GEORGIA BOARD OF PHARMACY
2 Peachtree St., NW, 6th Floor
Atlanta, GA 30303
February 16, 2022
9:00 a.m.

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

Staff present:
Eric Lacefield, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney

Visitors:
Jeffrey Pappas, Pharmscript of GA
Jonathan Marquess
Becca Hallum, Georgia Hospital Association
David White

Open Session

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

Mr. Lacefield asked the visitors on the call to send an email via the "Contact Us" portal on the website if he/she would like his/her name reflected as being in attendance in the minutes.

Approval of Minutes
Mr. Brinson made a motion to approve the Public and Executive Session minutes from the January 19, 2022, meeting. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

Report of Licenses Issued
Mr. Brinson made a motion to ratify the list of licenses issued. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance
Rule Waiver Petition from @ Home Medical Inc, PHDME000190: Mr. Brinson made a motion to grant the petition. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Dykes Pharmacy, PHRE0005795: Mr. Azzolin made a motion to grant the petition. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Maxor Specialty Pharmacy, PHHH000053: The Board discussed this request for a waiver of Rule 480-36-.02(1), which states that pharmacies that perform remote prescription drug order processing shall be independently licensed as a retail pharmacy by the Board and physically located within the State of Georgia. President Stone commented that the hospital has sister pharmacies out of state and the facility is requesting to process outside Georgia. He added that they did not request a waiver for Rule 480-36-.02, or ask for a waiver of section (2) of 480-36-.02, only section (1) of 480-36-.02.

Mr. Prather commented that there was a reason the Board had not allowed out of state pharmacies to do certain things because of something going wrong out of state. Director Troughton responded by stating that if it is the pharmacist and they have a Georgia license then the Board can take action on the person. He stated if they hold a non-resident pharmacy license, the Board can take action against the non-resident license. Director Troughton further stated that GDNA can investigate to the best of its ability without travel. He added that if they do not have a license that the Board is able to discipline, then they do not need to speak with GDNA.

Mr. Azzolin stated that Rule 480-36-.03(2) requires a Georgia licensed pharmacist as well. He further stated the goal is to make sure that everyone touching a prescription has a license. He added that GDNA does a routine inspection on every pharmacy in Georgia. Mr. Azzolin stated that Rule 480-36-.07 requires a posted sign in the pharmacy stating, "Remote Order Processing Utilized Here". He further stated that the secondary pharmacy is just processing the prescription from a distant location. He added that if mistake was done out of state, the Board could still pursue action against that out of state pharmacy through the non-resident pharmacy. Director Troughton commented that GDNA goes wherever the investigation takes them and presents those facts back to the Board.

Mr. Changus commented that the question is always establishing what has happened. He stated that a lot can be done electronically now and if the Board could establish the violation, it would be able to take action.

President Stone stated that a significant unique hardship must be shown in order for the Board to grant the petition. He stated that the Board has held discussion about amending its rules to make sure the citizens of Georgia are protected. He inquired as to what the hardship was in this particular case as in the past, the Board has seen where specific patient populations would be affected. Mr. David White, Pharmacist-In-Charge, Maxor Specialty Pharmacy, was on the call and spoke to the Board. President Stone inquired as to what specialty products the facility dispenses and what kind of population is serviced. Mr. White responded by stating that 80-90% of patients are pulmonary patients, with the primary patient base consisting of patients with cystic fibrosis. He confirmed that the sister pharmacies in Texas have non-resident pharmacy permits.

Mr. Page inquired as to whether any pharmacy technicians would be involved. Mr. White responded that there potentially would be. Mr. Azzolin commented that the rule does not permit the use of a pharmacy technician at the second location. Mr. Prather stated that the rules have been in effect for a long time. He further stated that he understood the changes in location. Mr. Prather commented that he thinks the Board should be very careful in changing rules that have been in place just on the back of changes in technology. He stated that he was concerned with people outside of the Board's jurisdiction.

Mr. Brinson asked Mr. White if there were any pharmacists in Texas licensed in Georgia. Mr. White responded that the Pharmacist-In-Charge for both Texas locations are licensed in Georgia, as well as the Director. Mr. Azzolin commented that the non-resident pharmacy application does not state that the Pharmacist-In-Charge had to be Georgia licensed. He added that they are meeting all the requirements of the rule except the physical location.

Mr. Changus commented that the rule waiver process was designed to provide an exception when someone has articulated a substantial hardship and there is a difficulty complying with a rule due to a unique circumstance. He stated that the Board has had this before for many pharmacies. He asked if they have articulated a unique situation or was this a situation where they think the rule prohibits their business model. Mr. Azzolin responded by stating that a waiver request has been made and that a hardship is subjective. He added that financial hardships have been a viable rule waiver

reason, and from that perspective he would argue that what they submitted was adequate. Mr. Azzolin stated that the Board started reviewing 480-36 last year and it is still not on the agenda. He further stated that he thinks the Board should address the current request and the rule. Mr. Changus responded by stating that the process had been utilized by people to address issues beyond unique hardships and just wanted the Board to have his thoughts.

President Stone commented that the Board has held discussions on this issue and it needs to consider the request presented. He added that the rules process does take some time. Mr. Cordle inquired as to how many additional pharmacists and technicians would be involved if the Board were to grant the waiver. Mr. White responded that the facility currently has six (6) pharmacists at the Lubbock location and four (4) to five (5) pharmacists at the Amarillo location due to the current workload, but normally there would be about 4 specialty pharmacists in Lubbock and 4-5 in Amarillo. He stated Amarillo largely works their own patients.

Mr. Lacefield commented that it was mentioned about what was presented in the rule wavier and the Board should only be ruling on that.

There being no further discussion, Mr. Azzolin made a motion to grant the request for a waiver of Rule 480-36-.02(1); however, it appears the facility would require a waiver of Rule 480-36-.02(2) and must submit a rule petition request for such as to not violate that rule. Mr. Brinson seconded, and the Board voted in favor of the motion, with the exception of Mr. Prather, who opposed.

Rule Waiver Petition from MedMark Treatment Centers Blairsville, PHOP000025: Mr. Brinson made a motion to grant the petition. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Pharmacy of Palmetto Health Council, Inc., PHRE009623: Mr. Brinson made a motion to grant the petition. Mr. Page seconded. Discussion was held. Mr. Azzolin commented that the petitioner requested a waiver of Rule 480-6-.01(3) and he did not see where it mentions a change of location. Ms. Emm stated that the Board can request the petition be resubmitted under the correct rule. There being no further discussion, the previous motion was withdrawn. Mr. Azzolin made a motion to deny the request and suggested the petitioner review Chapter 480-10 and resubmit an updated petition to the Board for reconsideration. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Pharmscript of GA, LLC, PHRE010776: Mr. Robert Brennan, counsel for Pharmscript of GA, LLC, and Mr. Jeff Pappas, Director of Operations, were on the call and spoke to the Board. Mr. Azzolin stated that in the past, and moments ago, the Board granted a request for a waiver of Rule 480-36-.02, but it has not previously waived Rule 480-36-.03(2) requiring a Georgia pharmacist. Mr. Pappas responded that they do have the ability to process from another state and could obtain other pharmacists that are licensed in Georgia. Mr. Azzolin inquired as to what the hardship would be as Rule 480-36-.03(2) requires the secondary remote entry pharmacy to have a Georgia licensed pharmacist on duty and physically present. Mr. Pappas responded that there would not be a hardship there.

