### GEORGIA BOARD OF PHARMACY

### 2 MLK Drive SE, 11<sup>th</sup> Floor, Atlanta, GA 30334 Minutes for May 21, 2025 Board Meeting

**Board Members present:** 

Cecil Cordle, PharmD, President Young Chang, Vice-President Michael Azzolin, PharmD

Michael Brinson

Jim Bracewell Young Chang Michael Farmer

Chuck Page

Dean Stone

**Board Staff present:** 

Clint Joiner, Executive Director Michael Karnbach, Director, GDNA, Alec Mathis, Deputy Director, GDNA

Rick White, Special Agent

Itovia Evans, Deputy Director of Licensing Dowlin Ryals, Assistant Attorney General Angela Johnson, Board Administrative

Secretary

**Visitors:** 

Brad Bolton, Cardinal Health NPHS

Heather Hughes, Publix Lauren Paul, CVS Healthcare Mike Duncan

Mark Clayton

Brandon Brooks, Publix Diane Sanders, Kaiser Permanente

Gau Soua Yang, GPhA

Trent Nesbit, McKesson

Cindy Jarret, Walmart

Patrick Gutherie, Impact Public Affairs

Jordan Khail, UGA

Jaclyn Howard, ElderCare Pharmacy Amanda Kiner – Green Acres Wellness Michelle Blalock, Cardinal Health NPHS Brad Bolton, Cardinal Health NPHS

Helen Sloat – Nelson Mullins Ben Wright – The Hudson Group

Tessa Dimick, UGA Veterinary Teaching

Hospital

Cindy Dyer, Northeast Georgia Rehab Institute

Jennifer, Sain - Walgreens

### **Open Session**

President Cordle established that a quorum was present and called the meeting to order at 8:08 a.m.

Mr. Page made a motion to enter into the Executive Session and Mr. Stone seconded, and the Board voted to enter into Executive Session.

At the close of the Executive Session, President Cordle declared the meeting to be back in Open Session.

President Cordle greeted the members of the public who were present.

### **Approval of Minutes**

Mr. Farmer made a motion to approve the Open and Executive Session minutes from the April 9, 2025, meeting. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

### **Report of Licenses Issued**

Director Joiner reported that the Board has issued 588 licenses since the last meeting and that 2,386 licenses have been issued year-to-date. Mr. Farmer made a motion to ratify the list of licenses issued. Mr. Stone seconded, and the Board voted unanimously in favor of the motion

### **Petitions for Rule Waiver or Variance**

Northeast Georgia Rehabilitation Hospital LLC – Rules 480-13-.05(2)(b) (1) and 480-11-.04(3)(b)(1) Request for waiver of rule regarding Laminar airflow hood.

Mr. Stone advised that this facility is requesting a waiver of Rules 480-13-.05(2)(b) (1) and Rule 480-11-.04(3)(b)(1) and is requesting to go to an immediate use model for compounding and that the laminar flow hood requirement be waived.

This facility submitted an incomplete waiver request at the April 9, 2025 meeting and the Board determined that Northeast Georgia Rehabilitation Hospital will need to submit a new waiver request with the correct rules.

Mr. Stone made a motion to approve the request for waiver of Rules 480-13-.05(2)(b) (1) and Rule 480-11-.04(3)(b)(1). Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

**River Edge Crisis Services Pharmacy** – Rules 480-13-.05(2)(b) (1) and 480-11-.04(3)(b)(1) Request for waiver of rule regarding Laminar airflow hood.

Mr. Stone advised that this facility is requesting a waiver of Rules 480-13-.05(2)(b) (1) and Rule 480-11-.04(3)(b)(1) and is requesting to go to an immediate use model for compounding and that the laminar flow hood requirement be waived.

Mr. Stone made a motion to approve the request for waiver of Rules 480-13-.05(2)(b) (1) and Rule 480-11-.04(3)(b)(1). Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Three Rivers Recovery and Wellness, LLC (formerly known as Platinum Recovery, LLC.) – Rule 480-18-.05(1). Request to waive the Physical Requirements and Equipment rule.

Mr. Stone asked if anyone was present from Three Rivers Recovery and Wellness. It was established that a representative was not present. This facility is requesting a waiver of the rule regarding the physical requirements of the facility. The new facility is limited to 110 square feet. The facility advised that the Board had granted a similar request when the facility was known as Platinum Recovery, LLC.

