GEORGIA BOARD OF PHARMACY
Philadelphia College of Osteopathic Medicine (PCOM)
625 Old Peachtree Rd, NW
Suwanee, GA 30024
August 16, 2023
9:00 a.m.

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

Staff present:
Eric Lacefield, Executive Director
Dennis Troughton, Director, GDNA
Rick White, Special Agent, GDNA
Max Changus, Senior Assistant Attorney General
Clint Joiner, Attorney
Brandi Howell, Business Support Analyst I

Visitors:
Perry Walden, GMCC
Lisa Harris, Trulieve
Christi Heys, Emory
Helen Sloat, Kaiser/HOG/PCOM/ScionHealth
Mary Kate Snead, Guardian Pharmacy
Amit Jain, Publix
Brandon Brooks, Publix
Travis J. Clark, CAPS Atlanta
Michelle Blalock, Cardinal Health
Faizan A. Mirza, Walmart
Becca Hallum, GHA
Amanda Roberson, Eldercare Pharmacy
Jennifer Duckett, Walgreens
Nabil Elkareh, Genoa
Susan Delmonico, Genoa
Anthony Gurreri, Genoa

Open Session

President Azzolin established that a quorum was present and called the meeting to order at 9:20 a.m.

Approval of Minutes

Mr. Brinson made a motion to approve the Public and Executive Session Pharmacy Board minutes from the July 19, 2023, meeting as amended. 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. Cordle seconded, and the Board voted unanimously in favor of the motion. Mr. Brinson commented on the number of licenses that are issued every month and commended staff for a job well done.

Petitions for Rule Waiver or Variance

Rule Variance Petitions from SGMC Lanier Campus, PHH007948, SGMC Lanier Campus, PHRE010059, Smith Northview Hospital, PHH007797, South GA Medical Center Pharmacy, PHH004025, and South Georgia Medical Berrien Campus, PHH007935: The Board considered each petition, which requested a variance of Rule 480-6-.01(3). Discussion was held by President Azzolin who commented that each petitioner demonstrated a substantial hardship in that patient care issues, such as delay of care, would occur as well as there being financial issues associated with a change of ownership. Mr. Brinson made a motion to grant each petition. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

Correspondences

Correspondence from Lori Duke, University of Georgia: The Board discussed this correspondence requesting clarification on whether there is a Board expectation for colleges of pharmacy to offer emergency preparedness in their curriculum. The Board directed staff to respond by stating the Board does not have a requirement regarding such and that it is up to the school whether or not include it in their curriculum.

Correspondence from Lisa Barrett: The Board discussed this correspondence regarding the status of Ms. Barrett's technician registration as being "Revoked". In her correspondence, Ms. Barrett requested information on what she could do to change the status. The Board directed staff to respond by stating that the information on the Board's website is considered public and by law, it cannot be removed or altered.

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

Director Troughton introduced Special Agent Rick White to the Board. Special Agent White covers the Gwinnett/Rockdale county areas.

Director Troughton reported that GDNA conducted 291 inspections and received 55 complaints for FY2024.

Director Troughton informed the Board that the two (2) low THC production companies will be meeting with GDNA to discuss packaging and go over what GDNA will see upon inspections in the pharmacies. Director Troughton stated that GDNA needs to know what they will inspect, how to review the records and how to retrieve them.

Attorney General's Report – Mr. Max Changus

No report.

Executive Director's Report – Mr. Eric Lacefield

Continuing Education Report: Mr. Stone made a motion to ratify the below continuing education programs approved since the previous meeting. Mr. Bracewell seconded. Discussion was held by Mr. Bracewell regarding the course, "Utilizing Social Media as an Education Resource for Learners". He inquired if the Board was stating this course was equivalent to an ACPE credit. Vice-President Page responded by stating that the Cognizant member reviews the course itself and who is administering the course. He added that the Cognizant does not go back and review the content. Mr. Bracewell commented that it is difficult to obtain ACPE accreditation and many organizations have courses that do not meet ACPE standards so the course is submitted to the Board for consideration. He stated that he felt it was circumventing the education requirement. Vice-President Page commented that the course dealt with utilizing that communication means to reach the participants. Mr. Stone stated it is a different era now. He explained that apps are being used to teach and educate professionals about diabetes, meal plans, etc., for example. President Azzolin commented that he believed the spirit behind the course is how to educate

pharmacists on how to utilize those tools. There being no further discussion, the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
3/30/2023 - Ongoing	3	Georgia Poison Center	Poison Prevention Education	2023-0005
08/08/23	1	Kaiser Permanente	Utilizing Social Media as an Education Resource for Learners	2023-0006
08/14/23	0.5	The Medical Center - Navicent Health	Sodium-Glucose Cotransport - 2 Inhibitors	2023-0007
09/06/23	0.5	The Medical Center - Navicent Health	Von Willebrand Disease	2023-0008
07/10/23	6	Peregrine WORx	Comprehensive Cannabis Education Course	2023-0009

NABP/MPJE Review Delegate: Mr. Stone made a motion to appoint Mr. Chang as the NABP/MPJE review delegate. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Legal Services – Mr. Clint Joiner

No report.

Miscellaneous

Demo Low THC Product Packaging: Mr. Joiner commented that he and Mr. Lacefield recently met with Ms. Jansen Head, General Counsel for the Georgia Access to Medical Cannabis Commission ("Commission"), to review demos of some of the products. Mr. Joiner stated that pictures of what the products would look like are available on Sharepoint for the members to review.

Mr. Stone stated that the law provides information on what the labeling requirements are. For clarification, he stated that since it is in law, pharmacies cannot change anything that they are required to put on the label. Mr. Joiner affirmed that was correct. Mr. Stone stated that since the Board does not have enforcement over the growers, this is what the Board had to build its rules around. Mr. Lacefield responded by stating that the pictures show the packaging, and the label will go on the package. Mr. Joiner stated that the Board's labeling requirements are set forth in the rules. Mr. Lacefield stated that if the Board would like any of the producers to make a presentation, he would be happy coordinate a meeting with the Board for a presentation.

Mr. Chang inquired if there was a requirement for child safety packaging or locks. Mr. Stone responded by stating that there would be no way enforce them to do something they are required to do by law. He added that the pharmacist cannot open the packaging. He stated that when the pharmacy receives the product, that is the way the pharmacy will have to dispense it. Mr. Joiner commented that the packaging he saw was child resistant.

The Board discussed labeling requirements. President Azzolin inquired if the label identifies what pharmacy it was dispensed from with all the typical labeling requirements of a pharmacy. Mr. Joiner responded by stating that the requirements will be listed in what will be Chapter 480-52. Mr. Stone commented that the Low THC Committee created the rules based on what the Commission laid out. He stated that it would be helpful to have a presentation before the Board.

Mr. Brinson inquired if the pharmacist was permitted to put the product in a bag and then put the pharmacy label on top. Mr. Stone responded by stating that the label has to be affixed to the product. President Azzolin suggested letting Director Troughton meet with them first and then report back to the Board as to

the functionality of it, how it will be used, and then schedule a presentation before the Board. Mr. Joiner stated that he and Mr. Lacefield would be attending the meeting at the GDNA office. He further stated that if the Board would like a presentation, he or Mr. Lacefield could let them know.

Rules with 'Null and Void' Language Change: President Azzolin noted that at its June meeting, the Board reviewed and approved the proposed language that was inserted into the applicable rules. He stated that Mr. Joiner revised the rules to include that language and presented the drafts to the Board at its July meeting. After much discussion, the Board voted to table the rules and further discuss them at the August meeting. He inquired if there were any questions or discussion. In regards to the rule petitions that were granted earlier in the meeting, Vice-President Page inquired as to how they will understand that history that follows the license number. Mr. Stone stated that the Board did previously discuss the concern regarding the history of the license. He explained that if there is a history and he was purchasing a pharmacy and did not know the history, he could present evidence reflecting when the purchase of the pharmacy occurred and state that any issues that happened prior to that time were under different ownership, for example. He added that he believes the pharmacist would have the opportunity to present his/her case.

President Azzolin suggested adding this topic to the newsletter. Vice-President Page inquired if there was another method of communicating that to the pharmacist other than the newsletter. The Board suggested adding language to the application.

Mr. Farmer inquired if the existing owner could reach out to GDNA and request a history of the license. Director Troughton responded by stating that investigations are confidential and cannot be discussed with anyone; however, any public orders would be available on the Board's website.

Mr. Lacefield stated that the language in the proposed drafts states "may reassign". He inquired if the word "may" should remain. President Azzolin recommended adding language to the application asking if the individual would like to be reissued the same license number upon completion of the application and acceptance by the Board. He stated that if the individual checks 'yes', then Board may reissue the license number at its discretion. He further stated that if the Board sees a reason not to reissue the license, it can deny the request. He added that if the applicant does not check the box, by default the license number does not get reissued and a new number would be issued.