Discussion was held. Mr. Pappas commented that Pharmscript of GA has specialized services set up in some pharmacies. He added that they have a narcotics team in New Jersey and New Jersey is the hub. He continued by stating that they have data entry on site in Georgia, but the waiver would give them the ability to approve prescriptions overnight.

President Stone inquired as to what was the patient population. Mr. Pappas responded by stating nursing homes. Mr. Azzolin asked if at any point in any of the remote processing would a prescription be processed by more than one (1) pharmacy. Mr. Pappas responded that if they

received a call requesting clarification about a script, it would be handled by customer service in New Jersey; however, if it concerns data entry, there is a possibility the prescription would be touched by multiple pharmacies but dispensed from Georgia. Mr. Azzolin stated that would be considered a violation of the rule. Mr. Pappas commented that if they can only have the prescription touched by one pharmacy, they could do that. Mr. Azzolin stated that the follow up to that is going to be an inspection and investigation. He further stated when the inspection takes place, GDNA would need to check if the prescription bounced between pharmacies. Mr. Brennan stated that Pharmscript of Georgia would be submitting non-resident pharmacy applications. Mr. Azzolin responded by stating that if they only submit the application for New Jersey, then only New Jersey could help and that would bring additional comfort level; however, if the pharmacy processed prescriptions from any other location, that would be a violation.

After further discussion, Mr. Azzolin made a motion to grant the waiver of Rule 480-36-.02(1) and (2). Mr. Chang seconded, and the Board voted in favor of the motion, with the exception of Mr. Prather, who opposed. In the same motion, the Board voted to deny the request for a waiver of Rule 480-36-.03(2).

Rule Waiver Petition from Jestine E. Collazo: Mr. Page made a motion to deny the petition. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Muhammad Zeeshan: The Board discussed this request for a waiver of Rule 480-2-.03(c)(1), which requires 1500 hours of practical pharmacy experience under the instruction of a licensed pharmacist. Mr. Page commented that none of Mr. Zeeshan's experience was in the United States. Mr. Zeeshan was on the call and spoke to the Board regarding his request. He stated that he has experience in Dubai, and more than twelve (12) years of Joint Commission International accredited hospital experience. He further stated that if the Board waived this requirement, he could take the NAPLEX and MPJE exams and pursue licensure. In regard to the hospital being Joint Commission accredited, Mr. Azzolin inquired if they match the standards in the United States. Mr. Zeeshan responded affirmatively.

Discussion was held regarding Mr. Zeeshan's financial hardship. President Stone inquired if Mr. Zeeshan wanted to move to Georgia. Mr. Zeeshan discussed the examinations he passed. He explained that it is now 2022, but he has had no opportunity to get the training because they have to sponsor his visa. He explained that a waiver is needed from the Board so he could work as a pharmacist in the United States.

After further discussion, Mr. Page made a motion to deny the petition. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA conducted 1432 inspections and received 322 complaints for FY2022.

Attorney General's Report – Max Changus

No report.

Executive Director's Report – Eric Lacefield

Invitation to 2022 ASHP Virtual Meeting of Health System Pharmacists on State Boards of Pharmacy: Mr. Lacefield reported that an invitation was received from ASHP regarding its Midyear Clinical Meeting scheduled for March 2nd. He stated that anyone wishing to participate must RSVP by Friday, February 18th.

Continuing Education Report: No report for February.

Legal Services – Kimberly Emm
No report.

Rules Discussion
Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed: Mr. Page made a motion to post Rule 480-10-.02 Prescription Department, Requirement, Supervision, Hours Closed. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

Rule 480-10-.02. Prescription Department, Requirement, Supervision, Hours Closed

(1) For the purpose of this rule, the following definitions shall apply:
   (a) "Direct supervision" shall mean that a pharmacist is physically present, providing care at the address listed on the pharmacy license, and is in the prescription department, consultation room, vaccination room, or areas where over-the-counter drugs, devices, or durable medical equipment are displayed. The supervising pharmacist is professionally responsible and accountable for all activities performed by authorized pharmacy personnel and is available to provide assistance and direction to authorized pharmacy personnel. This shall not require a pharmacist to maintain a direct line of sight to authorized pharmacy personnel. The supervising pharmacist shall provide a final check of prepared products and document final checks before any prescription drug is dispensed.
   (b) "Pharmacy care" shall mean those services related to the interpretation, evaluation, or dispensing of prescription drug orders, the participation in drug and device selection, drug administration, and drug regimen reviews, and the provision of patient counseling related thereto.
   (c) "Preparation" shall mean the functions of preparing a prescription to be dispensed, including product selection, data entry into a pharmacy dispensing system, and any other functions required to have the prescription ready to be verified, checked, and dispensed by a pharmacist or pharmacy intern working under the direct supervision of a pharmacist
   (d) "Pharmacy" shall mean all areas of a facility when the prescription department is not closed or locked separately from the facility or only the area of the prescription department in those facilities where the prescription department is locked and separated.
   (e) "Prescription Department" shall mean an area set aside for the preparation and dispensing of prescription drugs. In a facility offering other departments and types of merchandise not requiring a pharmacist to be open for business, this term shall apply only to the area in which prescriptions are prepared and dispensed.
   (f) "Vaccination room" is an area adjacent to the pharmacy where vaccinations are administered.
   (g) "Consultation room" is an area adjacent to the pharmacy where patient or customer consultations are done, and more in-depth pharmacy care may be provided.
(2) Except for ~~pharmacy benefit manager retail pharmacies and~~ retail pharmacies located in the same space as hospital pharmacies, the owner, manager**,** or proprietor of each pharmacy shall designate an area, room or rooms, which shall be known as the "Prescription Department," and which is primarily devoted to activities related to prescriptions, including preparation and dispensing.
(3) A licensed pharmacist shall be in charge of each pharmacy. His or her name shall be upon the application for the license of the pharmacy; he or she shall be the pharmacist in charge of and have supervision of not more than one pharmacy at one time; and he or she shall be

responsible and accountable for the conduction of business related to prescriptions within and access to said retail pharmacy.

(a) This regulation is not intended to prohibit any pharmacist from engaging in the practice of pharmacy at more than one pharmacy, if conducted in compliance with the other provisions of this rule and regulation.

(b) This regulation does not prohibit a pharmacist from being in charge of one separately licensed Home Health Care Pharmacy, as defined by Board Rule 480-21, and/or one Nursing Home Pharmacy, and/or one Long Term Health Care Facility Pharmacy, as both are defined in Board Rule 480-24, in addition to being in charge of a retail pharmacy, licensed under Rule 480-10, as long as each pharmacy is operated under the same ownership and is located under the same roof, provided that there is a physical separation of the two pharmacies and separate inventories are maintained for the two pharmacies.