Director Karnbach advised that GDNA did a site inspection of the new facility last week and did not see any problems approving this request. Mr. Stone made a motion to approve the request for waiver of Rule 480-18.05(01). Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

### **Correspondences**

## Letter from Jillian Fuhs with Eli Lilly & Company – Moujaro and Zepbound and Patient Safety Concerns

Mr. Page asked if anyone was present from Eli Lilly & Company. It was established that a representative was not present. Mr. Page gave a brief overview of the correspondence.

This letter from Eli Lilly and Company addresses concerns regarding the mass manufacturing, production, dispensing, promotion, and sale of compounded tirzepatide. Eli Lilly requests the Board's continued assistance in protecting Georgia patients from unlawfully compounded prescription drugs.

Mr. Brinson commented that many pharmacies are still seeing shortage of medications that contain tirzepatide.

Director Karnbach reminded everyone that while the Board regulates pharmacies for compliance with state rules, this compliance does not automatically equate to compliance with federal law, specifically FDA guidelines on compounding. Pharmacies are expected to adhere to both state and federal regulations. He added that Georgia's rules do not conflict with federal law but may not be as stringent. Therefore, state inspections do not certify a pharmacy's compliance with FDA guidelines.

Director Karnbach suggested that Eli Lilly's concern about pharmacies potentially violating federal law falls under the FDA's investigative purview, though the state board would investigate specific complaints regarding Georgia law and rules. The FDA is responsible for investigating federal law compliance.

Mr. Farmer raised a question regarding the process and potential impact of a drug company seeking to place its products on the FDA's Demonstrable Difficulties for Compounding (DDC) list. He asked if GDNA plays a role in companies applying for DDC status, and what federal changes, if any, would occur if these drugs were approved for the list. His core question was whether acknowledging 'demonstrable difficulties' for these drugs would alter their regulation or availability.

Director Karnbach replied that this is a legal matter, and that his first impression is that if a drug is placed on the DDC list, Georgia pharmacies would likely be prohibited from compounding it. He felt that this would be a definitive resolution.

The Board reviewed the correspondence and agreed it was for informational purposes only, requiring no further action at this time. The Board confirmed they would continue to investigate compounding allegations as complaints.

### **Email from Mark Clayton – Treatment and Advocacy Services Providers**

This email contains additional information, requested by the Board, supplementing the material previously provided by Mr. Clayton. Please consider it for upcoming discussions about technician reinstatement.

#### Email from Omolola Otubaga – Requesting Board to Reconsider Request

Ms. Otubaga is a nurse practitioner who is having difficulty ordering medications and was seeking board approval or guidance after being referred by the DEA. Mr. Page asked if Ms. Otubaga was present. It was established that she was not present.

At the November 7, 2024, meeting, the Board advised staff to respond to Ms. Otubaga's request that the Board is a state licensing board, responsible for licensing pharmacists and pharmacies, and for regulating the practice of pharmacy in the State of Georgia. This Board does not regulate medical practices or the practice of medicine. The Board suggested that she contact the Georgia Composite Medical Board for additional input on this matter.

The Board clarified that this is a Medical Board issue, not a Pharmacy Board issue, as it pertains to the nurse practitioner's authority to possess and administer drugs in the office, especially if a protocol is set up with a physician.

Mr. Page directed the Board Staff to respond to the correspondence as discussed.

### Georgia Drugs and Narcotics Agency – Mr. Michael Karnbach

Director Karnbach introduced Special Agent Rick White.

Director Karnbach reported that GDNA has conducted 3,202 inspections year-to-date and received 432 complaints year-to-date. He noted that while complaints (432) are slightly down compared to last

year's 459, inspections have increased significantly (3,202 this year versus 2,809 last year).

### Attorney General's Report - Mr. Dowlin Ryals

No Report.

### **Executive Director's Report - Mr. Clint Joiner**

No Report.

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

No Report.

### Miscellaneous

### Presbyterian Village Pharmacy Austell – Key Lockbox Request

President Cordle asked if anyone was present on behalf of Presbyterian Village Pharmacy Austell. It was established that a representative was not present.

Presbyterian Village Pharmacy Austell requested permission to use a lock box to store the entry key for the pharmacy located at 2000 East-West Connector, Austell, Georgia and provided documentation for the request. The Board reviewed the documentation provided and discussed this correspondence. Director Karnbach advised that GDNA did not see any problems approving this request. The Board approved the request.

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

### Presbyterian Homes of Quitman - Key Lockbox Request

President Cordle asked if anyone was present on behalf of Presbyterian Hones of Quitman. It was established that a representative was not present.

Presbyterian Homes of Quitman requested permission to use a lock box to store the entry key for the pharmacy located at 1901 W. Screven Street, Quitman, Georgia and provided documentation for the request. The Board reviewed the documentation provided and discussed this correspondence. Director Karnbach advised that GDNA did not see any problems approving this request. The Board approved the request.