Mr. Joiner noted that this will increase the number of applications the Board has to review. He explained that any application that requests the same license number would have to be considered by the Board as the application cannot be administratively approved by staff. President Azzolin responded by stating that it is the Board's job to do so. He added that the Board's job is to protect, promote and preserve the public's safety and welfare. Mr. Joiner responded by stating that he wanted the Board to be aware that there would be an administrative impact on the board. After further discussion, the Board directed staff to draft language to add to the application and present it to the Board for consideration.

Discussion was held regarding the history of a license still being available for the Board to consider when a case is presented. Director Troughton stated that every time GDNA presents a case, it will provide the history to the Board. He inquired if the Board also wanted GDNA to explain when the ownership changed. President Azzolin responded by stating that it would not be necessary unless when the Cognizant reviews the report and there is a recommendation made on that license holder that relates to the history. Mr. Farmer commented that it is on the impetus of those involved, owner or pharmacist-in-charge, for example, as to when the ownership change occurred. Director Troughton stated that GDNA will provide all the information to the Board.

Mr. Changus stated that if there was a pharmacy that had a history of misfills, the ownership changed, but the personnel remained the same and with the history of refills for the same pharmacy, having that

information would be beneficial to the Board. Director Troughton commented that it would be easier administratively if GDNA did not have to identify when ownership changed.

President Azzolin stated that if the Cognizant recommended taking action on a pharmacy based on the fact that there were historical things that occurred, it would be at the discretion of GDNA and the Cognizant to see if there was an ownership change. Director Troughton inquired if the Board wanted GDNA to identify when the ownership changed on a routine basis because that would take additional time administratively. President Azzolin responded by stating the Board did not want GDNA to identify that information on a routine basis. Mr. Farmer discussed the impetus being on the individual, not on GDNA, to provide a statement reflecting they were not involved at that time.

Mr. Joiner inquired as to what would happen if there were an ownership change with a pharmacy that is on probation. President Azzolin responded by stating that it would be up to the pharmacist who was buying the store. He added that the pharmacist may have reason to say they are willing to accept that probationary status because they need that license, or they may say they do not want the same license number.

Mr. Cordle made a motion to post 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 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. Mr. Farmer seconded, and the Board voted unanimously in favor of the motion.

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

(1) Licensure and Applications

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

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

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

1. Submission of an application with the following information:
   (i) The name, full business address, and telephone number of the licensee;
   (ii) All trade or business names used by the licensee;
   (iii)Address, telephone number, and the name of the Pharmacist in Charge;
   (iv)The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship);
   (v) The name(s) of the owner and/or operator of the licensee, including:
      (I) If a person, the name of the person;
      (II) If a partnership, the name of the partnership and the name of each partner;
      (III) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; or
      (IV) If a corporation, the corporate name, the name and title of each corporate officer and director, the state of incorporation; and the name of the parent company, if any.
   (vi)Where operations are conducted at more than one location by a single retail pharmacy, each such location shall be licensed by the Board.
2. Payment of an application fee. Application fees shall not be refundable.

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

(d) 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.

(e) 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.

(f) 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.

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

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

~~(f)~~(i) Changes in any information in this rule shall be submitted to the Board prior to such change. Change of ownership and change of location notification must be made via the formal application process. If application is for change of location only, then a new license number will not be required.

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

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under Federal, State, or local laws;
3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
4. Suspension or revocation by Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;
5. Compliance with licensing requirements under previously granted licenses, if any;
6. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by retail pharmacies; and
7. Other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

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

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

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

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

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

(3) Any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from

this, or any other rule, must be posted and/or displayed next to the current Board of Pharmacy renewal permit; and

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

Rule 480-13-.02. Licensure and Registration

(1) All hospital pharmacies shall renew biennially by June 30th of each odd-numbered year with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those hospital pharmacies which comply with the provisions of O.C.G.A. § 26-4-110, and with these Rules and Regulations.

(2) Minimum Required Information for Licensure. The Board requires the following information from each hospital pharmacy as part of the initial licensing procedure and as part of any renewal of such license:
   (a) The name, complete street address for the business, and telephone number of the applicant/licensee;
   (b) All trade or business names used by the applicant/licensee;
   (c) Address, telephone numbers, and the name(s) of the Hospital Administrator;
   (d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
   (e) The name(s) of the owner and/or operator of the applicant/licensee, including:
      1. If a partnership, the name of each partner, and the name of the partnership;
      2. If a sole proprietorship, the complete name of the proprietor;
      3. If a corporation, the name and title of each corporate officer and director, the corporate name and the state of incorporation; and the name of the parent company, if any.
   (f) Where operations are conducted at more than one location by a single hospital pharmacy, each such location shall be licensed by the Board.

(3) Applications for Licensure.
   (a) Registration of a hospital pharmacy shall be considered filed with the Board when an application is received by the Board, and the fee is paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license is received by the Board.

(4) Application fees shall not be refundable.

(5) 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.~~A license shall be null and void upon the sale, transfer or change of mode of operation or location of the business.~~

(6) 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.

~~(5)~~(7) 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.

~~(6)~~(8) Licenses may be renewed for two year periods and shall expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal for each place of business. If the application for renewal is not filed with the Board, and the fee paid before September 1st of each odd numbered year, the license shall lapse and may not be renewed except by application for a new license.

~~(7)~~(9) A licensee must submit any change of name, mode of operation or address to the Board prior to such change.

~~(8)~~(10) Minimum Qualifications.

(a) The Board shall consider the following factors when determining eligibility for licensure for each person in charge of the facility and when considering an application for a hospital pharmacy license:

1. Any convictions of the applicant under any Federal, State, or local laws relating to drugs, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under any Federal, State, or local laws;
3. The furnishing by the applicant of false or fraudulent material or information in any application;
4. Suspension or revocation by any Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;
5. Failure to comply with any licensing requirements under a previously held license, if any;
6. Failure to comply with any requirements to maintain records and/or make available, said records to any State Licensing Authority or to any Federal, State, or local law enforcement officials;
7. Other factors or qualifications the Board considers relevant to and consistent with the public's health and safety;

~~(9)~~(11) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

Rule 480-18-.02. Licensure and Registration

(1) All opioid treatment program (OTP) clinics must have an on-site pharmacy. All such pharmacies shall obtain a license by registering with the Georgia State Board of Pharmacy (Board). Such license shall be renewed biennially with the Board. Before a Board license can be issued, an opioid treatment program clinic must meet all the requirements for licensure and registration as provided by both state and federal law and all Board rules.

(2) Licensure and Applications. Certificates of registration or licensure shall be issued only to those opioid treatment program clinic pharmacies who meet the following requirements:

(a) Submission of an application with the following information:

1. The name, full business address, and telephone number of the licensee;
2. All trade or business names used by the licensee;
3. Address, telephone number, and the name of the Director of Pharmacy
4. The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
5. The name(s) of the owner and/or operator of the licensee, including:
   (i) If a person, the name of the person;
   (ii) If a partnership, the name of the partnership and the name of each partner;
   (iii)If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; or
   (iv)If a corporation, the corporate name, the name and title of each corporate officer and director, the state of incorporation; and the name of the parent company, if any.
   (v) If operations are conducted at more than one location by a single opioid treatment program clinic pharmacy, each such location shall be licensed by the Board.

(3) Payment of an application fee. Application fees shall not be refundable.

(4) Applicant must file a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.

(5) 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.

(6) 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.

(7) 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.

~~(5) Licenses become null and void upon the sale, transfer or change of mode of operation or location of the pharmacy.~~

~~(6)~~(8) Licenses are required to be renewed June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each pharmacy and the filing of an application for renewal. Said renewal is for a two year period. If the application for renewal is not filed with the Board and the fee paid before September 1st, of the odd numbered 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.

~~(7)~~(9) Changes in any licensee information pertaining to this rule shall be submitted in writing to the Board prior to such change.

~~(8)~~(10) The Board will consider the following factors in determining eligibility for licensure of applicants in charge of the facility who are applying for an opioid treatment program clinic pharmacy license:

(a) Convictions of the applicant under any Federal, State, or local laws relating to wholesale or illegal distribution of dangerous drugs or controlled substances;

(b) Any felony convictions of the applicant under Federal, State, or local laws;

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

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

(e) Compliance with licensing requirements under previously granted licenses, if any;

(f) Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by the opioid treatment program clinic pharmacies; and

(g) Other factors or qualifications the Board considers relevant to and consistent with the public health, safety and welfare.

~~(9)~~(11) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

~~(10)~~(12) The pharmacist's wall certificate issued by the Georgia State Board of Pharmacy (Board), along with the current renewal license of each full-time pharmacist, employed at the pharmacy, shall be displayed in a conspicuous place, near the prescription department where such pharmacist is actively engaged in the practice of pharmacy.