(4) Except for ~~pharmacy benefit manager retail pharmacies and~~ retail pharmacies located in the same space as hospital pharmacies, a Licensed Pharmacist shall be present and on duty in a licensed retail pharmacy as follows:

(a) Entire business establishments which are licensed under O.C.G.A. § 26-4-110 as a pharmacy shall have a pharmacist on duty at all times the pharmacy is open for business as follows:

1. Such times when the pharmacist is absent from the pharmacy cannot exceed three (3) hours daily, or more than one and one half (11/2) hours at any one time. If a pharmacist is absent less than five minutes from the prescription department, this absence is not considered an "absence" within the meaning of this rule and will not require a posted notice, provided that the prescription department's security is not compromised.
2. In the absence of a pharmacist from the pharmacy, the area designated as the prescription department shall be closed and locked in such a manner as to prevent unauthorized entry; and
3. Whenever the pharmacist is absent from the pharmacy, a sign shall be prominently displayed on the entrance to the prescription department announcing, "Prescription Department Closed" and such sign shall be clear and legible with letters not less than three (3) inches in size.
4. The pharmacist on duty shall be responsible and accountable for the direct supervision of all personnel working in the pharmacy or prescription department. Pharmacy technicians and pharmacy interns/externs can continue preparation of a prescription when the pharmacist is in the immunization or consultation room or is providing pharmacy care services.

(b) If a pharmacy is located in a general merchandising establishment, or if the owner of a business licensed as a pharmacy so chooses, a portion of the space in the business establishment may be set aside and permanently enclosed or otherwise secured; only the permanently enclosed area shall be subject to provisions of this rule and shall be licensed as a pharmacy;

1. In such cases, the area to be licensed or registered as a pharmacy shall be permanently enclosed with a partition built from the floor to the ceiling or in a manner which meets security guidelines submitted to and approved by the Board and upon inspection by the GDNA;
2. In the absence of a pharmacist from the Prescription Department, consultation room, vaccination room, and area where over-the-counter drugs, devices, and durable medical equipment are displayed, the area designated as the Prescription Department shall be closed and locked in such a manner as to prevent unauthorized entry; and

3. Whenever the pharmacist is absent from the Prescription Department, consultation room, vaccination room, and area where over-the-counter drugs, devices, and durable medical equipment are displayed, a sign shall be prominently displayed on the entrance to the Prescription Department announcing, "Prescription Department Closed" and such sign shall be clear and legible with letters not less than three (3) inches in size.
4. If a pharmacist is absent less than five minutes from the prescription department, this absence is not considered an "absence" within the meaning of this rule and will not require a posted notice, provided that the prescription department's security is not compromised. No prescription shall be dispensed in the absence of a licensed pharmacist. The pharmacist on duty shall be responsible and accountable for the direct supervision of all personnel working in the pharmacy or prescription department. Pharmacy technicians and pharmacy interns/externs can continue preparation of a prescription when the pharmacist is in the immunization or consultation room or is providing pharmacy care services.

(5) If a retail pharmacy license and hospital pharmacy license occupy the same physical space, nothing shall prohibit one nursing supervisor from having access to the pharmacy in accordance with Board Rule 480-13-.04(8).

Rule 480-10-.06 Licensure, Applications, and Display of License and Renewal Certificate: Mr. Chang made a motion to post Rule 480-10-.06 Licensure, Applications, and Display of License and Renewal Certificate. Mr. Cordle 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~~, and shall mean every pharmacy benefit manager, as defined in O.C.G.A. § 26-4-110.1, providing services or benefits in this State that constitute the practice of pharmacy as defined in O.C.G.A. § 26-4-4~~.

(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); and
   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.

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

~~(d)~~(e) 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.

~~(e)~~(f) 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.

~~(f)~~(g) 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.

~~(g)~~(h) 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.

~~(5) Every pharmacy benefit manager providing services or benefits in this state which constitutes the practice of pharmacy as defined in Code Section 26-4-4 shall be licensed as a retail pharmacy in this state and shall comply with the provisions of 26-4-110 as required under 26-4-110.1(b).~~

Rule 480-22-.12 Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia: Mr. Brinson made a motion to post Rule 480-22-.12 Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

Rule 480-22-.12. Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia

(1) Under O.C.G.A. § 43-34-103(e.1), a physician assistant (PA) licensed by the Georgia Composite Medical Board is permitted to issue a prescription drug order or orders for any dangerous drugs, as defined in O.C.G.A. § 16-13-71, or for any Schedule III, IV, or V controlled substance without the co-signature of a supervising physician under the following conditions:

(a) The supervising physician has delegated the authority to prescribe dangerous drugs and/or controlled substances in the PA's job description on file with the Georgia Composite Medical Board.

(b) If the prescription is for controlled substances, the PA has a DEA number.

(c) If the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.

(d) The prescription drug order must include the following:

(i) The name, address, and telephone number of the supervising physician and the PA;

(ii) The patient's name and address;

(iii) The drug name, strength and quantity prescribed;

(iv) The directions to the patient with regard to taking the drug;

(v) The number of authorized refills, if any; <u>and</u>

~~(vi) A NPI number; and~~

(vi~~i~~) If applicable, the DEA permit number of the PA.

(~~d~~<u>e</u>) If the prescription is transmitted by facsimile or computer, the prescription shall include:

(i) The complete name and address of the supervising physician and the PA;
(ii) In the case of a prescription drug order for a controlled substance, the DEA registration number of the PA;
(iii) The telephone number of the PA for verbal confirmation;
(iv) The name and address of the patient;
(v) The time and date of the transmission;
(vi) The full name of the person transmitting the order; ~~and~~
(vii) The drug name, strength and quantity prescribed;
(viii) The directions to the patient with regard to taking the drug;
(ix) The number of authorized refills, if any; and
~~(x) A NPI number; and~~
(x~~i~~) The signature of the PA as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.

(e~~f~~) No prescription drug order issued by a PA can be used to authorize refills more than twelve (12) months past the date of the original drug order.

(2) Under O.C.G.A. § 43-34-25, an advanced practice registered nurse (APRN) who is recognized by the Georgia Board of Nursing as having met the requirements to engage in advanced nursing practice, and whose registered nurse license and advanced practice registered nurse license are in good standing with the Georgia Board of Nursing, is permitted to issue a prescription drug order or orders for any dangerous drugs, O.C.G.A. § 16-13-71 except for drugs intended to cause an abortion to occur pharmacologically, or for any Schedule III, IV, or V controlled substance without the co-signature of a delegating physician under the following conditions:

(a) The APRN has been delegated the authority to issue prescription for the dangerous drugs and controlled substances by a physician licensed by the Georgia Composite Medical Board in a nurse protocol agreement and that agreement has been filed with the Georgia Composite Medical Board.
(b) If the prescription is for controlled substances, the APRN has a DEA number.
(c) If the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.
(d) The prescription drug order must include the following:
(i) The name, address, and telephone number of the delegating physician and the APRN;
(ii) The patient's name and address;
(iii) The drug name, strength and quantity prescribed;
(iv) The directions to the patient with regard to taking the drug;
(v) The number of authorized refills, if any; and
~~(vi) A NPI number; and~~
(vi~~i~~) If applicable, the DEA permit number of the APRN.

