty (60) days in advance. The Board may exempt programs from this advance time requirement period as set forth by Board policy.

**Rule 480-33-.01. Definitions**

- (1) Outpatient Clinic. An outpatient clinic shall be defined as a health care facility or location, other than a medical practitioner's office, providing outpatient treatment or ~~ease~~ care such as, but not limited to, an outpatient surgery center, outpatient urgent care center, infusion treatment center, or ambulatory care center.
- (2) ~~(b)~~ Outpatient Clinic Pharmacy. An outpatient clinic pharmacy shall be defined as that part of an outpatient clinic health care facility engaged in the practice of pharmacy.
- (3) Outpatient Clinic Pharmacy License. An outpatient clinic pharmacy license shall be defined as a pharmacy license issued by the Georgia State Board of Pharmacy to Clinic pharmacies, pursuant to the provisions of O.C.G.A. Title 26, Chapter 4, whereas the licensee shall be subject to special outpatient clinic pharmacy regulations as set forth herein, but exempt from other certain regulations and requirements.
- (4) Outpatient. An outpatient shall be defined as an ambulatory patient who comes to an outpatient clinic to receive health care services related to the objectives of the outpatient clinic and departs within 24 hours.
- (5) Standard Ward Inventory. The pharmacist-in-charge of the outpatient clinic pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of drugs to be kept at one or more locations at all times within the outpatient clinic and such stocks of drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the pharmacist-in-charge or his/her pharmacist designee.
- (6) Outpatient Prescription. An outpatient prescription shall be defined as a prescription drug order prescribed by a medical practitioner engaged in the practice of that clinic and prescribed for services received in that clinic in conjunction with health care services related to the objectives of that clinic.

**Rule 480-5-.04. ~~Impaired~~ Impaired 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.

#### **Rule 480-7-.05. Reverse Distributors**

- (1) Every firm, whether located inside or outside the State of Georgia, which receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant located in the State of Georgia which holds a permit or license to dispense or possess drugs, shall be known as a Reverse Distributor or a Reverse Drug Distributor.
- (2) In order for any Reverse Distributor, wherever located, to engage in the business of receiving drugs for destruction, return credit, or other disposal from a registrant located in Georgia, it must be licensed as a Reverse Distributor by the Georgia State Board of Pharmacy ("Board").
- (3) The minimum information required by the Board in order to register a Reverse Distributor will be the same as required under Rule 480-7-.03(2).
- (4) The minimum requirements for applications for registration as a Reverse Distributor with the Board will be the same as required under Rule 480-7-.03(3).
- (5) Personnel: The licensed Reverse Distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the process of receiving drugs for destruction, credit return, or other means of disposal. Each such person shall have a working knowledge of the requirements ~~for~~ of the law and rules for handling such drugs.
- (6) Violations:
  - (a) A license issued to a Reverse Distributor pursuant to this part may be subject to revocation or suspension upon conviction of the license holder or an employee of a reverse distributor for violations related to federal, state or local laws and/or rules.
  - (b) Violation of any provisions of any applicable Board Rules shall be grounds for the suspension, revocation, or other sanctions of the permit issued hereunder.
  - (c) Any action taken on a license pursuant to this part shall be carried out pursuant to the Georgia Administrative Procedure Act, O.C.G.A. Title 50, Chapter 13.
- (7) Minimum requirements for the storage and handling of prescription drugs and or the establishment and maintenance of prescription drug distribution records by Reverse Distributors. A Reverse Distributor shall follow the same requirements as listed under Board Rule 480-7-.03(7), except as follows:
  - (a) A Reverse Distributor does not have to maintain a separate quarantine area for storing drugs which are outdated, damaged, etc., as noted under Rule 480-7-.03;
  - (b) A Reverse Distributor does not have to maintain drugs under controlled temperature and humidity as required under Rule 480-7-.03;
  - (c) A Reverse Distributor does not have to ensure the condition of drugs that are received or shipped as required under Rule 480-7-.03(7)(d) or (e);
  - (d) Prior to a Reverse Distributor removing drugs from a registrant, the Reverse Distributor must generate paperwork, a copy of which must be provided to and maintained by the registrant and a copy ~~to be~~ maintained by the Reverse Distributor, both for two (2) years, which at minimum records the following:
    1. The date and time that the drugs left or were taken from the registrant;
    2. A complete inventory of the drugs being transferred to the Reverse Distributor;
    3. The name, Board permit number, address, and telephone number of the Reverse Distributor removing the drugs;
    4. The name and signature of the responsible person representing the Reverse Distributor physically removing the drugs;

5. The name and signature of the pharmacist representing a pharmacy or responsible person representing another type of registrant transferring the drugs to the Reverse Distributor and the name and principal address of the pharmacy or other registrant from which the drugs are removed; and
  6. Any and all other information required under Ga. Comp. R. & Reg. c. 480-50 and applicable federal law and regulation.
- (e) Upon a Reverse Distributor's receipt of drugs from a registrant by contract or common carrier, the Reverse Distributor must generate paperwork, a copy of which must be maintained by the Reverse Distributor for two (2) years, which at minimum records the following:
1. The date and time that the drugs were received by the Reverse Distributor;
  2. A complete inventory of the drugs received by the Reverse Distributor;
  3. The name and signature of the pharmacist representing a pharmacy or responsible person representing another type of registrant sending the drugs to the Reverse Distributor and the name and principal address of the pharmacy or other registrant from which the drugs are sent; and
  4. Any and all other information required under Ga. Comp. R. & Reg. c. 480-50 and applicable federal law and regulation.

### **Rule 480-7A-.03. Restriction on the Distribution of Listed Chemicals**

Chemicals listed in ~~480-71-.02~~ Rule 480-7A-.02 may only be distributed to retail outlets by a listed chemical drug wholesale distributor licensed by the Board, or a wholesale distributor licensed by the Board. In order for any person or firm to conduct an act of brokerage for any dangerous drug, controlled substance, or listed chemical which is received by retail outlet or pharmacy in this state, regardless of where the shipment originates, such person or firm is required to be licensed as a wholesale distributor or a listed chemical wholesale distributor. Any manufacturer which distributes a drug to any wholesale distributor or listed chemical wholesale distributor located in the State of Georgia must have been issued the appropriate wholesale distributor permit from the Board. Having been issued a manufacturing pharmacy permit by the Board does not authorize a manufacturing firm to distribute drugs to any firm located in this state.

**Rules with Board and/or GDNA Address Amendment:** Mr. Joiner discussed the rules that required updating due to the board office and GDNA changing addresses. Discussion was held regarding whether or not an address needed to be listed in the rules. Mr. Changus commented that the rules establish what the official address of the Board is.