(a) While employed in a pharmacy on a full-time basis, if a pharmacist has not yet received his/her Board issued pharmacist wall certificate, in its place such pharmacist shall post a copy of his/her current Board issued pocket license card;

(b) Any pharmacist employed on a part-time basis at a pharmacy shall post a copy of his/her current Board issued pocket license instead of posting his/her pharmacist wall certificate; and

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

~~(11)~~(13) Any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from this, or any other rule, must be posted and/or displayed next to the current Board of Pharmacy permit; and

~~(12)~~(14) No pharmacist or intern/extern shall display his/ her license in any pharmacy where he or she is not employed or engaged in the practice of pharmacy, and shall not knowingly permit any other person to use his or her license for the purpose of misleading anyone to believe that such person is the

holder or recipient of said license or intern certificate.

Rule 480-33-.02. Licensure and Registration

(1) All outpatient clinic pharmacies shall renew biennially by June 30th of each odd numbered year with the Georgia State Board of Pharmacy. Certificates of registration shall be issued to outpatient clinic pharmacies which meet the requirements for licensure and which comply with Chapter 480-33 of the Rules of the Georgia State Board of Pharmacy.

(2) Minimum Required Information for Licensure. The Board requires the following information from each outpatient clinic pharmacy as part of the initial licensing procedure and as part of each renewal of such license. The name, complete street address for the business (i.e., geographic location), and telephone number of the applicant/ licensee. All trade or business names used by the applicant/licensee. Address, telephone numbers, and the name(s) of the clinic administrator;

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

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

1. If a sole proprietorship, the complete name of the proprietor;
2. If a partnership, the complete name of each partner, and the name of the partnership;
3. If a corporation, the name and title of each corporate officer and director, the corporate name and the state of incorporation, and the name of the parent company, if any.

(i) Where operations are conducted at more than one location by a single outpatient clinic pharmacy, each such location shall be licensed by the Board.

(ii) Applications for Licensure.

(I) Registration of an outpatient clinic pharmacy shall be considered filed with the Board when an application is received by the Board, a fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying that the applicant possesses the necessary qualifications for a license.

(II) Application fees shall not be refundable.

(III) 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.

(IV) 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.

I. 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.

(V) 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.

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

~~(IV)~~(VI) Licenses are renewed for two year periods and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal. If the application for renewal is not filed with the Board and the fee paid before September 1st, of each odd numbered year, the license shall lapse and may not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

~~(V)~~(VII) Changes in any information in this section shall be submitted to the Board prior to such change.

(iii)Minimum Qualifications.

(I) To obtain an outpatient clinic pharmacy license, the outpatient clinic pharmacy must employ a pharmacist-in-charge.

(II) The Board shall consider the following factors in determining eligibility for licensure for each person(s) in charge of the facility when considering an application for an outpatient clinic pharmacy license:

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

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

III. The furnishing by the applicant of false or fraudulent material or information in any application;

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

V. Failure to comply with any licensing requirements under a previously held license, if any;

VI. Failure to comply with any requirements to maintain and/or make available to the state licensing authority or to Federal, State, or local law enforcement officials, any records required to be maintained by outpatient clinic pharmacies;

VII. Other factors or qualifications the Board considers relevant to and consistent with the public's health and safety; and

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

(3) An outpatient clinic pharmacy registered with the Board shall not be authorized to dispense refills on prescription drug orders.

(4) Nothing in these regulations shall be construed to prohibit an outpatient clinic from applying for a retail pharmacy license as provided for in O.C.G.A. §§ 26-4-110 and Rule 480-6-.01. Any retail pharmacy located in an outpatient clinic holding a retail pharmacy license, shall comply with all the laws, rules and regulations applicable to such licensed retail pharmacy.

(5) Nothing herein shall be construed to interfere with a practitioner of the healing arts practicing as authorized by law.

Rule 480-52-.07. Licensure, Applications, and Display of License and Renewal Certificate

(1) Licensure and Applications

(a) Every Low THC Pharmacy Dispensary must be licensed by the Board in accordance with the laws and regulations of this State. The term “Low THC Pharmacy Dispensary” shall have the meaning ascribed in Board Rule 480-52-.01.

(b) All Low THC Pharmacy Dispensary licensees shall renew this license annually by June 30th with the Georgia State Board of Pharmacy; pharmacy dispensary licenses shall be issued only to those pharmacies who comply with this rule.

(c) Low THC Pharmacy Dispensary licenses shall be issued only to those licensed retail pharmacies who meet the following requirements:

1. Submission of an application with the following information:

i. The name, full business address, telephone number, and current Georgia Board of Pharmacy license number of the licensee;

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

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

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

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

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

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

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

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

vii. Documentation of one of the following:

(I) Written certification from the applicant that the applicant's operation of a Low THC Pharmacy Dispensary at the proposed location would comply with the location restrictions imposed by O.C.G.A. § 16-12-215(a); or

(II) Certified copy of an Order from the local zoning authority permitting the applicant to operate a Low THC Pharmacy Dispensary in the proposed location, as provided by O.C.G.A. § 16-12-215(a).

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

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

(d) 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.~~Low THC Pharmacy Dispensary licenses shall be nontransferrable.~~

(e) 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.

1. 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.

(f) 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.

(~~e~~g) Low THC Pharmacy Dispensary licenses are renewed annually and expire on June 30th of each 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 same year, the license shall lapse and shall not be renewed except by application for a new license.

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

(~~g~~i) The Board will consider the following factors in determining eligibility for licensure of applicants in charge of the facility and the applicant licensee who are applying for a Low THC Pharmacy Dispensary license:

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under Federal, State, or local laws;
3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
4. Suspension or revocation by Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;
5. Compliance with licensing requirements under previously granted licenses;
6. Compliance with requirements to maintain and/or make available to the State

Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by the licensee pharmacy and by a Low THC Pharmacy Dispensary;

7. The disciplinary history of the Predicate Retail Licensee, if any; and
8. Other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

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

(2) The Low THC Pharmacy Dispensary wall certificate issued by the Georgia State Board of Pharmacy (Board), along with the current renewal license of each full-time Pharmacist employed at the Low THC Pharmacy Dispensary, as well as any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from this, or any other rule, shall be displayed in the same manner as that required by Rule 480-10-.06 for the Predicate Retail Licensee;

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

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, 11th Floor, Atlanta, GA 303342 ~~Peachtree Street, 6th Floor, Atlanta, GA 30303~~, along with the required fee.

(b) Application for the licensing of a pharmacy will be considered on the basis of the application filed and an approval letter received from the 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, 11th Floor, Atlanta, GA 30334~~2 Peachtree Street, NW, 6th Floor, Atlanta, Georgia 30303~~, along with the required fee.

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

1. The name, full business address, and telephone number of the applicant;
2. All trade or business names used by the applicant;
3. Address, telephone numbers, and the names of contact persons for each facility used by the applicant for the records, storage, handling, and distribution of prescription drugs into this state;
4. Address, telephone number and name of agent of service for the applicant;
5. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship);
6. The name(s) of the owner and/or operator of the pharmacy, including:
   (i) If a person, the name of the person;
   (ii) If a partnership, the name of each partner and the name of the partnership;
   (iii)If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the incorporation, and the name of the parent company, if any; or
   (iv)If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.
7. Where operations are conducted at more than one location by a single pharmacy, each such location shall be permitted by the Board;
8. Proof of a valid, unexpired license, permit, or registration to operate a pharmacy in the compliance with the laws and rules of each state in which the applicant receives and dispenses prescription drug orders;
9. The names and license numbers of the pharmacist-in-charge of each facility involved in dispensing drugs to residents of this state and evidence that the pharmacist(s) are licensed and in good standing in the state where they are located;
10. Information necessary to demonstrate compliance with O.C.G.A. T. 50, Ch. 36;
11. Evidence satisfactory to the Board that the applicant ~~in is~~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 480-7-.01. Manufacturer's Permit

(1) Applications for registration for a manufacturer's permit must be filed with the Office of the Georgia State Board of Pharmacy ("Board") with the required fee.

(2) Registration of a manufacturer will be considered on the basis of the application filed, fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a permit.

(3) Application fees shall NOT be refundable.

(4) 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 shall not be transferable. Permits become null and void upon the sale, or change of mode of operation of the business, or location of business.~~

(5) 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.

~~(4)~~(6) 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.

~~(5)~~(7) Licenses are renewed for two years and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st of the odd numbered year, the license shall lapse and shall not be renewed, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.