(~~d~~e) If the prescription is transmitted by facsimile or computer, the prescription shall include:
(i) The complete name and address of the delegating physician and the APRN;
(ii) In the case of a prescription drug order for a controlled substance, the DEA registration number of the APRN;
(iii) The telephone number of the APRN for verbal confirmation;
(iv) The name and address of the patient;
(v) The time and date of the transmission;
(vi) The full name of the person transmitting the order; ~~and~~
(vii) The drug name, strength and quantity prescribed;
(viii) The directions to the patient with regard to taking the drug;

(ix) The number of authorized refills, if any; and
~~(x) A NPI number; and~~
(x~~i~~) The signature of the APRN as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.

(~~e~~f) No prescription drug order issued by an APRN can be used to authorize refills more than twelve (12) months past the date of the original drug order unless the prescription drug order is for oral contraceptives, hormone replacement, or prenatal vitamins. Oral contraceptives, hormone replacement and prenatal vitamins may be refilled up to twenty-four (24) months from the date of the original drug order.

(3) Nothing in this Rule, Title 16, Chapter 13 or Title 43, Chapter 34, shall be construed to create a presumption of liability, either civil or criminal, on the part of a pharmacist who in good faith fills a prescription drug order presented by a patient that had been issued by a PA or an APRN consistent with this Rule.

(a) A pharmacist shall presume that a prescription drug order issued by a PA or APRN was issued by a PA or APRN duly licensed and qualified under Title 43, Chapter 34 to prescribe pharmaceutical agents.

(b) A pharmacist shall presume that the drug prescribed by the PA is a drug approved by the supervising physician in the PA's job description and that the drug prescribed by an APRN is a drug authorized by the delegating physician in the APRN's nurse protocol agreement, unless the pharmacist has actual or constructive knowledge to the contrary.

(4) Any prescription drug order form containing less information than that described in this Rule shall not be offered to or accepted by any pharmacist.

Rule 480-24-.04 Drug Distribution: Discussion was held by Mr. Azzolin regarding the proposed language in section (7)(i) that states in part, *"Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by the Board, the GDNA or one of their agents.*" Mr. Azzolin stated that the Board does not see these and inquired as to how this processed worked. Director Troughton responded by stating that in the past, the pharmacy does not tell GDNA what type of e-kit they are using. He stated that GDNA does receive questions if they are transitioning from a tackle box or drawers to the electronic boxes. He explained that in regard to the omnicell and pyxis type kits, there will not be a paper stuck to the outside. Director Troughton stated that the electronic boxes can pull up the list with expiration dates. He explained that every time the box is opened, the report goes to the pharmacy. He stated that GDNA tells them that a pharmacist must lay eyes on the box monthly to ensure proper use and stock. Mr. Azzolin stated that he would not want a pharmacy to be fined. Director Troughton responded that if GDNA found a system that was not in compliance, it would give them a chance to make the necessary corrections.

There being no further discussion, Mr. Brinson made a motion to post Rule 480-24-.04 Drug Distribution. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule 480-24-.04. Drug Distribution

(1) Dispensing of all drugs to the facility shall be pursuant to a legal prescription drug order for an individual patient~~s~~. Standing medication orders shall not be allowed. Policies may be established by the vendor pharmacist in conjunction with the appropriate committee of the facility. All drugs supplied to the facility must be obtained from a pharmacy having a retail pharmacy permit.

(2) For use inside the facility, all drugs dispensed shall be dispensed in appropriate containers, as defined by the Food and Drug Administration and the Consumer Protection Agency, and adequately labeled with the following information:

(a) Name, address, and telephone number of the pharmacy;

(b) Date of issuance and identifying serial number;
(c) Full name of patient;
(d) Brand and/or generic name of drug, strength, and quantity dispensed;
(e) Directions for use, which may be placed on the container label or on a Medication Administration Record available and consulted at the time of the administration of each dose, provided, however, that both methods may be utilized inside a single facility;
(f) Name of physician prescribing;
(g) Required precautionary information regarding controlled substances;
(h) Such other and further accessory cautionary information as may be required or desirable for proper use and absolute safety to the patient; and
(i) Expiration date.

(3) If a unit dose drug distribution system is utilized, the above information shall be readily available on the patient medication profile. A drug distribution system in a long term care facility may be regarded as a unit dose drug distribution system if:
(a) The pharmacist maintains medication profiles on each patient and refers to these files each time a medication is filled;
(b) Doses of solid oral medications dispensed are pharmacy-prepared or manufacturer-prepared in individually packaged and sealed doses which are identifiable and properly labeled to include, at a minimum:
1. Brand and/or generic name of the drug;
2. Strength;
3. Lot number; and
4. Expiration date.
(c) Doses of medication for individual patients are placed into individual patient containers, bins, compartments, or drawers and whenever possible, are subdivided by dose and administration time and not to exceed a 72-hour supply. Drug distribution systems which exceed a 72-hour supply must follow labeling requirements of 480-24-.04(2).

(4) Partial filling of Schedule II drugs will be allowed but limited to 60 days only.

(5) Drugs added to parenteral, enteral, or irrigation solutions. Whenever any drugs are added to such solutions, whether within or outside the direct and personal supervision of a registered pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and identity of the person so adding.

(6) Prescription drug orders.
(a) Drugs may be dispensed or administered only upon orders of an authorized prescriber. For schedule II drugs refer to the Georgia Controlled Substances Act, Code Section 16-13-41, and Chapter 480-22 of the Board rules and regulations. For other drugs orders may be received by the pharmacy by fax or delivery of:
1. A direct copy of a prescription drug order;
2. Obtaining a signed prescription drug order from the prescriber; or
3. A verbal or telephone order from an authorized prescriber or duly authorized agent.
(b) The consultant pharmacist will verify orders as required by current state and federal laws, rules and regulations.
(c) For purposes of recordkeeping under this chapter, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the retail pharmacy and must be filed by the usually consecutively serial numbered prescription file or by patient name or by any other means that assures a complete, retrievable and accurate record.

Any refill information subsequently authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(3).

(7) Emergency kits. Emergency kits may be placed in licensed nursing homes by the pharmacy of the consultant or vendor pharmacist provided the following guidelines are met:

(a) A record of the drugs to be kept in an emergency drug kit be kept in the nursing home and the provider pharmacy;

(b) Drugs shall not be accessed for use from the emergency drug kit in an emergency situation without a new prescription drug order from a licensed practitioner. A valid, signed prescription drug order for any such drug must be issued to the vendor pharmacy, supplying the emergency drug kit, within 72 hours of the drug being taken from the kit.

(c) Emergency drug kits shall be stored in limited access areas and sealed to prevent unauthorized access and to insure a proper environment for preservation of the drugs therein. The provider pharmacy shall develop a method to readily determine if an emergency drug kit has been accessed without authorization;

(d) An emergency drug kit must be inventoried at least once a month by a pharmacist from the provider pharmacy and sign a card attached to the kit indicating the date it was inspected. The provider pharmacy must maintain an adequate record of such inspections.