Mr. Stone made a motion to post Rule 480-1-.01 Organization of the Board, Rule 480-19-.04 Record Keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products Containing Pseudoephedrine, Rule 480-38-.04 Communications, Rule 480-40-.04 Witness Lists and Respondent Statements, Rule 480-6-.01 Pharmacy Licenses, Rule 480-6-.02 Nonresident Pharmacy Permit, and Rule 480-7A-.06 Records and Recordkeeping; Reporting Requirements. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

### **Rule 480-1-.01. Organization of the Board**

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 the Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334 ~~Peachtree Street, S.W., 6th Floor, Atlanta, Georgia 30303.~~

**Rule 480-19-.04. Record Keeping for Over-the-Counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products Containing Pseudoephedrine**

- (1) A record created this rule must be maintained in the pharmacy at which the transaction occurred, except that records may be kept either at a single, central location for the pharmacy or by a third party information technology company on behalf of the pharmacy only if the pharmacy has notified the GDNA of its intention to do so and received GDNA approval.
  - (a) Written notification must be submitted by registered or certified mail, return receipt requested, to the Director, Georgia Drugs and Narcotics Agency, ~~40 Pryor Street, SW, Suite 2000, Atlanta, Georgia 30303~~254 Washington Street SW, Suite G2000, Atlanta, GA 30334.
  - (b) This notification must include telephone and address contact information as well as a telephone number and email address for a point of contact person who is responsible for providing requested record for either the pharmacy's central record keeping location or any third party information technology company.
  - (c) The Director of the Georgia Drugs and Narcotics Agency shall issue written approval of any central record keeping location or third party information technology company prior to records being maintained in such a manner.
- (2) The records required to be kept under this rule must be readily retrievable and available for inspection and copying by GDNA or other law enforcement officers as requested as provided for under the provisions of 21 U.S.C. 880, and the U.S. Combat Methamphetamine Epidemic Act of 2005.
  - (a) A record developed and maintained to comply with federal law may be used to meet the requirements of this rule if the record includes the information specified by this rule.
  - (b) Readily retrievable shall mean records must be produced by the pharmacy or the pharmacy's third party information technology company in less than 6 hours for all electronically maintained records or 24 hours for any handwritten records.
- (3) If a pharmacy fails to produce records or to produce records in the required time, is such failure shall be considered a violation of O.C.G.A. ~~Sections §§~~ 16-13-37, 16-13-39, and 16-13-42.

**Rule 480-38-.04. Communications**

All communications, including correspondence, motions, and pleadings, shall be filed with the Executive Director, Board of Pharmacy, 2 Martin Luther King, Jr., Drive SE, East Tower, 11<sup>th</sup> Floor, Atlanta, GA 30334~~2 Peachtree Street, 6<sup>th</sup> 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.

**Rule 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, 6<sup>th</sup> Floor, Atlanta, GA 30303~~2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. 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, 6th Floor, Atlanta, GA 30303~~ 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. 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 *feri 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.

#### **Rule 480-6-.01. Pharmacy Licenses**

- (1) Application for license:
  - (a) Applications must be filed with the Georgia State Board of Pharmacy located at the Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11<sup>th</sup> Floor, Atlanta, GA 30334~~2 Peachtree Street, 6<sup>th</sup> 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 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) No license issued under this Rule shall be transferred or assigned by a licensee. However, the Board may reassign a license to a licensee or successor entity by request upon application to the Board. Licenses shall not be transferable. Licenses become null and void upon the sale, or change of mode of operation of the business.
- (4) Prior to any change in name, ownership, mode of operation or location of a pharmacy, licensees shall apply for approval of such change by submitting a Board-approved application to the Board and paying a fee. To comply with the requirements of this Rule, applications must be made and approved prior to the change.
- (a) A change of ownership is deemed to have occurred upon the closure of any transaction which results in a change to any of the ownership information submitted to the Board as part of the licensee's initial application for licensure or renewal of licensure.
- (3)(5) Licensees shall notify the Board in writing of the occurrence of any change to any of the information submitted to the Board as part of the licensee's initial application for licensure or application for renewal of licensure. This shall not apply to any event the occurrence of which these rules require immediate notification to the Board, in which event such immediate notification shall be made.
- (4)(6) 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 renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

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

- (1) Effective 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 Martin Luther King, Jr. Drive SE, East Tower, 11<sup>th</sup> Floor, Atlanta, GA 30334~~2 Peachtree Street, NW, 6<sup>th</sup> 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 in compliance with all laws and investigations from each regulatory or licensing agency in which the applicant holds a license; and
  12. If dispensing sterile or nonsterile compounding for practitioners to use in patient care in the practitioner's office, a copy of the most recent inspection report 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) No license issued under this Rule shall be transferred or assigned by a licensee. However, the Board may reassign a license to a licensee or successor entity by request upon application to the Board.~~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) Prior to any change in name, ownership, mode of operation or location of a pharmacy, licensees shall apply for approval of such change by submitting a Board-approved application to the Board and paying a fee. To comply with the requirements of this Rule, applications must be made and approved prior to the change.
- (a) A change of ownership is deemed to have occurred upon the closure of any transaction which results in a change to any of the ownership information submitted to the Board as part of the licensee's initial application for licensure or renewal of licensure.
- ~~(6)~~(8) Licensees shall notify the Board in writing of the occurrence of any change to any of the information submitted to the Board as part of the licensee's initial application for licensure or application for renewal of licensure. This shall not apply to any event the occurrence of which these rules require immediate notification to the Board, in which event such immediate notification shall be made.
- ~~(7)~~(9) 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 reinstatement shall be required.

Reinstatement is at the sole discretion of the Board.

- ~~(8)~~(10) 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)~~(11) 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)~~(12) 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)~~(13) 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)~~(14) Nonresident pharmacy permit holders shall comply with the laws and rules and regulations of the state where such pharmacies are located.
- ~~(13)~~(15) Nonresident pharmacy permit holders who compound drugs must comply with the federal compounding laws as required in Board Chapter 480-11.
- ~~(14)~~(16) 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)~~(17) 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)~~(18) 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)~~(19) Nonresident pharmacy permit holders shall cooperate with the Board in any investigation involving prescription drugs distributed by such permit holder into this state or related to the permit 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)~~(20) Notices to nonresident pharmacy permit holders shall be made on the agent of record with the Board. If notices are returned as undeliverable or unclaimed, service shall be made on the Executive Director, and any disciplinary proceedings shall proceed, or if a final decision, the decision shall become effective.

~~(19)~~(21) 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)~~(22) A nonresident pharmacy permit may be revoked or suspended or otherwise disciplined for any reason that a permit may be denied, for failure to comply with this rule, for disciplinary action by other states and federal agencies, for conduct causing bodily or psychological injuries to a resident of this state, and for failure to comply with Board laws and other applicable rules as provided herein.

~~(21)~~(23) If a nonresident pharmacy holder has an affiliate as defined by O.C.G.A. § 26-4-119, it shall annually file a disclosure statement identifying all such affiliates no later than June 30 every year.

#### **Rule 480-7A-.06. Records and Recordkeeping; Reporting Requirements**

(1) Listed chemical wholesale distributors and other wholesale distributors shall, at a minimum, maintain records regarding the distribution of listed chemicals as follows:

(a) Produce and maintain, for a minimum of three years from the date of the transaction, inventories and records of all transactions regarding the receipt, sale, credit, transfer, disposition, and distribution of all listed chemicals to any firm, person, or retail outlet located in this State. Inventories and records shall be made available for inspection and photocopying by any authorized agent of any State or federal agency for a period of three (3) years following their creation date.

(b) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any State and federal governmental agency charged with enforcement of these rules.

(c) Maintain an ~~up-to-date~~up-to-date list of firms, persons or retail outlets with whom they do business in regards to listed chemicals.

(2) Listed chemical wholesale distributors and other wholesale distributors shall, at a minimum, maintain and provide documents and reports regarding the distribution of listed chemicals as follows:

(a) Supply a copy of their Board issued permit to any firm, person, or retail outlet in this state which has received, purchased, or gained access to any product containing a listed chemical.