~~(6)~~(8) Upon request by the Board or its designee, any manufacturer holding a permit issued by the Board that causes a dangerous drug or controlled substance product to be marketed or distributed in this state shall provide, at no cost to this state, a quantity of one gram or more of the pure compound of each such product to the Georgia Drugs and Narcotics Agency. Such quantities of pure compound will only be used for testing and analysis purposes.

(a) All quantities of a pure compound provided to the Georgia Drugs and Narcotics Agency will be accounted for using a perpetual inventory system, and a copy of each product inventory will be available for review by the manufacturer providing the compound upon written request to the Board.

(b) As the manufacturer is required by this subsection to submit the dangerous drug or controlled substance for analysis, the results of any chemical analysis shall be considered a trade secret within the meaning of Code Section 50-18-72(b)(1).

Rule 480-7-.03. Drug Wholesale Distribution Licensing Requirements

(1) Every drug wholesale distributor, wherever located, who engages in drug wholesale distribution into, out of, or within the State of Georgia must be licensed by the Georgia State Board of Pharmacy in accordance with the laws and regulations of this State before engaging in wholesale distribution of prescription drugs.

(2) Minimum Required Information for Licensure: The Board requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license~~.~~:

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business names used by the licensee:;

(c) Address, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

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

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

1. If a person, the name of the person;
2. If a partnership, the name of each partner, and the name of the partnership;
3. 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;
4. If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.

(f) Where operations are conducted at more than one location by a single drug wholesale distributor, each such location shall be licensed by the Board.

(g) Every drug wholesale distributor in this state, which is licensed by the Board, is required to be located in a commercially zoned business district and possess the appropriate local business license in order to conduct business. No drug wholesale distributor may be located in or operate out of a residential dwelling, building, or location, or a building, dwelling or location attached to a residential location. A drug wholesale distributor located in a hospital pharmacy or a retail pharmacy is deemed to meet this requirement.

(3) Applications for Licensure.

(a) Registration of a drug wholesaler distributor 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 of a license.

(b) Application fees shall not be refundable.

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

(d) 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.

1. 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.

~~(c)~~(e) 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.

~~(d)~~(f) Licenses are renewed for two years and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

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

(4) Minimum Qualifications.

(a) The Board will consider the following factors in determining eligibility for licensure for persons who engage in the wholesale distribution of prescription drugs:

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under Federal, State, or local laws;
3. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
6. Compliance with licensing requirements under previously granted licenses, if any;
7. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be

maintained by drug wholesale distributors; and

8. Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The Board reserves the right to deny a license to any applicant if it determines that the granting of such a license would not be in the public's interest.

(5) Personnel. The licensed wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

(6) Violations:

(a) A license issued to a wholesale distributor pursuant to this part shall be subject to revocation or suspension upon conviction of the license holder for violations of Federal, State, or local drug laws and/or regulations.

(b) Violation of any of the provisions of any applicable Board laws or rules shall be grounds for the suspension or revocation of the license issued hereunder.

(c) Any revocation or suspension of 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.

(d) Drug samples shall not be sold in any licensed pharmacy.

(7) Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drugs Distribution Records. The following are required for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees.

(a) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
3. Have a quarantine area for storage or prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
4. ~~4.~~ Be maintained in a clean and orderly condition; and
5. ~~5.~~ Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

1. Access from outside the premises shall be kept to a minimum and be well controlled.
2. The outside perimeter of the premises shall be well lighted.
3. Entry into areas where prescription drugs are held shall be limited to authorized personnel.
4. All facilities shall be equipped with an alarm system to detect entry after hours.
5. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription drugs or chemicals shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia (USP) Compendium.

1. If no storage requirements are established for a prescription drug, the drug may be held at “controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
2. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.
3. The record keeping requirements in subparagraph (f) of this section shall be followed for all stored drugs.

(d) Examination of materials.

1. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
2. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
3. The record keeping requirements in subparagraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) Returned, damaged, and outdated prescription drugs.

1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.
2. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
3. If the conditions under which a prescription drugs has been returned cast doubt on the drug's safety, identify, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which the drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drugs has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.
4. The record keeping requirements in subparagraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) Record keeping:

1. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:
   (i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs are shipped;
   (ii) The identity and quantity of the drugs received and distributed or disposed of; and
   (iii)The date of receipt and distribution or other disposition of the drugs.

(g) For each person or firm, whether located inside or outside the State of Georgia, to which a drug wholesale distributor, located inside the State of Georgia, sells to, ships to, delivers to, or otherwise distributes drugs to, such drug wholesale distributor shall request and maintain a copy of that person or firm's current license or permit which authorizes them to purchase, buy, receive, or otherwise possess drugs.

1. ~~NO~~ No drug wholesale distributor, located inside the State of Georgia, may ship to, sell to, or otherwise deliver a dangerous drug or controlled substance to a person or firm unless that person or firm holds a license or permit which authorizes them to purchase, buy, receive or otherwise possess drugs.

(h) Nothing in this chapter or Georgia law authorizes any drug wholesale distributor, located inside the State of Georgia, to sell, ship, or otherwise distribute any drugs to any person or firm located outside the United States of America or its territories without first receiving written permission to do so from the Board. Such permission can only be granted by the Board after it has received a written request from the drug wholesale distributor giving the details of the proposed transaction. The Board reserves the right to have the GDNA investigate any and all such requests, and the Board reserves the right to

deny any such request.

(i) Inventories and all records required under this rule shall be made available for inspection and photocopying by any authorized official of a government agency charged with enforcement of these regulations for a period of two (2) years following deposition of the drugs.

(j) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be made readily available for authorized inspection during the retention period. Records kept at a central record keeping location apart from the inspection site and not electronically retrievable, shall be made available for inspection within two (2) working days of a request by an authorized official of any governmental agency charged with enforcement of these regulations.

(8) Written Policies and Procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies the following:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the FDA or other Federal, State, or local law enforcement or other government agency, including the Georgia State Board of Pharmacy;
2. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
3. Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or natural emergency.

(d) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(9) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officer, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(10) Compliance with Federal, State, and local laws. Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(a) Wholesale drug distributors shall permit the Georgia State Board of Pharmacy and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operation procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, Local, and DEA regulations.

(11) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

Rule 480-7-.04. Researcher's Permit

(1) Applications for registration must be filed with the Office of the Georgia State Board of Pharmacy

("Board") with the required fees.
(2) Registration of a Researcher will be considered on the basis of the application filed and a report from the director of the GDNA certifying the applicant possesses the necessary qualifications for a permit.
(3) Application fees shall NOT be refundable.
(4) 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.
(5) 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.
~~(4)~~(6) 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.~~Permits shall not be transferable. Permits become null and void upon the change of mode, operation and/or location of the permit-holder.~~
~~(5)~~(7) Permits are renewable every two (2) years and expire on June 30th of the even- numbered years. Permits may be renewed upon the payment of the required renewal fee and the filing of the renewal application form. If the application is not made and the fee not pa id before September 1st of the even-numbered year, the permit shall lapse and shall not be renewable except by application f or a new permit.
~~(6)~~(8) Minimum Qualifications:
(a) The Board will consider the following factors in determining eligibility for persons or entities applying for permits to engage in research.
1. Any convictions of the applicant under any Federal, State, or local laws related to dangerous drugs or controlled substances;
2. Any felony convictions of the applicant under any Federal, State, or local laws;
3. The applicant's past experience in research related to dangerous drugs including controlled substances;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug research;
5. Suspension or revocation by Federal, State or local government of any permit currently or previously held by the applicant for drug research;
6. Compliance with the requirements under previously granted permits or licenses, if any;
7. Compliance with requirements to maintain and/or make available to the State licensing or permitting authority or to Federal, State or local law enforcement officials those records required to be maintained by researchers;
8. Any other factors or qualifications such as age, education, training, etc. the Board considers relevant to be inconsistent with the public health and safety; and
9. Having a Peace Officer Certification suspended or revoked by the Georgia Peace Officers Standard and Training (POST) or other professional licensing authority.
(b) The Board reserves the right to deny a permit to any applicant if it deter mines that the granting of such a permit would not be in the public interest.
~~(7)~~(9) Storage and Security:
(a) All drugs including dangerous drugs and controlled substances shall be stored at appropriate temperatures and under appropriate conditions in accordance with labeled requirements or those published in the current edition of an official compendium, such as the United States Pharmacopoeia (USP) Compendiums;

(b) All facilities used for storage of drugs including dangerous drugs and controlled substances shall be of suitable size and construction to facilitate cleaning, maintenance and proper operations; and shall provide security from unauthorized entry as approve d by the Board or GDNA.

1. All such facilities will be located in an appropriately zoned district, such as a college, school, university, law enforcement off ice, or commercial area. No permit will be issued to any researcher whose facility is located in a residential area, dwelling, or location. The Board may choose to grant an exception to this rule upon receipt of a written request from such applicant stating the reason for such an exemption.