(e) Special Agents of the GDNA shall have the authority to check emergency drug kits as well as the records in the provider pharmacy to determine that drugs and records are accurate and the emergency drug kit is being properly used;

(f) The provider pharmacy must apply on an individual basis to the Board, in care of the GDNA Director, for approval to place an emergency drug kit in each individual nursing home and a copy of this approval will be kept on file in both the nursing home and the provider pharmacy. Upon recommendation by the GDNA Director, the Board may revoke the approval for an emergency drug kit in any nursing home where abuse or misuse of drugs from the emergency drug kit is used for any purpose other than emergency purposes;

(g) The Board shall have the authority to approve on an individual basis the drugs and the amounts of each individual drug allowed to be kept in an emergency drug kit. Any change in the drugs and amounts kept in a kit must be submitted in writing to the GDNA Director who shall make recommendations to the Board. After Board approval, a copy of this approval will be maintained in the GDNA provider pharmacy file and by the nursing home. Any emergency drug kit approval becomes null and void once the approved pharmacy ceases to provide that kit.

(h) Each solid oral dosage form placed in an emergency drug kit must be individually labeled with the name and strength of the drug, lot number, expiration date, and other appropriate cautionary information; and

(i) The exterior of an emergency drug kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for "EMERGENCY USE ONLY", and the label shall be physically signed and dated by the pharmacist who sealed the kit. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents, as well as the name, address, and telephone number(s) of the provider pharmacy shall be attached to both the exterior and the interior of an emergency drug kit. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by the Board, the GDNA or one of their agents.

(8) Accountability of scheduled drugs and other specified drugs.

(a) Proof of use. Proof of use of Schedule II, III, IV and V controlled substances and such other drugs as may be specified by the appropriate committee of the facility, shall be upon proof of use forms which shall specify at a minimum:

1. Name and strength of the drug;
2. Dose and route of administration for the drug;
3. Name of ordering prescriber;
4. Name of patient;
5. Date and time of administration to patient;
6. Signature and title of individual administering, the medication; and 7. Documentation of destruction of all unused portions of single doses shall include signature verifications of two licensed authorized personnel.

(b) Container requirement. Any medication that has to be counted and accounted for with proof of use forms must be dispensed in a container that allows verification of individual doses. Containers for solid oral doses must allow identification of individual doses and individual accountability.

(9) Medications brought by patients. When patients bring drugs into the facility, such drugs shall be sent to the vendor pharmacist who shall handle these drugs in accordance with guidelines established by the appropriate committee within the facility.

Rule 480-27-.01 Definitions: Mr. Brinson made a motion to post Rule 480-27-.01 Definitions. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Rule 480-27-.01. Definitions

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

(a) Authentication. Any process by which the identities of the parties sending and receiving electronic prescription data are verified.

(b) Automated Electronic Data Processing System. A system utilizing computer software and hardware for the purpose of record-keeping and/or receiving prescription drug orders. Any and all such systems that are compatible and capable of interacting with, and electronically transferring prescription drug data with any other system must be in compliance with the rules of the Board for use in electronic prescription monitoring.

(c) Board. The Georgia State Board of Pharmacy.

(d) Computer. Programmable electronic device capable of multifunctions including but not limited to storage, retrieval, and processing of information.

(e) Controlled Substances. Those drug items regulated by federal law and/or the Georgia Controlled Substances Act.

(f) Dangerous Drugs. Those drug items and devices regulated by the Georgia Dangerous Drug Act.

(g) Digital ID. An authenticated identifiable signature than can be attached to an electronic e-mail and is tamper proof.

(h) Downtime. That period of time when a computer is not operable.

(i) Electronic Means. An electronic device used to send, receive, and/or store prescription drug order information, including computers, facsimile machines, etc.

(j) Electronic Signature. An electronically reproduced visual image signature or an electronic data signature of a practitioner, which appears on, is attached to, or is logically associated with an electronic prescription drug order.

(k) Facsimile. A hard copy prescription drug order sent via a facsimile machine.

(l) Hard Copy. A fileable prescription drug order which is written or printed via electronic means.

(m) Hardware. The fixed component parts of a computer.

(n) HIPPA. The Health Insurance and Portability and Accountability Act and the associated security standards for the protection of electronic protected health information.

(o) Intervening Electronic Formatter. An entity that is not prohibited under O.C.G.A. Section 26-4-80(c)(1) and (5), and that provides the infrastructure that connects a computer or automated electronic data processing system or other electronic device used by a prescribing

practitioner with a computer or automated electronic data processing system or another electronic device used by the pharmacy to facilitate the secure transmission of:

1. An electronic prescription drug order;
2. A refill authorization request;
3. A communication; and
4. Other patient care information between a practitioner and pharmacy.

~~(p) NPI. National Provider Standard Identifier.~~

(~~q~~p) Practitioner Drug Order. A drug order written in an institutional practice/setting in a patient's chart for a specific patient. It is not necessary to reduce to writing as required for a prescription drug order.

(~~r~~q) Prescriber. A practitioner authorized to prescribe and acting within the scope of this authorization.

(~~s~~r) Prescription Drug Order. A lawful order from a practitioner, acting within the scope of his or her license to practice, for a drug or device for a specific patient. Such order includes a written order from the practitioner, a telephone order reduced to writing by the pharmacist, and electronic image prescription drug order and an electronic data prescription drug order.

(~~t~~s) Print-out. A hard copy document generated by computer or other electronic means that is readable without the aid of any special device.

(~~u~~t) Regulatory Agency. Any federal or state agency charged with enforcement of pharmacy or drug laws and regulations, i.e., the Georgia Drugs and Narcotics Agency (GDNA), the Drug Enforcement Administration (DEA), or the Georgia Department of Medical Assistance (Medicaid).

(~~v~~u) Security Paper. Paper with security features on which the electronic visual image prescription drug order of a practitioner is printed and presented to a patient so as to ensure that a prescription drug order is not subject to any form of copying, reproduction, or alteration, and may include a watermark produced by the electronic digital process when a prescription is printed that clearly shows if a prescription has been reproduced or copied in an unauthorized manner. Such security paper shall include, at a minimum, but not limited to, the following security features:

1. A latent, repetitive pattern shall be visible across the entire front of the prescription blank if the prescription is scanned or photocopied; and
2. A chemical void protection that prevents alteration by chemical washing.

(~~w~~v) Software. Programs, procedures, and systems for receipt and/or storage of required information data.

(~~x~~w) Stop Date. In institutional settings, the practitioner normally indicates on his/her drug order, the length of time to administer the medication. In absence of such a notation, a committee will have determined by policy, the length of time to administer the medication by category.

Rule 480-27-.02 Prescription Drug Order Requirements: Mr. Brinson made a motion to post Rule 480-27-.02 Prescription Drug Order Requirements. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule 480-27-.02. Prescription Drug Order Requirements

(1) Prescription drug orders shall include, but not be limited to, the following information:
   (a) Date of issue;
   (b) Name and address of patient (or patient location if in an institution):
   (c) Name, ~~and~~ address ~~of prescriber~~, and telephone number of the prescriber~~, and NPI as assigned under federal law~~;
   (d) DEA registration number of the prescriber in the case of controlled substances;
   (e) Name, strength, dosage form and quantity of drug prescribed;
   (f) Number of authorized refills;
   (g) Directions for use by patient;

(h) If a written prescription drug order, the signature of the prescribing practitioner; and
(i) Any cautionary statements as may be required or necessary.