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

Rare Disease Research – Request for Board Approval of Clinical Research Pharmacy Internship Program - Christian Hanson submitted a Clinical Research Pharmacy Internship Program Outline for the Board's approval. The Board reviewed the submission and discussed the request.

President Cordle asked if anyone was present on behalf of this request, and it was confirmed that no representative was present. Several members questioned the program's validity and why the request was being brought before the Board for approval.

The Board suggested that Mr. Hanson and his preceptor, Dr. Darwin Nguyen, present the proposal to the Board to provide clarification on their questions. President Cordle directed the Board Staff to respond to the correspondence as discussed.

### **Piedmont Healthcare Encompass Health Rehabilitation Hospital of Newnan** - Remote Order Entry Request

This facility submitted its remote pharmacy information along with policy and procedures for remote pharmacy services requesting approval for the implementation of remote pharmacy services for the Rehabilitation Hospital in Newnan.

The Board reviewed the documentation provided and discussed this correspondence. It was determined that the Board did not see any problems with the request.

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

# **Piedmont Healthcare Encompass Health Rehabilitation Hospital of Henry** - Remote Order Entry Request

This facility submitted its remote pharmacy information along with policy and procedures for remote pharmacy services requesting approval for the implementation of remote pharmacy services for the Rehabilitation Hospital in Henry County.

The Board reviewed the documentation provided and discussed this correspondence. It was determined that the Board did not see any problems with the request.

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

### **Work Session**

• **Rule Amendment**: Laminar Flow Hood requirement for pharmacies adopting "immediate use model" for compounding.

Rules:

- R. 480-13-.05(2)(b)(1)
- R. 480-13-.06(2)(a)
- R. 480-11-.04(3)(b)(1)

Director Joiner requested that the Board defer discussion until a committee could be assigned to develop a draft. This draft would serve as a basis for future discussion. The Board subsequently decided to appoint a committee to draft a proposed rule for future discussion. Dr. Azzolin and Mr. Stone agreed to assist Director Joiner.

- **Discussion/Update HIPAA Reproductive Privacy Rule**: The HIPAA Reproductive Privacy Rule presents ongoing challenges for investigations and inspections. It was clarified that while the rule introduces procedural "bumps," it does not ultimately prevent inspections, as it can be "overwritten" when necessary information is required. The Board determined not to take any action at this time and GDNA will bring it back as a case should it become a problem.
- **Rule Amendment**: Review of Pharmacy/Pharmacist language in R. 480-24-.06, tabled from December 2024 meeting.

Director Joiner suggested the Board postpone discussion until a committee was formed to develop a preliminary draft. The Board agreed, assigning Mr. Chang and Mr. Farmer to this committee to prepare the proposed rule.

- **Policy Review**: Review of Misfill Policies
  Policies that provide guidance for board decisions are being reviewed periodically to ensure they align with current objectives. The Board reviewed the current policies and had no
  - they align with current objectives. The Board reviewed the current policies and had no changes.

• Rule Adoption: Pharmacy Smart Lockers – Secure Prescription Pick-up Lockers (SPPL)

This discussion was a continuation of conversations from the Board's December 2024 and January 2025 meetings regarding the regulatory framework for smart lockers. A proposed draft rule introducing a new chapter to the regulations was presented for review.

Director Karnbach sought clarification on whether the intent of the proposed rule remained consistent with earlier discussions—specifically, that the SPPLs would be physically connected to an operating pharmacy. He also asked whether the Board intended to require separate licensure for these lockers apart from the pharmacies themselves.

The Board confirmed that its intent is for SPPL to be located within and physically attached to an operational pharmacy, sharing the same building and address.

Mr. Brinson commented that the original concept limited SPPL use to secure, controlled environments within pharmacy operations, accessible only to hospital personnel. He noted that the current draft could allow for broader and possibly less secure use cases.

Director Karnbach further pointed out that the proposed rule does not currently prevent one pharmacy from dispensing medications prepared by another pharmacy. He suggested the Board consider adding language to address this. In response, Dr. Azzolin recommended including a provision that only prescriptions filled by the licensed holder of the SPPL may be dispensed through the locker.

The Board also discussed whether a standalone pickup locker, unaccompanied by a fully operational pharmacy, would be permissible under the new rule. If such setups are not intended to be allowed, it was agreed that the rule must clearly state this.