(b) Supply each firm, person, or retail outlet with a copy of all records involving sales, credits, transfers or the like whenever such transaction involves a product containing a listed chemical.

(c) Report to GDNA of shortages or losses of listed chemicals within seven (7) business days.

(d) Within seven days, notify the GDNA of any purchases of a product containing a listed chemical from the listed chemical wholesale distributor which the wholesaler judges to be excessive, or have knowledge or suspicion of said purchases being used in the unlawful manufacture of a controlled substance or file with the GDNA any reportable transaction. A reportable transaction should be sent to the attention of the Director of the GDNA. Such reports should be sent to GDNA located at 40



~~Pryor Street, SW Suite 2000 in Atlanta, Georgia 30303~~254 Washington Street SW, Suite G2000, Atlanta, GA 30334.

- (e) Upon verbal or written request from the GDNA, the GBI, or the sheriff of a county or the police chief of a municipality located in this state, submit reports to account for the transactions of any listed chemicals with persons or firms located within this state; such transactions shall include all sales, distribution, or transactions dealing with products containing a listed chemical; All such records shall be submitted by the distributor within two working days.
- (3) Any and all retail outlets or persons receiving a listed chemical product from a licensed listed chemical wholesale distributor, licensed by this State, are required to maintain records of all such transactions for a minimum of three years, and upon request, by law enforcement officials, are required to provide such records for review within five business days, with failure to provide such records accounting for the presence of such products shall result in the embargo or seizure of such products.
- (4) Changes in any information required on the initial application shall be submitted to the Board no less than 30 days prior to such change.

**Rules with ‘Null and Void’ Language Change:** Mr. Joiner noted that at its June meeting, the Board reviewed and approved the proposed language that was inserted into the applicable rules.

Director Troughton discussed his concerns with the proposed language in Rule 480-6-.01(3), which reads as follows:

(3) No license issued under this Rule shall be transferred or assigned by a licensee. However, the Board may reassign a license to a licensee or successor entity by request upon application to the Board.

Director Troughton stated that everything that is brought to the Board for the Cognizant’s Report contains historical information on the facility or licensee, if there is any. He further stated that those histories are found and reviewed based on a license number. He added that he understood the concept that the license number is not the license, but when GDNA investigates and researches the history, the license number relates to a certain owner. Director Troughton explained that he knows there are exceptions, which are rare, but those go back to different staffing with the Attorney General’s office or GDNA. He stated that there could be issues with that history. He added that it would not be an issue now for first six (6) months to year, but later on down the line it could be a concern. He continued by stating that if there is a history with that license number, GDNA will need to go back to verify who the owner was. He stated that any public order on the Board’s website is attached to a license number. Director Troughton stated that for facility name changes or a change in location, it makes sense. He explained that it is different for a change of ownership. He stated that there are public orders on the website and inquired as to what happens to those orders if there is a new owner of that facility. He further stated that is including the history of another owner. Director Troughton explained that he thought there could be issues with putting that history on the new owner.

Director Troughton discussed another concern he had regarding whether or not the DEA would be okay with the issuance of a DEA number based on the identical Georgia license number with new owner. He stated that he felt this needed to be explored further because the number is associated with a certain license owned by certain people. He explained that he understood wanting to make sure the flow of the business is not disrupted, but he believes, from an investigative standpoint, there is a potential for issues to arise in the future with recycling a license number.

President Azzolin inquired if the Board ever allowed a license number to be recycled with a change of ownership. Director Troughton responded affirmatively. President Azzolin commented that the “null and void” language is fairly new. He stated that, at one time, it was not in the rule and people could recycle the license number with a change of ownership.

Mr. Stone commented that he understood the argument, but the key phrase in the draft rule is “may reassign”. He stated that he purchased a pharmacy in 1998 and wanted a new number because of the history associated with that license number. He continued by stating that in 2001 he purchased another pharmacy and kept the license number because he knew the history. Mr. Stone stated that with the 2001 purchase, there was a pharmacist that had a complaint. Mr. Stone explained that he kept the license number because he felt he could argue that he was not part of the issue and he could say that pharmacist no longer worked there. He stated that he felt it was up to the person purchasing the pharmacy and choosing to keep that same license number or not.

President Azzolin stated that the Cognizant Report is presented with case numbers. He further stated that in the investigation process, agents are familiar with who they are investigating and those involve personal interactions with those pharmacists and owners. He continued by stating that he would assume an owner who has bought a pharmacy, if a previous investigation was involved, the person would bring up that he/she was not involved. Director Troughton responded by stating that not everyone is truthful and GDNA would have to go back and verify the history.

When reviewing the history for the cases, Director Troughton inquired if the Board wanted to know when the ownership changed. He asked if GDNA needed to inform the Board and note that it is part of the history for the specific license number, but not the owner. He added that it would be more work for the agents. President Azzolin responded by stating that he did not feel it was necessary every time and it would be at GDNA’s discretion. He stated that, if it is relevant, the Board would defer to GDNA as to whether or not look up the history. He further stated that once the information is presented to the Board, and if the Board saw a reason to ask if there was a history, the problem could be addressed then. He added that he does not feel it has to be done on every case and thinks there is ample opportunity for the Board to discern on a case by case basis if it is relevant.

Mr. Cordle commented that if the licensee was issued a consent order, the owner has a chance to say that occurred prior to the change of ownership. Director Troughton stated that GDNA will provide the Board with the history every time. He added that he does not decide what is relevant or what should not be included in the history. He stated that GDNA will provide the Board with information on when the change of ownership occurred and at what point these are not part of the history and it will be up to the Board to decide what to do with that information.

Mr. Cordle stated that he does not feel like this could create an extra step for GDNA in the investigation. He further stated that if anything comes up and it is relevant, GDNA would notify the board anyway. He inquired if this would cause conflict with the DEA. Director Troughton commented that if the DEA does not issue a number for a reason, the pharmacist trying to get a new license will call GDNA or the board office. After further discussion, President Azzolin requested Mr. Cordle contact the DEA and report back to the Board.

President Azzolin commented that, as times have changed, this has become a bigger and bigger issue. He stated that for businesses that take care of patients in multiple states, he sees it as a patient care issue if the business has to stop servicing those patients due to a change of ownership. He stated that it could take months to get the license. He added that he likes having the phrase “may reassign” in the draft and feels it should be up to the applicant as to whether or not keep the same license number. He suggested including an option on the application asking if the applicant would like to retain the same license number or request a new license number. He continued by stating it would still come to the Board for verification, and if the Board saw an issue, it could intervene. President Azzolin stated that he believes the pathway needs to be there for patient safety.

Mr. Farmer asked if the same license number was retained due to a change of ownership, would there be capability of removing a license number's history. Director Troughton responded by stating that GDNA will not remove any information. Mr. Lacefield commented that if there is a public consent order for a license number, that information is on the Board's website. He added that if there is a new owner and they keep the same license number, he did not know if he could legally remove the public order.

Mr. Lacefield stated that in regard to the word "may", administratively he can do whatever the Board would like; however, it would be easier for staff and less of a delay in the process if all ownership change license numbers were reassigned or all ownership changes received new numbers. He explained that staff have to enter the application a certain way in order to keep same license number. Mr. Lacefield stated that the application is entered differently if the license number is changing. President Azzolin suggested including a checkbox on the application. Mr. Lacefield responded by stating that would then make it the applicant's decision and not the Board's. He stated that the application is entered a specific way in the system if the applicant wants to keep the same license number. However, if the Board decides months later that the applicant cannot keep the same number, staff will have to go back in the system, remove the fee, and re-enter the application a different way so the number will change. Mr. Lacefield stated that he would do what the Board requested, but it does increase staff's workload and create delays if those changes have to be made.