~~(8)~~(10) Record Keeping and Accountability:

(a) Researchers shall establish and maintain records of all transactions regarding receipt, distribution or other disposition of dangerous drugs or controlled substances.

(b) All records required by these regulations shall be retained for a minimum period of two (2) years following any disposition of any drugs received.

(c) Such records shall be kept at the storage site or shall be immediately retrievable by computers or other electronic means for authorized inspection during the retention period

~~(9)~~(11) Sanctions and Penalties:

(a) The Board under these regulations shall have the power to suspend or revoke any permit issued or to reprimand or to fine, not to exceed $500 per violation, the holder of such permit when such holder shall have:

1. Become unfit or incompetent;
2. Been convicted of a felony or any other crime involving moral turpitude;
3. Violated any Pharmacy laws or rules or regulations promulgated by the Board, or violated any other state, federal, or local laws and rules related to drugs.
4. The Board may refuse to grant a permit or renewal to any person, firm, corporation, agency, department or other entity for any of the grounds set forth in O.C.G.A. Section 26-4-49 and/or 26-4-60 of the Georgia Pharmacy Practice Act.

Rule 480-7A-.04. Requirements for Licensure as a Listed Chemical Wholesale Distributor

(1) Listed chemical wholesale distributors that provide services within this State, whether the listed chemical wholesale distributor is located within this State or outside this State, shall be licensed by the Board and shall biennially renew their permit or license with the Board using an application provided by the Board.

(2) Where listed chemical wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the Board.

(3) A person or firm holding a valid permit issued by the Board and licensed as a wholesale distributor under Code Section 26-4-113 shall not be required to obtain an additional license under this Code section; Wholesale distributors licensed under Code Section 26-4-113 shall be subject to the provisions of this Code section in the same manner as chemical wholesale distributors licensed under this Code section.

(4) 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.

(5) 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.

~~(4)~~(6) 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.~~Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business.~~

~~(5)~~(7) The Board requires the following and such additional information as found on an approved Board application from each listed chemical wholesale distributor as part of the initial licensing procedure and as part of any biennial renewal of such license:

(a) The name, trade or business name, full business address, and telephone number of the applicant. Trade or business names cannot be identical to that of another Board licensee.

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

(c) Name(s) of the owner and operator of the licensee (if not the same person), including:

1. If a person: the name, address, and social security number;
2. If a partnership: the name, address, and social security number of each partner, and the name of the partnership and federal employer identification number;
3. If a corporation: the name, address, social security number, and title of each corporate officer and director, the corporate names, the name of the State of incorporation, federal employer identification number, and the name of the parent company, if any; the name, address, and social security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter;
4. If a sole proprietorship: the full name, address, and social security number of the sole proprietor, and the name and federal employer identification number of the business entity;
5. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and
6. Any other relevant information that the Board requires.

(d) Name(s), address(es), telephone number(s), date(s) of birth of a person(s) to serve as the designated representative(s) for listed chemicals and additional information as required.

(e) A non-refundable application and/or renewal fee as determined by the Board and set forth in the fee schedule.

~~(6)~~(8) By submitting an application for licensure as a listed chemical wholesale distributor, said applicant consents to a criminal background check of the applicant, all personnel involved in the operations of the listed chemical wholesale distributor, all shareholders involved in operations, and anyone owning or being involved in operations to determine if an applicant or others associated with the ownership, management, or operations of the listed chemical wholesale distributor has committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state laws, at the applicant's expense, and will be sufficient to include all states of residence since the person has been an adult.

~~(7)~~(9) Each facility which engages in listed chemical wholesale distribution must undergo an inspection on behalf of the Board by an agent with the GDNA for the purpose of inspecting the in-state listed chemical wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board but no less than once every three (3) years.

~~(8)~~(10) Each facility which is located outside the State and engages in listed chemical wholesale distribution must undergo a background investigation by GDNA on behalf of the Board and be approved by the GDNA prior to being approved for licensure, and as necessary submit to an inspection by either GDNA or an agent contracted with by GDNA.

Rule 480-8-.02. Registration

(1) Every prison clinic pharmacy, wherever located within the State of Georgia must be licensed by the Georgia State Board of Pharmacy ("Board") in accordance with the laws and regulations of this State. All prison clinic pharmacies shall renew biennially by June 30th of the odd-numbered years with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those prison clinic

pharmacies as follows:

(2) Minimum Required Information for Licensure: The Board requires the following information from each prison clinic pharmacy as part of the initial licensing procedure and as part of any renewal of such license.

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business names used by the licensee;

(c) Address, telephone numbers, and the name(s) of the Prison Clinic Administrator;

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

(e) The name(s) of the owner and/or operator of the licensee, including;

1. If a person, the name of the person;
2. If a partnership, the name of each partner, and the name of the partnership;
3. If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.
4. If a corporation, the name and title of each corporate officer and director, the corporate names and the name of the State of incorporation; and the name of the parent company, if any.

(f) Where operations are conducted at more than one location by a single prison clinic pharmacy, each such location shall be licensed by the Board.

(3) Administration of Applications for Licensure.

(a) Registration of a prison clinic pharmacy will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.

(b) Application fees shall not be refundable.

(c) 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.

(d) 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.

1. 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.

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

~~(d)~~(f) Licenses are renewed for two years periods and expire on June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

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

(4) Minimum Qualifications.

(a) The Board will consider the following factors in determining eligibility for licensure for person(s) in charge of the facility and are applying for a prison clinic pharmacy:

1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under Federal, State, or local laws;
3. The furnishing by the applicant of false or fraudulent material in any application made in

connection with drug manufacturing or distribution;

4. Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant.
5. Compliance with licensing requirements under previously granted licenses, if any;
6. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained prison clinic pharmacies; and
7. Other factors or qualifications the Board considered relevant to and consistent with the public health and safety.
8. The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel: President Azzolin stated that the Board voted to post Rule 480-15-.02 Registration of Pharmacy Technicians and Continuing Education Requirements at last month's meeting. Vice-President Page inquired if that was a cleanup on the specifics for applying for registration and continuing education requirements. President Azzolin responded affirmatively. Vice-President Page inquired if language stating two (2) hours of continuing education in relation to immunization training should be added due to House Bill 416 giving technicians the ability to provide immunizations. President Azzolin responded by stating that the Board already voted to post amendments to Rule 480-15-.02 at its July meeting. Mr. Joiner commented that the rule could be pulled if the Board wanted to make changes. He added that the Board would need to repost the rule. After further discussion, the Board decided to not retract the rule since the information was in the law.

The Board held discussion regarding Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel. President Azzolin inquired if there were any questions or comments. Vice-President Page discussed the proposed language to subsection (3), which states, "Pharmacy technicians must be registered in Georgia, or when assisting with remote drug order processing functions, in the state in which such remote drug order processing functions are performed." He inquired if the language implied the pharmacy technician was required to be registered in the state they are doing work. Mr. Joiner responded by stating that if the pharmacy technician was located in Alabama, he/she would need to be registered in Alabama. Vice-President Page stated that the rule is mandating the pharmacy technician be registered in another state doing work for another state.

President Azzolin commented that the spirit behind the language was to say whatever state the pharmacy technician is in, he/she must abide by the rules of that state. Mr. Chang stated that he thought the spirit behind the language was that the Board wanted registered pharmacy technicians performing the work. President Azzolin responded by stating that would only be in Georgia because some states may not require registration. He stated that Rule 480-6-.02 requires them to be compliant with laws of their state. He requested the language be modified to read, "Pharmacy technicians must be registered in Georgia, or when assisting with remote drug order processing functions, if required in the state in which such remote drug order processing functions are performed." Mr. Joiner stated he would make the requested change.

Mr. Brinson inquired about a scenario where a pharmacy technician is working remotely and entering information at the end of the day. He stated that the next morning when the pharmacist comes in, it is the pharmacist's responsibility to do the final verification. President Azzolin commented that the technician cannot do anything that requires clinical judgement and that part of the technician's boundaries has not changed. Mr. Brinson stated that he wanted to make sure the pharmacist realizes when they do the final verification, they are responsible. President Azzolin stated that the only time a remote technician scenario would even apply is when operating under 480-36. He added that remote technicians cannot be sitting at home as they have to be in a Georgia licensed pharmacy or licensed non-resident pharmacy. He continued

by stating that the pharmacy still has to adhere to the ratio in that remote setting. President Azzolin stated that the pharmacy technician can only perform remote services when they are in a licensed pharmacy per Rule 480-36-02.