(2) Electronically transmitted prescription drug orders shall contain all information required for written prescriptions above and required by state and federal law including the prescriber's name, address, and phone number, except the signature may be an electronic signature as provided below and the electronically transmitted prescription must include the time and date of transmission.
   (a) Electronically transmitted prescription drug orders transmitted from the practitioner and received by a pharmacy via facsimile must contain either an electronically reproduced visual image signature or original signature of the practitioner.
   (b) Electronically generated prescription drug orders transmitted from the practitioner and received by a pharmacy as e-mails must contain an electronic data signature of the practitioner.
   (c) All electronic prescription drug orders generated by a practitioner containing an electronically reproduced visual image signature or an electronic data signature must bear wording that appears on the face of the prescription which indicates the signature was electronically generated.

(3) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists are entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from an intervening electronic for matter that comply with this rule.

(4) An electronic visual image prescription drug order that bears an electronic reproduction of the visual image of the practitioner's signature and is given directly to the patient must be printed on security paper with the wording that indicates the signature was electronically generated.
   (a) Every hard copy prescription drug order for any Schedule II controlled substance written in this state by a practitioner shall be written on security paper. If a hard copy of an electronic data prescription drug order for any Schedule II controlled substance is given directly to the patient, the manually signed hard copy prescription drug order must be on security paper.

(5) Pharmacies are prohibited from receiving electronic data from intervening electronic for matters that do not meet all of the following requirements:
   (a) Utilize recognized encrypted technology and secure servers.
   (b) Maintain HIPAA compliance.
   (c) Maintain a combination of technical and administrative security measures, such as, but not limited to those listed in Security Standards for the Protection of Electronic Protected Health Information (HIPAA), to ensure a reasonable and appropriate level of:
      1. Practitioner and dispenser authentication;
      2. Content integrity; and
      3. Confidentiality.
   (d) Refrain from collecting and disseminating patient and/or prescriber data to sources other than the originating prescriber and the receiving pharmacy.

Rule 480-27-.04 Use of Facsimile Machine to Transmit or Recieve Prescription Drug Order: Mr. Brinson made a motion to post Rule 480-27-.04 Use of Facsimile Machine to Transmit or Recieve Prescription Drug Order. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule 480-27-.04. Use of Facsimile Machine to Transmit or Rec~~i~~e<u>i</u>ve Prescription Drug Order

(1) All prescription drug orders sent via facsimile or other electronic means must meet the requirements of O.C.G.A. § 26-4-80 and Chapter 480-22 of the Board Rules and the requirements for electronically transmitted prescriptions or drug orders.

(2) All persons engaged in the practice of pharmacy in this state, which includes accepting or receiving a prescription drug order, must be licensed by the Board.

(3) All dangerous drugs and controlled substances must be dispensed pursuant only to a valid prescription drug order. A pharmacist shall not dispense a prescription drug order which the pharmacist knows or should know is not a valid prescription drug order.

(4) A prescription drug order may be accepted by a licensed pharmacist, a pharmacy intern or extern, acting under the direct supervision of a registered pharmacist, in written form, orally, via facsimile, or electronically as set forth in O.C.G.A. § 26-4-80 and the Rules of the Board. Provisions for accepting a prescription drug order for a schedule II controlled substance are set forth in Chapter 480-22.

(5) Prescription drug orders transmitted either electronically or via facsimile shall include the following requirements:

(a) Electronically transmitted prescription drug orders shall be transmitted directly by the prescribing practitioner or indirectly utilizing intervening electronic formatters as permitted under Georgia law, except in the case of a prescription drug order sent via facsimile equipment by the practitioner or the practitioner's agent acting under the direct supervision of the practitioner, to the pharmacy of the patient's choice with no other intervening person or intermediary having access to or retaining information contained in the prescription drug order. No patient or agent for a patient may transmit a prescription drug order to a pharmacy.

(b) Prescription drug orders transmitted or received by facsimile or other electronic means shall include:

1. In the case of a prescription drug order for a dangerous drug, the complete name, address and telephone number of the prescribing practitioner;
2. In the case of a prescription drug order for a controlled substance when authorized by federal law, the complete name, address, telephone number, and DEA registration number of the prescribing practitioner;
3. The complete name and address of the patient;
4. The time and date of transmission;
5. The complete name of the person transmitting the prescription drug order and a telephone number for verbal confirmation; and
~~6. The NPI for the prescriber as assigned under federal law; and~~
~~7~~6. The practitioner's signature in the manner required in 480-27-.02(2).

(c) An electronically transmitted prescription drug order which meets the requirements of this Chapter shall be deemed sufficient to serve as the original prescription drug order for the pharmacy~~;~~.

(d) Electronically generated prescriptions may be transmitted directly or indirectly thru one or more Intervening Electronic Formatters to a pharmacy's computer or other similar electronic device~~;~~.

(e) Intervening electronic formatters not compliant with the requirements of this chapter will be considered an invalid source and are prohibited~~;~~.

(f) Electronically generated prescriptions as e-mails directly from the prescriber to a pharmacy of the patient's choice shall be encrypted and accompanied by a digital ID for authentication purposes. The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists is entitled to rely

on the accuracy and authenticity of electronically transmitted prescriptions. E-mail prescriptions should comply with the following:

1. E-mails shall be reduced to hard copy and maintained as a prescription order record and maintained as required by rules and statute for all other prescription orders; and
2. The prescription may not be for a controlled substance unless allowed by federal law.

(6) The pharmacist or pharmacy intern or extern acting under the direct supervision of a licensed pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the transmitted prescription drug order consistent with Federal and State Laws and rules and regulations adopted pursuant to same.

(7) A prescription drug order electronically transmitted from a prescriber or a prescriber's agent acting under the direct supervision of the prescriber, shall be considered a highly confidential transaction, and said transmission shall not be compromised by interventions, control, change, altering, or manipulation by any other person or party in any manner whatsoever except by an intervening electronic formatter as permitted by law and these rules.

(8) Any pharmacist or pharmacy intern or extern acting under the direct supervision of a licensed pharmacist that transmits, receives, or maintains any prescription or prescription refill either orally, in writing, or electronically shall ensure the security, integrity, and confidentiality of the prescription drug order and any information contained therein.

(9) The Board may provide exceptions to this Rule by establishing policies for institutional settings such as hospital pharmacies, nursing home pharmacies, outpatient clinic pharmacies, opioid treatment program clinic pharmacies, or pharmacies owned and operated directly by health maintenance organizations.

(10) Receiving computers or other similar electronic devices used to view the prescription shall be located within the pharmacy or pharmacy department with only authorized personnel having access.

(11) Transmission of prescriptions to answering machines and electronic voice recording devices by an authorized practitioner or approved agent shall be retrieved by a licensed pharmacist, intern, or extern and is considered to be a direct transmission of a prescription order.

Rule 480-27-.05 Record-Keeping When Utilizing an Automated Data Processing System: Mr. Brinson made a motion to post Rule 480-27-.05 Record-Keeping When Utilizing an Automated Data Processing System. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Rule 480-27-.05. Record-Keeping When Utilizing an Automated Data Processing System
In order to comply with the record keeping requirements of this Chapter, an automated electronic data processing system may be utilized for the record keeping system if the following conditions have been met:

(a) Except as otherwise provided herein, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the usual consecutively serial numbered prescription file. Any refill information subsequently authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(e).