President Azzolin stated that he does not perceive receiving a high volume of applications where the Board states the facility cannot keep the same license number. He inquired if there could be a different application if there were to be an issue. Mr. Lacefield responded by stating that the applicant can request the same license number, but it is ultimately the Board's decision as to whether or not that can happen, and that will not occur until later in the application process. President Azzolin responded by stating that this was a data entry/logistics issue. Mr. Lacefield commented that staff will do as the Board directs it to, but it will not make the application process any faster.

Mr. Cordle commented that this would mitigate all rule waiver requests that have to be processed if the Board changed the rule.

Mr. Brinson stated that if there is a change of ownership and the applicant wants to keep same license number, they are assuming responsibility for what has occurred in the past. He further stated that any history associated with that license number should be reported to the Board.

Mr. Changus commented that the proposed language in Rule 480-6-.01(3) reads in part, "...the Board may reassign a license to a licensee...". He stated that the statute states that licenses shall not be transferable or assignable. He stated that he interprets that to say that the person holding the license cannot transfer or assign it to someone else. He further stated that with a new application, a license number is not being reassigned. He added that the Board may reissue a license number. Mr. Changus continued by stating that the language in the rule states, "No license issued under this Rule shall be transferred or assigned by a licensee" was acceptable; however, the term "may" is adding a question of arbitrary decision making the Board may not want. He stated that the applicant can ask to retain that license number or they cannot.

President Azzolin suggested the Board make the default to be the license number is reassigned, but allow for an applicant to request a new license number if they chose to. Mr. Changus responded by stating that it goes back to the discussion regarding past consent orders. He used the example of someone buying an independent pharmacy and changing the name. He stated that he would think if that pharmacy had a disciplinary history tied to it, the new owner would want a clean slate. Mr. Changus further stated that he does not think the default should be that they would want to keep that same license number. He added that this is in response to concerns President Azzolin mentioned regarding the impact of business operations

when you go out of state. He stated that the Board is taking on some complexity to address the business concerns.

President Azzolin stated that the Board has done it in the past and that he believes it is a possibility. He further stated that the potential severity of issues of not being able to keep the same license number outweigh the complexities. Mr. Stone suggested if the applicant wants to keep the same license number, then a rule petition must be submitted. President Azzolin agreed and suggested leaving the language as is or add language that implies if the applicant desires to maintain the current license number a rule petition will have to be submitted. Mr. Changus responded by stating that he thinks it would prevent it from being an automatic issue that affected everything; however, the Board would be getting into the same position it was trying to get away from regarding rule petitions. He stated that the question would be what is the unique hardship that says the Board should reissue this number. He further stated that it would not be considered a hardship issue as keeping it the same would be for legitimate business reasons.

Director Troughton commented that, from GDNA's standpoint and as a previous owner, he has never seen anyone getting a new license number stop them from filling prescriptions. He stated that GDNA has not received a complaint regarding such. Mr. Stone responded by stating that he had to drop insurance plans and patients could not come see him. He added that the issue was that patients had to go somewhere else and care was delayed. Director Troughton responded by stating that it is not a big problem in terms of any complaints being received regarding having to obtain a new license number. Mr. Stone stated that he could not determine how long the process would take, but it ended up being longer than anticipated.

President Azzolin stated that there are many avenues for practices of pharmacies and that is just from a retail perspective where you see how it impacted a board member. He added that there are so many other methods of pharmacy that can negatively impact patient care as a result of a license number change. He continued by stating that it is frustrating that a number change could impact patient care and there should be an avenue for this type of situation.

Mr. Farmer agreed with President Azzolin. Director Troughton responded by stating that it would be more work, but GDNA will do what the Board directs them to do. President Azzolin suggested the Board voting to post the impacted rules and if the Board felt it needed to change the rules it can come back and do so at a later time. He stated that the Board would value the public's comments on the subject and thinks the Board needs to hear from those that are impacted by this. Mr. Changus commented that with the rules process, if the Board votes to post, the rules will come to the Attorney General's office to be reviewed for statutory authority. He stated that he will think about the issues brought up today and see if there are any additional hurdles that need to be discussed.

After further discussion, Mr. Stone made a motion to table discussion on Rule 480-10-.06 Licensure, Applications, and Display of License and Renewal Certificate, Rule 480-13-.02 Licensure and Registration, Rule 480-18-.02 Licensure and Registration, Rule 480-33-.02 Licensure and Registration, Rule 480-52-.07 Licensure, Applications, and Display of License and Renewal Certificate, Rule 480-6-.01 Pharmacy Licenses, Rule 480-6-.02 Nonresident Pharmacy Permit, Rule 480-7-.01 Manufacturer's Permit, Rule 480-7-.03 Drug Wholesale Distribution Licensing Requirements, Rule 480-7-.04 Researcher's Permit, Rule 480-7A-.04 Requirements for Licensure as a Listed Chemical Wholesale Distributor, and Rule 480-8-.02 Registration until the Board's August meeting. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

**Rule 480-34-.16 Naloxone Hydrochloride Nasal Spray:** Mr. Joiner explained that this proposed rule amendment removes naloxone hydrochloride nasal spray from the dangerous drug list. Mr. Stone made a motion to post Rule 480-34-.16 Naloxone Hydrochloride Nasal Spray. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

**Rule 480-34-.16. Naloxone Hydrochloride Nasal Spray**

- (1) This rule was adopted to protect the health, safety, and welfare of the public. Four mg naloxone hydrochloride nasal spray, is hereby deleted from the dangerous drug list as referenced in the Official Code of Georgia Annotated (O.C.G.A.) §§ 16-13-71(b)(635) and 16-13-71(c)(14.25).
- (2) This rule is based on the following findings of the Board:
- (a) that Narcan, 4mg naloxone hydrochloride nasal spray, does not have a high potential for abuse;
  - (b) that the Board has considered the scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; the potential of the drug to produce psychic or physiological dependence liability; and
  - (c) that the drug, when in nasal spray form of 4 mg per spray has been approved for non- prescription status by the Federal Food and Drug Administration.

**Rule 480-15-.02 Registration of Pharmacy Technicians and Continuing Education Requirements:**

President Azzolin stated that section (2)(a) of this rule states that in order to be registered as a pharmacy technician in Georgia, an applicant shall “Submit an application to the Board on the form prescribed by the Board.” He further stated that nowhere else in section (2) does it indicate currently that the application has to be approved for the technician to be able to practice.

Mr. Stone referred President Azzolin to section (5), which states in part, “A registration, once issued, is renewable biennially...”. President Azzolin commented that section (5) is speaking to renewability. He stated that there is an implication there that is not clearly spelled out from his perspective. He stated that what the Board has always seemed to adhere to is strict application of the law and rules. He added that, based on the number of cases the Board has where the pharmacist states that an application was submitted and the technician had been working but had not received the registration yet, could be due to the way the rule is currently written. President Azzolin stated that it could be in part due to it being allowed when the pharmacy technician registration process was required in 2011. He noted that the continuing education requirements have been added to the proposed draft.