Mr. Changus inquired if there was a design for pharmacy technicians to work from home. President Azzolin responded by stating that Rule 480-36-.02 prevents that. He added that the pharmacy technician can only do it when they are in a Georgia licensed pharmacy. Mr. Changus commented that if the pharmacy technician was working in a Georgia licensed pharmacy, the ratio would apply. President Azzolin responded by stating that was correct, if the technician was working in Georgia. He stated that if the pharmacy technician was working remotely in another state, the pharmacy can have as many technicians as they want if outside a pharmacy, but in that state, or as many technicians as a pharmacy license in that state allows to be present, if inside a pharmacy. He further stated that the non-resident pharmacy permit holder has to abide by their own state's rules and regulations. He continued by stating that when the pharmacy technician operates remotely in Georgia they have to be in a licensed pharmacy. President Azzolin stated that if the pharmacy is a non-resident pharmacy, it will have to abide by its state's requirements and if the pharmacy were a Georgia licensed pharmacy, the pharmacy would have to abide by Georgia's requirements.

Mr. Changus commented that the supervision is being done at the pharmacy whether it is the primary or other pharmacy. President Azzolin responded by stating that the pharmacy technician is never operating remotely outside of a pharmacy as they must always be in the presence of a pharmacist. President Azzolin stated that the concept behind changing Rule 480-36-.02 was so that in Georgia, even if the Board allowed the pharmacy technician to not count towards the ratio in the primary pharmacy, the Board was still forcing pharmacy technicians to work in the presence of a pharmacist, meaning in the pharmacy. He further stated that in Georgia that pharmacy is limited to four (4) technicians. He added that the secondary pharmacist, when operating in a pharmacy, is allowed to use a pharmacy technician to support the primary pharmacy from a remote perspective. He continued by stating that, by definition in Rule 480-10 and Rule 480-13, and any other location where there is a pharmacy license applied, in Georgia the ratios have to be adhered to in the secondary location.

Mr. Stone stated that it was his understanding this was allowing the pharmacy technician to be able to work remotely outside of the pharmacy. Mr. Farmer and Mr. Chang stated that was their understanding as well. Mr. Joiner commented that the issue last month was with the language in section (1) of Rule 480-36-.03, which states in part, "…Pharmacy technicians and pharmacy interns/externs may assist a pharmacist located at the primary dispensing pharmacy with remote prescription drug order processing..."

Mr. Joiner stated that the definition of "Remote prescription drug order processing" states in part that it shall mean the processing of prescription or patient information from a location other than the location from which the prescription medication is received and dispensed. Mr. Joiner continued by stating that with reading section (1) of Rule 480-36-.03 with the definition seems to says the primary pharmacy could use remote technicians. Mr. Chang added that they could be utilized outside of a licensed pharmacy.

President Azzolin stated that if you are in a primary pharmacy by definition, you are in that pharmacy and cannot be outside that pharmacy. He further stated that the spirit behind that language is to say that if a remote pharmacist assists a primary pharmacy with processing a prescription, and there is a technician in that primary pharmacy, they can still work on that prescription. He continued by stating that section (2) of Rule 480-36-.03 states, "If the secondary remote entry pharmacist is engaging in the remote services listed in rule 480-36-.01 from a Georgia Board of Pharmacy licensed pharmacy, then pharmacy technicians and pharmacy interns/externs may assist the secondary remote entry pharmacist with remote prescription drug order processing." President Azzolin continued by stating that, if operating from a Georgia licensed pharmacy, then they may use interns, externs and technicians, which means the pharmacy has to adhere to

ratios. Mr. Joiner noted that the first paragraph is talking about the primary dispensing pharmacy and not the secondary pharmacy. President Azzolin responded by stating that was correct, but if you are in the primary dispensing pharmacy you are in the pharmacy. Vice-President Page commented that, to him, that means pharmacy technicians, interns and externs may assist the primary pharmacy with remote orders without having to physically be in the pharmacy.

Mr. Changus stated that the definition of a pharmacy technician is someone that assists in a pharmacy, per O.C.G.A. § 26-4-5. Mr. Joiner responded by stating that the Board should clarify the language since the definition uses the word "in". President Azzolin stated that Chapter 480-36 was on the Board's October workshop agenda and could clarify at that time.

Mr. Stone stated that it was his understanding from when the Board discussed technicians working remotely that because they were working remotely, they would not apply to the ratio of the store. He further stated that was the reason the language in the draft states that the pharmacist shall be present and shall have direct supervision of the activities of any registered pharmacy technician at all times. Mr. Stone added that he previously discussed working conditions and stress and if there is a technician working remotely, that could help alleviate some of that. He continued by stating that he felt the rule was not ready to be posted yet.

Mr. Chang stated that when he and Mr. Stone worked with Mr. Joiner on the rule, the intent was for the pharmacy technician to have the ability to work from a remote location knowing the final product/verification goes to a licensed pharmacist in Georgia to be dispensed. He further stated that if there are other rules the Board should look at, it should hold off on posting this rule and correct the other rules.

President Azzolin suggested correcting Rule 480-15-.03 move forward with it. He stated that the Board can correct the other rules at a later time. He further stated that he believes section (3) can be applied to just that secondary pharmacist when they are in a pharmacy.

Mr. Changus commented that what happened during the pandemic has clouded ideas of how pharmacy technicians can be utilized. He stated that O.C.G.A. § 26-4-5 defines "Pharmacy Technician" as meaning those support persons utilized in pharmacies whose responsibilities are to provide nonjudgmental technical services concerned with the preparation for dispensing of drugs under the direct supervision and responsibility of a pharmacist. Mr. Changus stated that the contemplation was this was location specific. Mr. Stone stated that the definition uses the term "in pharmacies" and asked if the Board could say how technicians can be used in pharmacies. Mr. Changus responded by stating that when the law was passed, technicians were there to assist pharmacists in their day to day activities. He added that this was prior to the pandemic; however, the law specifically states "in pharmacies".

Vice-President Page stated that the Board thought the pharmacy technician was working remotely from home or other locations. He further stated that with the way it is written today, if the pharmacy technicians are with a pharmacist in a licensed pharmacy in another state or in Georgia, that is clear. Director Troughton commented that is happening now with other stores assisting other locations. Vice-President Page stated that with a pharmacy technician working remotely from home, that is tricky with ratios. He further stated that he was unsure if it was permitted by law and may require a legislative change.

Mr. Changus commented that when speaking about "what is direct supervision and responsibility" seems to indicate there is someone present overseeing the actions of the pharmacy technician. President Azzolin stated that he could not remember if it is in the law or rules, but it states that the pharmacist must be physically present, not the technician. Mr. Stone commented that if the pharmacist is not physically present, the pharmacy technician cannot be doing remote work after hours. He stated that the pharmacist would be held responsible for that. He added that direct supervision means he is directly supervising at work.

President Azzolin stated that in regard to the definition of a pharmacy technician meaning someone that assists "in a pharmacy" implies that pharmacy has to be defined as well. He further stated that O.C.G.A. § 26-4-5(30) states that "Pharmacy" means the following:
(A) The profession, art, and science that deals with pharmacy care, drugs, or both, medicines, and medications, their nature, preparation, administration, dispensing, or effect; or
(B) Any place licensed in accordance with this chapter wherein the possessing, displaying, compounding, dispensing, or selling of drugs may be conducted, including any and all portions of the building or structure leased, used, or controlled by the licensee in the conduct of the business or profession licensed by the board at the address for which the license was issued.

President Azzolin stated that if "pharmacy" can mean either or, then they do not have to be physically in a place where you are performing "The profession, art, and science that deals with pharmacy care, drugs, or both, medicines, and medications,…" Mr. Changus responded by stating that the problem is that it does not say "pharmacy". He stated that you engage in the practice of pharmacy which is defined and then you also operate in pharmacies which are buildings where dispensing takes place. He further stated that he thinks the use of the word "pharmacies" is implying it is a building. He explained that he does not think one can make the plural of the practice fit into that definition.

President Azzolin stated that when a pharmacy technician is in a hospital and carries drugs to a nursing floor, they are outside the pharmacy. He inquired if they are considered a pharmacy technician in that moment. Mr. Changus responded by stating that they are operating out of a hospital pharmacy. President Azzolin commented that they are remote and not in a pharmacy. Mr. Changus stated that the pharmacy technician is still tethered to a pharmacy. President Azzolin responded by stating that the remote technician is also tethered to a pharmacy.

Mr. Changus asked, in regards to the distribution of the medications, if it was overseen by a pharmacist. President Azzolin responded by stating that it is not out on the floor, they are in the pharmacy. President Azzolin inquired as to how far can the Board takes the implication that the word "in" is going to prevent what obviously is a logical utilization of a technician. He stated that if you are going to apply it in that scenario, you have to apply in the hospital scenario too. Mr. Changus inquired if the ratio will apply in the hospital. President Azzolin responded affirmatively. He stated that, per Chapter 480-13, a hospital can submit a rule petition for additional technicians.