(b) The system shall at a minimum produce sight-readable records for all dangerous drug and controlled substance prescriptions filled or refilled during each 24-hour period. The term "sight-readable" means that a representative of the Board or GDNA shall be able to immediately retrieve and examine the record and read the information during any on-site visit to the pharmacy. For purposes of off-site audits and review, a separate copy of any sight-readable hard-copy printout or electronic readable file (such as a PDF file) of each

daily record shall be made available to a representative of the Board of GDNA upon verbal request by that representative. These daily prescription records can:

1. Be generated as hard-copy print-outs at least once weekly, separated into each 24-hour period, by the pharmacy and maintained for at least two years after the last date on which the prescription was filled or refilled. If a hard-copy printout of each day's filled and refilled prescription is generated, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date; or
2. Be maintained electronically. The computers on which the records are maintained may be located at another location, but the records must be immediately retrievable as hard-copy print-outs or viewing on a computer monitor set aside for such viewing at each individually registered pharmacy upon a verbal request by a representative from the Board or GDNA. The computer software must be capable of printing out or transferring the prescription records in a format that is readily understandable to the representative for the Board or GDNA at the registered location. Prescription records must also be sortable and retrievable by prescriber name, patient name, drug dispensed, and date filled. When utilizing electronic daily prescription fill and refill records, each pharmacy shall maintain a bound log-book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the prescription information entered by him or her into the computer that day has been reviewed by him or her and is correct as shown. Such a book or file must be maintained at the pharmacy employing such software for a period of two years after the date of dispensing the appropriately authorized refill.

(c) The information maintained by the automated electronic data processing system shall include, but not be limited to the following:

1. Date of dispensing;
2. Prescription number;
3. Patient's name;
4. Patient's address;
5. Drug name, strength, and dosage form;
6. Quantity prescribed, and if the quantity dispensed is different from the quantity prescribed, the quantity dispensed;
7. Prescriber's name;
8. Identification of dispensing pharmacist;
9. Indication whether drugs are being dispensed pursuant to a new prescription or for a refill order;
10. In case of a controlled substance as allowed by federal law, the name, address and DEA registration of the practitioner and the schedule of the drug;
11. Directions for administration of the prescription to the patient; and
12. Total number of refills authorized~~; and~~
13. ~~NPI of the prescriber as assigned under federal law~~.

(d) Permanent records of electronic prescriptions for dangerous drugs and controlled substances do not have to be reduced to hard copy provided the following requirements are met:

1. Electronic prescription data must be maintained in the original format received for a minimum of two years; and
2. Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1 hr. UL approved) container, stored in a secured offsite location or backed up to a documented offsite secure storage device within 48 hours following each work-day.

(e) The individual pharmacist responsible for completeness and accuracy of the entries to the system must provide documentation that prescription information entered into the computer is correct, by dating and signing the print-out in the same manner as signing a check or legal document (e.g., Mary A. Smith or M. A. Smith).

(f) An auxiliary record-keeping system shall be established for the documentation of filling new prescriptions, refills, and transfers if the automated electronic data processing system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When this automated electronic data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated electronic data processing system as soon as possible. However, nothing in this section shall preclude the pharmacist from using his/her professional judgment for the benefit of a patient's health and safety.

(g) Any pharmacy using an automated electronic data processing system must comply with all applicable State and Federal laws and regulations.

(h) A pharmacy shall make arrangements with the supplier of data processing services or materials to ~~i~~ensure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall insure continuity in the maintenance of records.

Chapter 480-36 Retail Pharmacy Requirements for Remote Prescription Drug Order Processing: President Stone requested the members review and be prepared to discuss further at the Board's March meeting.

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

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

(~~a~~1) Effective August 1, 2011, a pharmacy may only employ registered pharmacy technicians to perform pharmacy technician duties.

(~~b~~2) In order to be registered as a Pharmacy Technician in this State, an applicant shall:

(~~1~~a) Submit an application to the Board on the form prescribed by the Board;

(~~2~~b) Attest that applicant is at least 17 years old;

(~~3~~c) Attest that applicant is currently enrolled in high school, or has a high school diploma, or has a GED, or has a postsecondary education or college degree;

(~~4~~d) Consent to~~,~~ provide the necessary information to conduct, and pay for a background check to be conducted by the Board, its agent or a firm or firms approved by the Board, which background check will include a criminal history, driver license history and other information as the Board deems necessary, and will authorize the Board and the Georgia Drugs and Narcotics Agency to receive the results;

(~~5~~e) Submit the name and address of employer and place of employment;

(~~6~~f) Pay application fees; and

(~~7~~g) If certified, submit evidence of training supporting designation as certified.

(~~c~~3) The Board may deny registration or conditionally grant registration for any of the reasons set forth in Code sections 26-4-60 or 43-1-19. This includes convictions, pleas of nolo contendere and guilty pleas related to misdemeanor crimes of moral turpitude or marijuana and to felonies. In addition, no pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered as a pharmacy technician.

(~~d~~4) The denial of an application for registration as a pharmacy technician shall not be a contested case and the applicant shall not be entitled to a hearing under the Georgia

Administrative Procedures Action, O.C.G.A. T. 50, Ch. 13, but such applicant may be entitled to an appearance before the Board.

(e5) A registration, once issued, is renewable biennially, upon payment of a fee. Registrations shall expire on June 30th of each odd-numbered year. If the application for renewal is not made and the fee paid before September 1st of the odd-numbered year, the registration shall lapse and shall not be renewed. An application for a new registration shall be required.

(6) On and after July 1, 2023, as a requirement for the biennial renewal of his/her registration, a pharmacy technician must complete not less than twenty (20) hours of approved continuing education.

(a) "Approved continuing education" means courses approved by the Board as described in rule 480-3-.03.

(b) One hour of C.E. is defined as 0.1 C.E.U. Each pharmacy technician in the State of Georgia must obtain 20 hours of continuing education or 2.0 C.E.U.'s per biennium for registration renewal.

1. Certificates documenting 20 hours of approved continuing education or 2.0 C.E.U.'s must be completed and dated within the biennium.

(c) During the technician's first registration cycle,

1. A pharmacy technician registered during the first six (6) months of the biennium (January to June), shall be required to obtain 20 hours of C.E.
2. A pharmacy technician registered during the following twelve (12) months (July to June) shall be required to obtain 10 hours of C.E.
3. A pharmacy technician registered during the last six (6) months (July to December) of the biennium shall be exempt from continuing education for that biennium only.

(d) In the event of an audit and a pharmacy technician fails to submit certificates, which document his/her required continuing education credits, the Board will not process his/her request to renew the registration until the continuing education requirements are provided to the Board.

1. The pharmacy technician may not carry over continuing education credits from one registration period to the next.
2. Nothing is meant to prohibit representatives from the Georgia Drugs and Narcotics Agency (GDNA) from checking, auditing, or verifying a pharmacy technician's continuing education certificates as needed.
3. Each registered pharmacy technician shall maintain these certificates of attendance at continuing education meetings for a period of two (2) years from the date of the preceding renewal period.