Mr. Stone made a motion to post Rule 480-15-.02 Registration of Pharmacy Technicians and Continuing Education Requirements. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

**Rule 480-15-.02. Registration of Pharmacy Technicians and Continuing Education Requirements**

- (1) Effective August 1, 2011, a pharmacy may only employ registered pharmacy technicians to perform pharmacy technician duties.
- (2) In order to be registered as a Pharmacy Technician in this State, an applicant shall:
- (a) Submit an application to the Board on the form prescribed by the Board;
    - 1. Mere submission of an application to the Board is not registration pursuant to this Rule.
    - 1-2.No applicant shall be deemed registered until such time as his/her application has been completely processed by the Board’s administrative office, to include receipt and processing of any applicable fees, and a registration number has issued to the applicant;
  - (b) Attest that applicant is at least 17 years old;
  - (c) Attest that applicant is currently enrolled in high school, or has a high school diploma, or has a GED, or has a postsecondary education or college degree;
  - (d) Consent to, provide the necessary information to conduct, and pay for a background check to be conducted by the Board, its agent or a firm or firms approved by the Board, which background check will include a criminal history, driver license history and other information as the Board deems necessary, and will authorize the Board and the Georgia Drugs and Narcotics Agency to receive the results;
  - (e) Submit the name and address of employer and place of employment;
  - (f) Pay application fees; and

- (g) If certified, submit evidence of training supporting designation as certified.
- (3) The Board may deny registration or conditionally grant registration for any of the reasons set forth in Code sections 26-4-60 or 43-1-19. This includes convictions, pleas of nolo contendere and guilty pleas related to misdemeanor crimes of moral turpitude or marijuana and to felonies. In addition, no pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.
- (4) The denial of an application for registration as a pharmacy technician shall not be a contested case and the applicant shall not be entitled to a hearing under the Georgia Administrative Procedures Action, O.C.G.A. T. 50, Ch. 13, but such applicant may be entitled to an appearance before the Board.
- (5) A registration, once issued, is renewable biennially, upon payment of a fee. Registrations shall expire on June 30th of each odd-numbered year. If the application for renewal is not made and the fee paid before September 1st of the odd-numbered year, the registration shall lapse and shall not be renewed. An application for a new registration shall be required.
- (6) On and after July 1, 2023, as a requirement for the biennial renewal of his/her registration, a pharmacy technician must complete not less than twenty (20) hours of approved continuing education.
- (a) "Approved continuing education" means courses approved by the Board as described in Rule 480-3-.03.
- (b) One hour of C.E. is defined as 0.1 C.E.U. Each pharmacy technician in the State of Georgia must obtain 20 hours of continuing education or 2.0 C.E.U.'s per biennium for registration renewal.
1. Certificates documenting 20 hours of approved continuing education or 2.0 C.E.U.'s must be completed and date within the biennium.
- (c) C.E. requirements ~~D~~uring the technician's first biennial registration cycle;:
1. A pharmacy technician registered during the first six (6) months of the biennium (~~January~~ July 1, Year-One to June ~~December 31, Year-One~~), shall be required to obtain 20 hours of C.E.
  2. A pharmacy technician registered during the following twelve (12) months (~~July~~ January 1, Year-Two to June ~~December 31, Year-Two~~), shall be required to obtain 10 hours of C.E.
  3. A pharmacy technician registered during the last six (6) months (~~July~~ January 1, Year-Three to December ~~June 30, Year-Three~~) of the biennium, shall be exempt from continuing education for that biennium only.
- (d) In the event of an audit and a pharmacy technician fails to submit certificates, which document his/her required continuing education credits, the Board will not process his/her request to renew the registration until the continuing education requirements are provided to the Board.
1. The pharmacy technician may not carry over continuing education credits from one registration period to the next.
  2. Nothing is meant to prohibit representatives from the Georgia Drugs and Narcotics Agency (GDNA) from checking, auditing, or verifying a pharmacy technician's continuing education certificates as needed.
  3. Each registered pharmacy technician shall maintain these certificates of attendance at continuing education meetings for a period of two (2) years from the date of the preceding renewal period.
- (e) The staff of the Georgia Board of Pharmacy may audit, or otherwise select randomly, the continuing education of a percentage of registrants as determined by the Board.
- (7) A registrant has a responsibility to update the Board with a change of home address and employment address within ten (10) days of such change.

**Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel:** Mr. Joiner provided the Board with an overview of the proposed changes. He explained that there were changes to how the way the technician to pharmacist ratio is worked out when there are remote technicians involved. He stated that the remote technicians are not counted towards the ratio and certified remote technicians do not count towards the number of certified technicians for having a third or fourth technician onsite.

President Azzolin stated that the intention of reviewing this rule is not for the Board to vote to post this month. He further stated that it will be brought back to the August meeting since there were several board members that could not be physically present for today's discussion.

Director Troughton commented that, from an enforcement standpoint, the pharmacy has to be able to identify each person for each step of the filling the prescription and the information needs to be readily available to GDNA. He stated that what GDNA will get through that prescription record is an initial. He added that GDNA needs to be able to trace that initial to the remote technician. President Azzolin responded by stating that is applicable to all technicians, not just remote technicians. He stated that this is being done over electronic means. He further stated that there should be a way to tie it in for all technicians involved in the processing of the prescription and that information should be readily retrievable. Director Troughton stated that GDNA should be able to walk in and the pharmacy should be able to produce that information at any moment without having to request it from corporate. President Azzolin stated that the onsite pharmacy needs to have the level of access to know who those people are in real time. Director Troughton agreed. He stated that the pharmacist is doing the final verification and GDNA would want to know that information as well. President Azzolin stated that he thinks that complements 480-36 relative to remote drug order processing and sees no issues with that.

Mr. Cordle inquired if that was covered in the proposed language that states:

3. When electronic systems are intended to establish direct supervision of pharmacy technicians:

i) it shall be the responsibility of the pharmacy licensee to ensure that any such system utilized in the pharmacy is capable of compliance with all state and federal laws and rules governing the practice of pharmacy, and that such system is maintained in a compliance-capable state;

Director Troughton responded by stating that there are chain stores that have their own IT departments, whereas smaller chains or stores may not have that and may contract with someone to do remote entry. He stated it would be helpful if the language could be clarified to state what needs to be readily available upon inspection.

President Azzolin stated that Rule 480-36-.05(4) states, "These records maintained by the primary dispensing pharmacy shall be readily retrievable for at least two years through the primary dispensing pharmacy, and shall be available for inspection by the Board or its representative." He further stated that because that rule also authorizes the use of technicians, where allowed, in certain states it seems it may be covered there. He added that in retail, it is relative to remote drug order processing. President Azzolin continued by stating that is the only time it will be applicable; otherwise it would not have to be a technician. He stated that if someone was being utilized to order products for in front of the store, for example, a technician would not be needed for that. He continued by stating that if you are going to utilize a remote technician, the purpose would be for remote drug order processing and the applicability would be under Rule 480-36-.05(2) which states, "In addition to any other required records, the primary dispensing pharmacy shall maintain retrievable records which show, for each prescription remotely processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function."

President Azzolin added that section (4) of Rule 480-36-.05 states, "These records maintained by the primary dispensing pharmacy shall be readily retrievable for at least two years through the primary dispensing pharmacy, and shall be available for inspection by the Board or its representative."

Director Troughton stated that the simpler the rule is, the better. He added that if the Board was satisfied it was covered, that was sufficient for him. Mr. Stone inquired if the language could be referenced in Rule 480-15-.03. President Azzolin suggested adding language to state that when using remote technicians remotely, the rules in 480-36 have to be followed.