Mr. Changus inquired as to what direct supervision is in a remote situation. President Azzolin responded by stating that it is making sure whatever the pharmacy technician does is appropriately reviewed. He stated that it is no different than being 100 miles away and not being able to see the pharmacy technician. He added that all of the functions of making sure the prescription is accurate filters through that pharmacist. He continued by stating that if they are not physically present, then you have just removed every other issue associated with a pharmacy technician diverting drugs or doing things wrong inside that pharmacy.

President Azzolin inquired as to who will review the rule for statutory authority. Mr. Changus responded by stating that if the Board votes to post the rule, it will come to him to review for statutory authority. President Azzolin inquired if the rule has any weight whatsoever. Mr. Changus asked what the intent of the rule was. He stated that a few minutes earlier President Azzolin was noting 480-36 and talking about what happens in a pharmacy. He further stated that several members thought the intent was to allow pharmacy technicians to work from home. He explained that if the Board feels the rule as drafted is sufficient, then he will review it and provide the Board with an answer that is not off the cuff. He stated that once he has time to review the rule, he will write a memo to the Board stating whether or not there is statutory authority. He noted that one item of question is concerning the ratio. Mr. Changus stated that the Board is envisioning the rule to say the ratio would not apply if pharmacy technicians can work remotely from home. He explained

that the statute is very clear. He added that if there is statutory authority for the rule, it would be posted for a public hearing. He stated that if there is not statutory authority, the Board would need to revisit the rule.

After further discussion, Mr. Joiner noted the requested change to section (3) of the draft had been made and was posted to Sharepoint for the members to review.

Mr. Cordle made a motion to post Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel. Mr. Bracewell seconded, and the Board voted unanimously in favor of the motion.

Rule 480-15-.03. Use of Registered Pharmacy Technicians and Other Pharmacy Personnel

(~~a~~1) ~~In dispensing drugs, no~~No individual other than a licensed pharmacist, intern or extern working under direct supervision of a licensed pharmacist shall perform or conduct those duties or functions which require professional judgment. It shall be the responsibility of the supervising pharmacist to ensure that no other employee of the pharmacy, excluding pharmacy interns or externs, performs or conducts those duties or functions which require professional judgment.

(~~b~~2) ~~For all prescription drug orders, it~~It shall be the responsibility of the Pharmacist on duty at a facility to ensure that only a pharmacist or a pharmacy intern and/or extern under the direct supervision of a pharmacist provides professional consultation and counseling with patients or other licensed health care professionals and that only a pharmacist or a pharmacy intern or an extern under the direct supervision of a pharmacist accepts telephoned oral prescription drug orders or provides or receives information in any manner relative to prescriptions or prescription drugs.

(3) Pharmacy technicians must be registered in Georgia, or when assisting with remote drug order processing functions, as required by the state in which such remote drug order processing functions are performed.

(~~c~~4) Registered pharmacy technicians and other pharmacy personnel, i.e. clerks, cashiers, observers, etc., in the prescription department shall be easily identifiable by use of a name badge or other similar means which prominently displays their name and the job function in which the personnel are engaging at that time. Any pharmacy personnel or other person present in the pharmacy department must be under the direct supervision of a licensed pharmacist.

(~~d~~5) In the dispensing of all prescription drug orders:

~~1.~~(a) The pharmacist shall be responsible for all activities of any registered pharmacy technician ~~in the preparation of the drug for delivery to the patient~~.

~~2.~~(b) The pharmacist shall be present and ~~personally supervising~~shall have direct supervision of the activities of any registered pharmacy technician at all times.

1. A pharmacist, as an adjunct to assist in the direct supervision of the pharmacy technician, may use electronic systems or alternative communication systems to communicate with or observe the pharmacy technician.

2. When electronic systems are used to establish direct supervision of pharmacy technicians, such systems shall be sufficient to provide the personal assistance, direction, and approval required to meet the standard of practice for the delegated tasks.

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;

(ii) prior to authorizing the use of any such system in the pharmacy, it shall be the responsibility of the pharmacist in charge to ensure that the electronic system, in the state and condition in which it has been maintained, is compliant with all state and federal laws and rules governing the practice of pharmacy, and to disallow use of said electronic system in the pharmacy in the event it enters a non- compliant state or condition; and

(iii) prior to using any such system in the practice of pharmacy, it shall be the responsibility of the pharmacist to ensure that the electronic system, in its present state and condition, is compliant with all state and federal laws and rules governing the practice of pharmacy, and to discontinue use of said electronic system in the event it enters a non-compliant state or condition.

~~3.~~(c) ~~When electronic systems are employed within the pharmacy, registered pharmacy technicians may enter information into the system and prepare labels; provided, however, that i~~It shall be the responsibility of the pharmacist to verify the accuracy if the information entered and the label produced in conjunction with the prescription drug order.

~~4.~~(d)When a prescription drug order is presented for filling or refilling, it shall be the responsibility of the pharmacist to review all appropriate information and make the determination as to whether to fill the prescription drug order, and

~~5.~~(e) Any other function deemed by the Board to require professional judgment.

(e6) ~~The pharmacist to registered pharmacy technician ratio~~When the pharmacist and registered pharmacy technicians are physically located on the same premises, the pharmacist to technician ratio shall not exceed one pharmacist providing direct supervision of four registered pharmacy technicians in accordance with the certification requirements below.

~~1.~~(a) Any time during which a pharmacist is directly supervising one or two technicians, no certification is required.

~~2.~~(b)Any time during which a pharmacist is directly supervising three technicians, at least one must be certified as outlined below in subsections ~~i-iii~~(c)(1-3).

~~3.~~(c) Any time during which a pharmacist is directly supervising four technicians, at least two must be certified as outlined below in subsections ~~i-iii~~(1-3).

~~(i)~~1. Have successfully passed a certification program approved by the Board of Pharmacy;

~~(ii)~~2. Have successfully passed an employer's training and assessment program which has been approved by the Board of Pharmacy; or

~~(iii)~~3. Have been certified by the Pharmacy Technician Certification Board.

(7) When the pharmacist has under his or her direct supervision both pharmacy technicians who are physically located on the same premises as the pharmacist and pharmacy technicians who are engaged in remote drug order processing functions, and who are not physically located in a pharmacy, 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).

(a) Only those certified pharmacy technicians who are physically present within the licensed pharmacy may be counted toward the number of certified pharmacy technicians required by paragraphs (6)(b) and (6)(c), above.

(8) When the pharmacist has under his or her direct supervision only pharmacy technicians who are engaged in remote drug order processing functions, and who are not physically located in a pharmacy, the pharmacist to pharmacy technician ratio specified in paragraph (6) shall not apply.

(~~f~~9) In addition to the utilization of four (4) registered pharmacy technicians as outlined in ~~subsection (e)~~paragraph (6), a pharmacist may be assisted by ~~and directly supervise at the same time~~ one (1) pharmacy intern, one (1) pharmacy extern, and one (1) pharmacy observer at the same time. The pharmacist shall be present and shall have direct supervision of the activities of any such pharmacy intern, pharmacy extern, or pharmacy observer.~~.~~

(10) Other pharmacy personnel (e.g. clerks, cashiers, etc.) are excluded from the pharmacist to registered pharmacy technician ratio.

(~~g~~11) The board may consider and approve an application to increase the ratio in a pharmacy located in a licensed hospital. Such application must be made in writing and may be submitted to the Board by the pharmacist in charge of a specific hospital pharmacy in this state.

(~~h~~12) No completed prescription drug order shall be given to the patient requesting the same unless the contents and label thereof have been verified by a pharmacist.

(~~i~~13)The Board of Pharmacy may revoke or suspend the registration of a pharmacy technician for any of the grounds set forth in O.C.G.A. Sections 43-1-19 or 26-4-60. The revocation or suspension of the registration of a pharmacy technician is not a contested case under the Georgia Administrative Procedures Act, O.C.G.A.T. 50, Ch.13, and the technician is not entitled to a hearing, but the technician may be entitled to an appearance before the Board.

In regards to the rules that the Board voted to post, which were 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 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, Rule 480-8-.02 Registration, and Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel, Mr. Stone made a motion, and Vice-President Page 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.

November Workshop: President Azzolin commented that there are several topics within Chapter 480-36 that need to be revisited by the Board at its November workshop.

Georgia Society of Health-System Pharmacists Meeting: Mr. Brinson commented that he, along with Director Troughton and Special Agent Tommy Roe, provided a legislative/rules update at the Georgia Society of Health-System Pharmacists July meeting. He said it was a great hit. He personally thanked Director Troughton and Special Agent Roe for helping. Mr. Brinson stated that they also discussed diversion, along with the history of the Board of Pharmacy and GDNA.

Mr. Farmer made a motion and Mr. Brinson 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, Chuck Page, and Dean Stone.