(e) The staff of the Georgia Board of Pharmacy may audit, or otherwise select randomly, the continuing education of a percentage of registrants as determined by the Board.

(f7) A registrant has a responsibility to update the Board with a change of home address and employment address within ten (10) days of such change.

A motion was made by Mr. Prather, seconded by Mr. Brinson, and the Board voted that the formulation and adoption of these rule amendments does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rules 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 voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these 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.

Mr. Brinson made a motion and Mr. Chang 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, Michael Brinson, Young Chang, Cecil Cordle, Chuck Page, Bill Prather, and Dean Stone.

Executive Session

Cognizant's Report – Michael Azzolin

- GDNA Case #A34040
- GDNA Case #T34102
- GDNA Case #A34074
- GDNA Case #A34088
- GDNA Case #A34076
- GDNA Case #B33998
- GDNA Case #A33935
- GDNA Case #B34079
- GDNA Case #B34027
- GDNA Case #B34048
- GDNA Case #B34062
- GDNA Case #B34050
- GDNA Case #B34067
- GDNA Case #B34057
- GDNA Case #B33978
- GDNA Case #B34060

Georgia Drugs and Narcotics Agency – Dennis Troughton

- G.H.
- GDNA Case #A34040

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- M.P.
- C.V.S.P.
- Z.E.S.
- B.P.
- C.M.C.

Mr. Changus discussed the following case:

- GDNA Case #B33944

Executive Director's Report – Eric Lacefield

No report.

Legal Services – Kimberly Emm

No report.

Applications

- A.S.M.
- G.A.F.

- K.S.D.
- C.T.P.
- D.J.W.
- G.C.B.
- A.N.H.
- Q.I.J.
- V.M.M.
- C.N.D.
- H.A.F.

Correspondences/Requests

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

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

Open Session

Miscellaneous

Rules Information on Sharepoint: President Stone informed the members that there is a new folder on Sharepoint called "Rules Information". He stated that staff have provided information regarding the rules process and an assessment of the rules. Ms. Emm explained the rule assessment document to the members.

Newsletter: Mr. Chang explained that he and Mr. Page have put together a template for a newsletter, which could be distributed quarterly. He stated that they reached out to NABP and looked at over a dozen newsletters from other states. He explained that NABP does have a service for a fee.

Mr. Page stated that the newsletter could be a two page document and stated that email would be the best way to distribute it. He added that it could also be posted to the Board's website and sent to the associations.

Mr. Azzolin inquired about posting the newsletter on the Board's website and Twitter. Ms. Emm responded that the Board does not maintain any social media presence. She stated that an organization called Georgia Association of Medical Equipment Suppliers (GAMES) posts information for durable medical equipment suppliers.

Mr. Lacefield commented that providing a newsletter for the first quarter seemed a little rushed for him. He inquired if he would need to provide any input for the newsletter. Mr. Page responded that input may be needed from a general standpoint, and maybe during the 3rd quarter that a reminder that it is a renewal year. Mr. Chang commented that general updates would be things such as "Start thinking about your CE".

Mr. Prather inquired if the newsletters would be sent to individual emails. Mr. Page responded that he could distribute to all Kroger pharmacies. Mr. Chang stated that there is a service through NABP, but there is a cost that was prohibitive.

Mr. Azzolin asked if any member could provide suggestions or content for the newsletter. Mr. Page responded affirmatively. President Stone commented the members do not want to make it complicated. He added that they just want there to be a connection between the Board and the pharmacists. Mr. Page stated that it will be a learning process along the way.

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

Cognizant's Report – Michael Azzolin

- GDNA Case #A34040 — Accept Private Interim Consent Order
- GDNA Case #T34102 — Accept Voluntary Surrender
- GDNA Case #A34074 — Null and void permit
- GDNA Case #A34088 — Close with letter of concern
- GDNA Case #A34076 — Refer to the Department of Law
- GDNA Case #B33998 — Refer to the Department of Law
- GDNA Case #A33935 — Refer to the Department of Law
- GDNA Case #B34079 — Close with no action
- GDNA Case #B34027 — Close with no action
- GDNA Case #B34048 — Close with no action
- GDNA Case #B34062 — Close with no action
- GDNA Case #B34050 — Close with no action
- GDNA Case #B34067 — Close with no action
- GDNA Case #B34057 — Close with no action
- GDNA Case #B33978 — Close with no action
- GDNA Case #B34060 — Accept Private Interim Consent Order

Georgia Drugs and Narcotics Agency – Dennis Troughton

• G.H.	Correspondence	The Board viewed this correspondence for informational purposes only.
• GDNA Case #A34040	Correspondence	The Board viewed this correspondence for informational purposes only.

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- M.P. — Ratified acceptance of Public Consent Order
- C.V.S.P. — Public Consent Order accepted
- Z.E.S. — Private Consent Order accepted
- B.P. — Public Consent Order to be accepted and signed with express permission upon receipt of the original.

- C.M.C. Private Consent Order to be accepted and signed with express permission upon receipt of the original.

Mr. Changus discussed the following case:

- GDNA Case #B33944 Deny counterproposal

Executive Director's Report – Eric Lacefield

No report.

Legal Services – Kimberly Emm

No report.

Applications

• A.S.M.	Pharmacy Technician	Table pending receipt of additional information
• G.A.F.	Pharmacy Technician	Approved for registration
• K.S.D.	Pharmacy Technician	Approved for registration
• C.T.P.	Pharmacy Technician	Approved for registration
• D.J.W.	Pharmacy Technician	Denied registration
• G.C.B.	Pharmacy Technician	Table pending receipt of additional information
• A.N.H.	Pharmacy Technician	Approved for registration
• Q.I.J.	Pharmacy Technician	Approved for registration
• V.M.M.	Pharmacy Technician	Table pending receipt of additional information
• C.N.D.	Pharmacist Reinstatement	Table pending receipt of additional information
• H.A.F.	Pharmacist Reinstatement	Schedule to meet with the Board

Correspondences/Requests

• P.H.P.	Notice of Discipline	No action
• A.H.G.I.	Notice of Discipline	No action
• M.D.I.	Notice of Discipline	No action
• G.U.S.A.S.	Notice of Discipline	No action
• S.I.	Notice of Discipline	No action
• J.J.S.	Request to lift PIC restriction	Approved request
• J.L.A.	Appearance request	Denied request
• N.L.F.	Appearance request	Denied request
• M.E.M.	Appearance request	Approved request
• G.A.T.	Request to terminate probation	Approved as of 02/21/2022
• S.P.C.	Correspondence	Board directed staff to respond by stating that individual can send list signed by the pharmacist on duty.
• L.I.T.	Correspondence regarding Policy 3A	Board directed staff to respond by stating that hours are acceptable as long as they are completed under the direct supervision of a pharmacist.
• U.O.U.	Correspondence	The Board viewed this correspondence for

		informational purposes only.
• J.B.P.	Request for 4th attempt to retake MPJE	Approved request
• V.G.H.	Request for 4th attempt to retake MPJE	Approved request

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

There being no further business to discuss, the meeting was adjourned at 1:54 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, March 16, at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6th floor, Atlanta, GA 30303.

Minutes recorded by Kimberly Emm, Attorney
Minutes edited by Eric Lacefield, Executive Director