Mr. Lacefield commented that President Azzolin keeps referring back to 480-36, but he did not think 480-36 allowed Georgia pharmacies to use remote technicians. President Azzolin responded by stating that it does in Rule 480-36-.03(1), which states, “The primary dispensing pharmacy shall have a licensed pharmacist on site during business hours and his/her duties shall include the verification of the validity of all prescriptions. Such pharmacist shall be responsible for obtaining and recording all information needed. This shall include but not be limited to the following patient information: biographical information, medication history, drug allergies, and other information as required. Pharmacy technicians and pharmacy interns/externs may assist a pharmacist located at the primary dispensing pharmacy with remote prescription drug order processing. Such pharmacies shall comply with Georgia laws and rules set forth pertaining to ratios and the supervision of pharmacy technicians and pharmacy interns/externs.”

President Azzolin stated that right now Georgia technicians cannot because of Rule 480-15-.03. He further stated that the pharmacy can if the technician is working in another state, and that state allows such, and they can use them in the application of 480-36. He added that the way Chapter 480-36 was structured will allow for it once technicians are allowed to work remotely. Mr. Lacefield stated that currently Chapter 480-36 is a rule. He inquired if a Georgia pharmacy can have a technician working remotely. President Azzolin responded by stating that it can if that technician is located outside the state of Georgia and that state allows for such. Mr. Lacefield stated that he was asking if a technician is allowed to work remotely here in Georgia. President Azzolin responded by stating that the technician cannot in Georgia. He stated the reason the technician cannot do it in Georgia now is because of 480-15. Mr. Lacefield stated that he would prefer not to have 480-15 refer back to 480-36. He added that he would rather state it in 480-15 since this rule is the section that is allowing this new function.

Mr. Farmer discussed Rule 480-15-.03(7), which states in part, “...then only those pharmacy technicians physically present within the licensed pharmacy shall be subject to the pharmacist to pharmacy technician ratio specified in paragraph (6).” He stated that with regard to patient safety and patient care, he would like feedback from Board about that specific area. Mr. Stone responded by stating that the pharmacist does the final verification and everything comes back to a dispensing pharmacy in Georgia. He stated that if this was approved and the technician was working outside a pharmacy remotely, the prescription will go to a pharmacist that is verifying these orders. He added that this is trying to alleviate working conditions and workflow. Mr. Stone stated that during the pandemic, errors decreased and there were not as many distractions. He added that it can help with patient safety and improving patient care.

Mr. Farmer stated that he was interested in hearing from those in different practice settings. He stated that his question pertained to the fact that the technician ratio does not apply to those remotely versus those physically present.

Mr. Cordle commented that this is a business model used in other channels of pharmacy and based on the misfill reports the Board sees, it must be much safer because there are not the same level of misfills with that. He added that the Board is trying to make the retail rules equitable to the other areas of pharmacy that are already using this model successfully.

President Azzolin commented that one is distracted when more people are coming at you from different angles whereas when a person is sitting in a quiet room without those distractions, they are going to tend to be more accurate with their work. However, the other side of this is that no matter which technician is doing the data entry, they cannot do anything that involves clinical judgement.

Mr. Changus stated that what Mr. Farmer raised was interesting in terms of where the authority for the exception is. He further stated that the technician, as originally conceived, is in the pharmacy assisting the pharmacist. He added that the language in statute does not differentiate between in the pharmacy and



remote. He inquired as to how many offsite technicians can be supervised and not be included in the ratio and are they really being supervised. Mr. Changus stated that there is the understanding that pharmacy technicians need to be supervised in their activities. He continued by stating that he can see how it would be beneficial in the pharmacy to not be distracted by other people getting things right, submitting it, and the pharmacist checks it. He added that the question is whether or not this is what was anticipated by the statute in terms of actively supervising those technicians engaging in whatever pharmacy function since the data entry is still a pharmacy function.

President Azzolin stated that the Board does not have the ability to discern the statutory authority outside of the gray area. He further stated that in reality, the pharmacist is only supervising the data the remote pharmacy technician entered as there is nothing else to supervise. He added that the pharmacist has the responsibility of evaluating everything that technician does. President Azzolin stated that the remote pharmacy technician is not in the pharmacy so they cannot divert from the pharmacy and the supervision is complete at this point. He continued by stating that he believes this already occurs and the technician is not licensed. He stated that it occurs by physician's office staff who put in a prescription drug order or call in the prescription. He further stated that is office staff relaying prescription information to a pharmacist, which is equivalent to a remote technician function relative to transcription or data processing.

Mr. Lacefield stated that the law specifically talks about how many people can be supervised by a pharmacist and it is written down and is specific. He further stated that if the Board is not going to say anything about the number of remote technicians that can be supervised, that will be a call to the Board office. He added that it sounds like it is a business decision. President Azzolin responded by stating that it is how the rule is drafted. Mr. Lacefield stated the language regarding supervision of remote technicians using electronic means could be more specific.

President Azzolin stated that the Board welcomes more discussion at its August meeting relative to this rule. He further stated that if the Board votes to post the rule, it will be a big topic and will receive a lot of feedback from the public. Director Troughton commented that Mr. Lacefield's office will receive calls about it and GDNA will be asked questions when the agents are face to face with them. He stated that if the rule is adopted and approved as is, GDNA would not ask how many technicians the pharmacy has working remotely because it would not matter. He added that GDNA would not ask how the remote technician is being supervised electronically. After further discussion, Mr. Stone made a motion to table Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel until its August meeting. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

In regards to the rules that the Board voted to post, which were Rule 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes, Rule 480-3-.03 Continuing Pharmacy Education, Rule 480-33-.01 Definitions, Rule 480-5-.04 Impaired Pharmacists, Interns and Externs, Rule 480-7-.05 Reverse Distributors, and Rule 480-7A-.03 Restriction on the Distribution of Listed Chemicals, Rule 480-34-.16 Naloxone Hydrochloride Nasal Spray, Rule 480-15-.02 Registration of Pharmacy Technicians and Continuing Education Requirements, Mr. Stone made a motion, and Mr. Cordle seconded, that the formulation and adoption of the proposed rule amendments does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

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

**Correspondence from Anas Damiri, Curant Health:** Mr. Joiner discussed this correspondence regarding allowing for remote/hybrid technician order entry under the current rules. The Board directed Mr. Joiner to respond by stating that it would be allowed under Chapter 480-36, but prohibited under the Board's current rule, 480-15.

**Correspondence from Dawn Sasine:** Mr. Joiner discussed this correspondence requesting the Board to consider a revision to allow for the partial filling of schedule II drugs. Mr. Joiner stated that this question was presented to the Board at the GPhA convention. President Azzolin commented that there was discussion as to whether or not the Board could change a rule that would allow for partial filling of schedule II drugs based on the way the current law is written. He stated that the reasoning behind it is due to current the opioid abuse situations. He discussed the concept behind the request. Mr. Joiner commented that the rule directly comes from 21 CFR 1306.13 concerning the partial filling of prescriptions. He explained that if the Board changed its rule, operating under the federal regulation would still be required.

Director Troughton discussed the Comprehensive Addiction and Recovery Act, which discusses the partial filling of prescriptions for schedule II drugs under certain conditions. He requested additional time to consult with the DEA and review the matter further.