Executive Session

Appearance

- J.H.

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

- M.N.H.C.

Cognizant's Report – Mr. Chuck Page

- GDNA Case # T34865
- GDNA Case # A34671
- GDNA Case # A34867
- GDNA Case # B34812
- GDNA Case # B34841
- GDNA Case # A34818
- GDNA Case # A34825
- GDNA Case # A34822
- GDNA Case # B34695
- GDNA Case # B34738
- GDNA Case # B34840
- GDNA Case # A34769
- GDNA Case # A34872

Cognizant's Report – Mr. Michael Azzolin

- GDNA Case # B34781
- GDNA Case # B34863

Attorney General's Report – Mr. Max Changus

Mr. Changus discussed the following cases:

- P.P.A.P./U.P.S.
- P.P.

Mr. Changus presented the following consent orders for acceptance:

- K.W.P.
- A.D.S.
- P.P.

Executive Director's Report – Mr. Eric Lacefield

No report.

Legal Services – Mr. Clint Joiner

No report.

Applications

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

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

Correspondences/Requests

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

- M.E.M.
- W.C.M.
- R.W.C.
- K.H.G.
- F.P.
- G.H.
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No votes were taken in Executive Session. President Azzolin declared the meeting back in Open Session.

Open Session

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

Appearance

• J.H.	Request to reinstate pharmacist license	Denied request

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

• M.N.H.C.	Pharmacy Technician	Approved for renewal

Cognizant's Report – Mr. Chuck Page

- GDNA Case # T34865 Accept Voluntary Surrender
- GDNA Case # A34671 Close with Letter of Concern
- GDNA Case # A34867 Refer to the Department of Law
- GDNA Case # B34812 Close with Letter of Concern
- GDNA Case # B34841 Misfill Guidance #1A
- GDNA Case # A34818 Refer to the Department of Law
- GDNA Case # A34825 Refer to the Department of Law
- GDNA Case # A34822 Deny technician application/Refer to the Department of Law
- GDNA Case # B34695 Close with no action
- GDNA Case # B34738 Close with no action
- GDNA Case # B34840 Close with no action
- GDNA Case # A34769 Refer to the Department of Law
- GDNA Case # A34872 Accept Voluntary Surrender

Cognizant's Report – Mr. Michael Azzolin

- GDNA Case # B34781 Misfill Guidance #1A
- GDNA Case # B34863 Misfill Guidance #1A

Attorney General's Report – Mr. Max Changus

Mr. Changus discussed the following cases:

- P.P.A.P./U.P.S. Close with Letter of Concern
- P.P. Accept counterproposal

Mr. Changus presented the following consent orders for acceptance:

- K.W.P. Private Consent Order accepted
- A.D.S. Private Consent Order accepted
- P.P. Private Consent Order accepted

Executive Director's Report – Mr. Eric Lacefield

No report.

Legal Services – Mr. Clint Joiner

No report.

Applications

• Z.M.	Pharmacy Technician	Approved for registration
• B.B.W.	Pharmacy Technician	Approved for registration
• T.L.L.	Pharmacy Technician	Tabled pending receipt of additional information
• K.A.E.	Pharmacy Technician	Approved for registration
• J.K.H.	Pharmacy Technician	Approved for registration
• G.A.P.	Pharmacy Technician	Approved for registration
• T.X.N.	Pharmacy Technician	Approved for renewal
• A.K.T.	Pharmacy Technician	Denied renewal
• M.K.Y.	Pharmacy Technician	Approved for renewal
• K.A.R.	Pharmacy Technician	Approved for renewal
• I.C.I.	Pharmacist Certification of DTM	Approved application
• J.Y.D.	Pharmacist Certification of DTM	Approved application
• K.M.D.	Pharmacist Certification of DTM	Approved application
• J.D.F.	Pharmacist Certification of DTM	Approved application
• S.D.B.	Pharmacist Certification of DTM	Approved application
• A.M.B.	Pharmacist Certification of DTM	Approved application
• D.R.S.	Pharmacist Certification of DTM	Approved application
• G.T.N.	Pharmacist Certification of DTM	Approved application
• H.L.	Pharmacist Certification of DTM	Approved application
• R.R.K.	Pharmacist Certification of DTM	Approved application
• L.S.S.	Pharmacist Certification of DTM	Approved application
• M.K.C.	Pharmacist Certification of DTM	Approved application
• M.P.	Pharmacist Certification of DTM	Approved application
• N.P.H.	Pharmacist Certification of DTM	Approved application
• T.Q.T.	Pharmacist Certification of DTM	Approved application
• Y.H.D.	Pharmacist Certification of DTM	Approved application
• A.C.C.	Pharmacist Certification of DTM	Table pending receipt of

		additional information
• B.R.T.	Pharmacist Certification of DTM	Approved application
• D.S.A.	Pharmacist Certification of DTM	Table pending receipt of additional information
• J.B.M.	Pharmacist Certification of DTM	Approved application
• K.M.O.	Pharmacist Certification of DTM	Approved application
• T.M.T.	Pharmacist Certification of DTM	Approved application
• W.	Non-Resident Pharmacy	Approved for renewal
• H.P.	Non-Resident Pharmacy	Approved for renewal
• A.H.G.I.	Non-Resident Pharmacy	Approved for renewal
• A.H.G.I.	Non-Resident Pharmacy	Approved for renewal
• A.H.G.I.	Non-Resident Pharmacy	Approved for renewal
• A.H.G.I.	Non-Resident Pharmacy	Approved for renewal
• E.S.	Non-Resident Pharmacy	Approved for renewal
• A.E.P.	Non-Resident Pharmacy	Approved for renewal
• F.B.I.	Non-Resident Pharmacy	Approved for renewal
• T.P.S.	Non-Resident Pharmacy	Approved for renewal
• V.C.P.	Non-Resident Pharmacy	Approved for renewal
• A.U.	Wholesaler Pharmacy	Approved for renewal
• B.D.D.C.	Wholesaler Pharmacy	Approved for renewal
• B.D.D.C.	Wholesaler Pharmacy	Approved for renewal
• J.O.M.P.S.	Wholesaler Pharmacy	Approved for renewal
• J.O.M.P.S.	Wholesaler Pharmacy	Approved for renewal
• M.T.	Wholesaler Pharmacy	Approved for renewal
• M.V.S.I.	Wholesaler Pharmacy	Approved for renewal
• M.V.S.I.	Wholesaler Pharmacy	Approved for renewal
• M.V.S.I.	Wholesaler Pharmacy	Approved for renewal
• M.V.S.I.	Wholesaler Pharmacy	Approved for renewal
• P.M.S.	Wholesaler Pharmacy	Approved for renewal
• C.M.P.C.	Wholesaler Pharmacy	Approved for renewal
• F.B.S.	Wholesaler Pharmacy	Approved for renewal
• L.G.E.I.	Wholesaler Pharmacy	Approved for renewal
• L.G.E.I.	Wholesaler Pharmacy	Approved for renewal
• M.I.H.	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
• P.M.	Wholesaler Pharmacy	Approved for renewal
• G.L.	Third Party Distributor	Approved for renewal

Correspondences/Requests

• P.I.	Notice of Discipline	No action
• O.C.I.	Notice of Discipline	No action

• P.P.A.P.	Notice of Discipline	No action
• A.R.W.P.	Notice of Discipline	No action
• A.A.	Notice of Discipline	No action
• A.A.	Notice of Discipline	No action
• E.C.P.	Notice of Discipline	No action
• P.I.	Notice of Discipline	No action
• A.J.G.	Request for extension of intern license	Approved request through 07/31/2024
• J.C.E.	Request for extension of intern license	Approved request through 09/30/2024
• D.A.T.	Request for extension of intern license	Approved request through 07/31/2025
• A.T.C.	Request for 4th attempt to retake NAPLEX	Approved request
• F.S.E.	Request for 4th attempt to retake NAPLEX	Approved request
• A.M.G.	Request to lift PIC restriction	Approved request
• M.E.M.	Request to lift PIC restriction	Approved request
• W.C.M.	Request to lift PIC restriction	Approved request
• R.W.C.	Request to terminate probation	Approved request effective 09/22/2023
• K.H.G.	Request to terminate probation	Approved request effective 09/22/2023
• F.P.	Request for waiver of late renewal fee	Denied request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request
• G.H.	Lockbox approval request	Approved request

Mr. Cordle seconded, and the Board voted in favor of the motion, with the exception of Mr. Page, who recused himself from the vote regarding GDNA Case #B34781 and GDNA Case #B34863.

There being no further business to discuss, the meeting was adjourned at 2:41 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, September 13, 2023, at 9:00 a.m. at 2 MLK Jr., Drive, SE, 11th Floor, East Tower, Atlanta, GA 30334.

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