Ms. Sasine was present and spoke to the Board. She stated that the Comprehensive Addiction and Recovery Act of 2016 amended the federal law and they do allow for partial filling of schedule II's. She further stated that she feels she can make an impact on the community if permitted to partial fill schedule II's by reducing the amount of unused medication and thereby reducing the potential for addiction, overdose and diversion. There being no further discussion, the Board directed GDNA to research the matter and report back to the Board at its August meeting.

Mr. Stone made a motion and Mr. Cordle seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h) and § 43-1-2(h) to deliberate and to receive information on applications, investigative reports, and the Assistant Attorney General's report. Voting in favor of the motion were those present who included Michael Azzolin, Jim Bracewell, Michael Brinson, Young Chang, Cecil Cordle, Michael Farmer, and Dean Stone.

### **Executive Session**

#### **Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton**

- GDNA Case #A34768

#### **Cognizant's Report – Mr. Dennis Troughton**

- GDNA Case # A34793
- GDNA Case # B34765
- GDNA Case # A34777
- GDNA Case # A34778
- GDNA Case # A34767
- GDNA Case # B34783
- GDNA Case # SB34690
- GDNA Case # SB34505
- GDNA Case # SB34488

#### **Attorney General's Report – Mr. Max Changus**

Mr. Changus presented the following consent orders for acceptance:

- U.N.S.

- N.M.
- J.W.I.S.
- W.
- L.W.R.
- T.H.M.
- J.M.E.

Mr. Changus discussed the following cases:

- C.E.E.S.
- U.T.G.

The Board received legal advice regarding Board Rules 480-10A-.05 Transmission and Labeling, 480-27-.04 Use of Facsimile Machine to Transmit or Receive Prescription Drug Order, and 480-35-.04 Requirements for a Protocol.

**Executive Director’s Report – Mr. Eric Lacefield**

- J.B.
- L.A.

**Legal Services – Mr. Clint Joiner**

- P.P.J.C.
- R.P.
- W.P.
- G.P.
- M.P.
- L.P.P.

**Applications**

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

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

- O.M.H.L.
- M.I.
- A.M.I.
- M.A.I.
- A.L.
- A.M.S.
- B.I.A.H.U.S.A.
- B.I.A.H.U.S.A.
- B.I.A.H.U.S.A.
- C.M.P.C.
- K.N.I.
- K.N.I.
- K.N.I.
- K.N.I.
- C.B.
- M.C.
- M.I.H.
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- M.I.
- M.I.
- M.S.I.
- N.D.C.
- P.D.S.I.
- P.
- P.S.I.
- S.M.M.P.P.
- T.A.P.
- T.H.C.P.
- T.D.P.
- A.S.S.S.
- A.S.S.S.
- A.S.S.S.
- A.B.D.C.
- A.B.S.C.
- O.S.
- A.H.G.
- A.P.
- A.S.P.N.P.
- B.S.S.P.
- C.F.S.P.
- E.P.I.
- E.P.I.
- E.P.I.



- C.P.
- C.P.
- C.P.
- C.P.
- C.P.
- W.P.
- S.P.
- P.R.P.
- N.

**Correspondences/Requests**

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

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

**Open Session**

Mr. Stone made a motion for the Board to take the following actions:

**Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton**

- GDNA Case #A34768                      Table pending receipt of additional information

**Cognizant’s Report – Mr. Dennis Troughton**

- GDNA Case # A34793                      Refer to the Department of Law



- GDNA Case # B34765 Misfill Guidance #1A
- GDNA Case # A34777 Refer to the Department of Law
- GDNA Case # A34778 Refer to the Department of Law
- GDNA Case # A34767 Refer to the Department of Law
- GDNA Case # B34783 Close with no action
- GDNA Case # SB34690 Table pending receipt of additional information
- GDNA Case # SB34505 Table pending receipt of additional information
- GDNA Case # SB34488 Table pending receipt of additional information

**Attorney General’s Report – Mr. Max Changus**

Mr. Changus presented the following consent orders for acceptance:

- U.N.S. Private Consent Order accepted
- N.M. Private Consent Order accepted
- J.W.I.S. Private Consent Order accepted
- W. Private Consent Order accepted
- L.W.R. Public Consent Order accepted
- T.H.M. Ratified acceptance of Public Consent Order
- J.M.E. Ratified acceptance of Public Consent Order

Mr. Changus discussed the following cases:

- C.E.E.S. Close with no action
- U.T.G. Close with no action and flag file

The Board received legal advice regarding Board Rules 480-10A-.05 Transmission and Labeling, 480-27-.04 Use of Facsimile Machine to Transmit or Receive Prescription Drug Order, and 480-35-.04 Requirements for a Protocol.

**Executive Director’s Report – Mr. Eric Lacefield**

- J.B. Correspondence
  
- L.A. Correspondence

Board directed staff to respond by stating that the Board of Pharmacy intends to comply with all laws and rules regarding the regulation of dangerous drugs in Georgia. Additionally, if the individual would like to submit a complaint, he/she may do so via the Board’s website. Board directed staff to respond by stating that the Board of Pharmacy intends to comply with all laws and rules regarding the regulation of dangerous drugs in Georgia. Additionally, if the individual would like to submit a complaint, he/she may do so via the Board’s website.

**Legal Services – Mr. Clint Joiner**

- P.P.J.C. Open records request Approved request
- R.P. Open records request Approved request

- W.P. Open records request Approved request
- G.P. Open records request Approved request
- M.P. Open records request Approved request
- L.P.P. Open records request Approved request

### Applications

- S.K.C. Pharmacy Technician Approved for registration
- S.G.D. Pharmacy Technician Approved for registration
- S.J. Pharmacy Technician Approved for registration
- T.N.G. Pharmacy Technician Approved for renewal
- M.H.W. Pharmacy Technician Approved for renewal
- C.X.W. Pharmacy Technician Approved for renewal and flag file
  
- B.A.S. Pharmacy Technician Approved for renewal and flag file
  
- L.C.T. Pharmacy Technician Approved for renewal
- J.F.A. Pharmacy Technician Approved for renewal
- C.R.W. Pharmacy Technician Approved for renewal
- A.K.T. Pharmacy Technician Table pending receipt of additional information
  
- L.U.B. Pharmacy Technician Approved for renewal
- K.H.H. Pharmacy Technician Approved for renewal
- N.N.H. Pharmacy Technician Approved for renewal
- J.M.S. Pharmacy Technician Approved for renewal
- S.A.C. Pharmacy Technician Approved for renewal
- C.E.K. Pharmacy Technician Approved for renewal
- W.L.H. Pharmacy Technician Approved for renewal
- L.H.H. Pharmacy Technician Approved for renewal
- A.R.D. Pharmacy Technician Approved for renewal
- R.J.B. Pharmacy Technician Approved for renewal
- J.B. Pharmacy Technician Approved for renewal
- A.L.S. Pharmacy Technician Approved for renewal
- M.N.H.C. Pharmacy Technician Table pending receipt of additional information
  
- D.R.T. Pharmacy Technician Approved for renewal
- M.D.F.R. Pharmacy Technician Approved for renewal
- D.O.O. Pharmacy Technician Table pending receipt of additional information
  
- C.B.S. Pharmacist Examination Approved application
- E.J.E. Pharmacist Examination Approved application
- M.W.D. Pharmacist Reinstatement Denied application
- N.L.A. Pharmacist Reinstatement Approved application
- K.L.N. Pharmacist Reciprocity Approved application
- J.O.S. Pharmacist Reinstatement Approved application
- A.R.G. Pharmacist Certification of DTM Table pending receipt of additional information
  
- D.B.W. Pharmacist Certification of DTM Approved application
- K.A.O. Pharmacist Certification of DTM Approved application





• M.C.	Wholesaler Pharmacy	Approved for renewal
• M.I.H.	Wholesaler Pharmacy	Approved for renewal
• M.I.	Wholesaler Pharmacy	Approved for renewal
• M.I.	Wholesaler Pharmacy	Approved for renewal
• M.I.	Wholesaler Pharmacy	Approved for renewal
• M.I.	Wholesaler Pharmacy	Approved for renewal
• M.I.	Wholesaler Pharmacy	Approved for renewal
• M.I.	Wholesaler Pharmacy	Approved for renewal
• M.I.	Wholesaler Pharmacy	Approved for renewal
• M.I.	Wholesaler Pharmacy	Approved for renewal
• M.S.I.	Wholesaler Pharmacy	Approved for renewal
• N.D.C.	Wholesaler Pharmacy	Approved for renewal
• P.D.S.I.	Wholesaler Pharmacy	Approved for renewal
• P.	Wholesaler Pharmacy	Approved for renewal
• P.S.I.	Wholesaler Pharmacy	Approved for renewal
• S.M.M.P.P.	Wholesaler Pharmacy	Approved for renewal
• T.A.P.	Wholesaler Pharmacy	Approved for renewal
• T.H.C.P.	Wholesaler Pharmacy	Approved for renewal
• T.D.P.	Wholesaler Pharmacy	Approved for renewal
• A.S.S.S.	Wholesaler Pharmacy	Approved for renewal
• A.S.S.S.	Wholesaler Pharmacy	Approved for renewal
• A.S.S.S.	Wholesaler Pharmacy	Approved for renewal
• A.B.D.C.	Wholesaler Pharmacy	Approved for renewal
• A.B.S.C.	Wholesaler Pharmacy	Approved for renewal
• O.S.	Wholesaler Pharmacy	Approved for renewal
• A.H.G.	Non-Resident Pharmacy	Approved for renewal
• A.P.	Non-Resident Pharmacy	Approved for renewal
• A.S.P.N.P.	Non-Resident Pharmacy	Approved for renewal
• B.S.S.P.	Non-Resident Pharmacy	Approved for renewal
• C.F.S.P.	Non-Resident Pharmacy	Approved for renewal
• E.P.I.	Non-Resident Pharmacy	Approved for renewal
• E.P.I.	Non-Resident Pharmacy	Approved for renewal
• E.P.I.	Non-Resident Pharmacy	Approved for renewal
• R.C.M.	Non-Resident Pharmacy	Approved for renewal
• C.C.S.I.S.	Non-Resident Pharmacy	Approved for renewal
• C.C.	Non-Resident Pharmacy	Approved for renewal
• C.P.	Non-Resident Pharmacy	Approved for renewal
• C.S.	Non-Resident Pharmacy	Approved for renewal
• C.S.	Non-Resident Pharmacy	Approved for renewal
• E.P.	Non-Resident Pharmacy	Approved for renewal
• E.P.	Non-Resident Pharmacy	Approved for renewal
• E.P.	Non-Resident Pharmacy	Approved for renewal
• E.P.	Non-Resident Pharmacy	Approved for renewal
• E.S.P.	Non-Resident Pharmacy	Approved for renewal
• E.M.P.I.	Non-Resident Pharmacy	Approved for renewal
• H.H.	Non-Resident Pharmacy	Approved for renewal
• I.R.	Non-Resident Pharmacy	Approved for renewal
• I.R.S.C.V.S.S.	Non-Resident Pharmacy	Approved for renewal

• S.H.P.	Non-Resident Pharmacy	Approved for renewal
• P.P.	Non-Resident Pharmacy	Approved for renewal
• R.P.C.C.C.	Non-Resident Pharmacy	Approved for renewal
• O.P.	Non-Resident Pharmacy	Approved for renewal
• O.I.S.	Non-Resident Pharmacy	Approved for renewal
• P.H.I.	Non-Resident Pharmacy	Approved for renewal
• R.P.	Non-Resident Pharmacy	Approved for renewal
• R.R.	Non-Resident Pharmacy	Approved for renewal
• R.E.P.	Non-Resident Pharmacy	Approved for renewal
• S.P.	Non-Resident Pharmacy	Approved for renewal
• S.V.P.	Non-Resident Pharmacy	Approved for renewal
• T.A.P.	Non-Resident Pharmacy	Approved for renewal
• T.	Non-Resident Pharmacy	Approved for renewal
• Z.H.	Non-Resident Pharmacy	Approved for renewal
• W.P.N.	Non-Resident Pharmacy	Approved for renewal
• W.P.N.	Non-Resident Pharmacy	Approved for renewal
• A.C.S.	Non-Resident Pharmacy	Approved for renewal
• A.C.S.	Non-Resident Pharmacy	Approved for renewal
• P.P.S.	Non-Resident Pharmacy	Approved for renewal
• C.	Non-Resident Pharmacy	Approved for renewal
• K.K.	Manufacturing Pharmacy	Approved for renewal
• S.P.	Manufacturing Pharmacy	Approved for renewal
• A.H.G.I.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• C.P.	Retail Pharmacy	Approved for renewal
• W.P.	Retail Pharmacy	Approved for renewal
• S.P.	Retail Pharmacy	Approved for renewal
• P.R.P.	PBM-Retail Pharmacy	Approved for renewal
• N.	Reverse Distributor Pharmacy	Approved for renewal

**Correspondences/Requests**

• B.	Notice of Discipline	No action
• H.V.	Notice of Discipline	No action
• L.S.L.	Notice of Discipline	No action
• L.S.L.	Notice of Discipline	No action

• L.S.L.	Notice of Discipline	No action
• M.D.I.	Notice of Discipline	No action
• I.W.P.	Notice of Discipline	No action
• C.N.A.	Notice of Discipline	No action
• C.N.A.	Notice of Discipline	No action
• C.N.A.	Notice of Discipline	No action
• C.N.A.	Notice of Discipline	No action
• C.N.A.	Notice of Discipline	No action
• C.N.A.	Notice of Discipline	No action
• C.N.A.	Notice of Discipline	No action
• J.H.	Appearance request	Approved request
• N.D.S.	Appearance request	Approved request
• T.S.Q.	Request to lift PIC restriction	Approved request
• C.P.L.	Request for extension of intern license	Approved request through 07/31/2025
• S.F.R.	Request for extension of intern license	Approved request through 07/31/2024
• K.O.	Request for extension of application date	Approved request through 10/30/2023
• H.R.E.	Request for 4 <sup>th</sup> attempt to retake NAPLEX	Approved request
• M.M.W.	Request for 4 <sup>th</sup> attempt to retake MPJE	Approved request
• E.J.C.H.	Remote order entry	Approved request
• E.U.H.M.	Remote order entry	Approved request
• S.J.H.A.	Remote order entry	Approved request
• A.B.W.C.	Request for waiver of renewal fee	Approved request

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

There being no further business to discuss, the meeting was adjourned at 2:18 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, August 16, 2023, at 9:00 a.m. at the Philadelphia College of Osteopathic Medicine, 625 Old Peachtree Rd, NW, Suwanee, GA 30024.

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