President Cordle noted that North Carolina permits secure locker or kiosk systems for prescription pickup. He specified that these off-site units require licensing and must be within 60 miles of the home pharmacy, suggesting this model could help address "pharmacy deserts" in rural Georgia.

Concerns were also raised regarding potential criminal activity associated with the use of SPPLs. President Cordle observed that the widespread use of ATMs demonstrates how institutions have effectively secured their physical locations. He commented that if banks can secure ATMs for cash, the pharmacy industry should certainly be able to develop secure smart lockers for prescriptions.

The Board discussed whether the units themselves would be licensed or if the Board would issue permits. Mr. Farmer expressed concerns about the administrative burden that could arise from having to inspect and license potentially numerous off-site locker locations, noting the strain this would place on resources and staff workload.

Director Karnbach advised that GDNA would need to inspect the units. Dr. Azzolin suggested that the Board handle the requests in the same manner as it handles lockbox requests: the licensee would submit a request to the Board, GDNA would perform the inspection, and the Board would vote to approve or deny it. Director Karnbach expressed support for the idea of handling these units similarly to how the Board manages lockbox requests.

There was deliberation about whether to proceed with approving the current draft or continue revising it. The consensus was that the draft was only about 30% complete and required further work.

Mr. Stone recommended reviewing how other states—such as North Carolina, South Carolina, Texas, and Washington—regulate smart locker systems.

Dr. Azzolin proposed forming a subcommittee to further develop the rule. In the interim, he suggested the Board consider SPPL applications on a case-by-case basis until the regulation is finalized.

Mr. Brinson made a motion to table the discussion and allow a subcommittee to gather additional information and present recommendations to the Board. Mr. Page seconded the motion. The Board voted in favor, and a subcommittee was formed. Mr. Brinson and Mr. Page volunteered to lead the project, and Director Karnbach offered to assist with drafting the revised language.

• **Rule Amendment:** "Hospital at home" Rule(s) 480-13-.01, 480-13-.11 & 480-13-.12

Director Joiner stated that the Board has explored several potential definitions for "hospital" but hasn't reached a consensus. While the DCH and DPH definitions have been discussed in meetings, the current draft proposes the definition from O.C.G.A. § 31-6-2 as a starting point. He noted this statutory definition is crucial because the Board's definition cannot be broader, and it's also the basis for the DCH and DPH definitions.

### **Rule 480-13-.01 Definitions** (Proposed changes)

For purposes of these Rules and Regulations, the following definitions apply As used in this chapter, the term:

- (1) "Hospital" Hospital. As defined by the Department of Human Resources; means any building, facility, or place in which are provided two (2) or more beads and other facilities and services that are used for persons received for examination, diagnosis, treatment, surgery, or maternity care for periods continuing for twenty-four (24) hours or longer and which is classified by the department as a hospital.
  - a. As it is used in this chapter, the term "hospital" shall also include:
    - 1. Federally designated Rural Emergency Hospitals.
- (2) "Hospital pharmacy." Hospital pharmacy is defined as means that portion of a hospital facility which is engaged in the manufacture, production, sale and distribution of drugs, medications, devices, and other materials used in the prevention, diagnosis and treatment of injury, illness and disease (hereinafter referred to as "drugs"); and which is registered with the State Board of Pharmacy pursuant to O.C.G.A. § 26-4-110;
- (3) <u>"Hospital pharmacy license." Hospital pharmacy license shall mean means</u> a pharmacy license issued by the Georgia State Board of Pharmacy to <u>said</u> hospital pharmacies, which license is subject to special hospital pharmacy regulations as set forth herein, but <u>exempt from other certain regulations and requirements</u> pursuant to the provisions of O.C.G.A. <u>§</u> <u>Sections</u> 26-4-27, 26-4-28, and 26-4-110. <u>whereas the licensee shall be</u>

- subject to special hospital pharmacy regulations as set forth herein, but exempt from other certain regulations and requirements. To obtain the hospital pharmacy license, there must be employed a Director of Pharmacy.
- a. The Board authorizes the holder of a hospital pharmacy license to service patients of Nursing Homes, Long Term Care Facilities or Hospices as long as these entities are under the same ownership as the hospital pharmacy; however, such entities can only be serviced by the hospital pharmacy subject to the requirements as set forth by Georgia State Board of Pharmacy Rules 480-24, the rule for providing services to nursing homes, long term care facilities, and hospices. The hospital pharmacy is prohibited from maintaining standard ward (Floor Stock) inventories in such entities, but, it would allow the hospital pharmacy to supply emergency kits.
- (4) <u>"In-patient" means</u>. <u>In-patient shall mean a patient who is confined to the hospital a person admitted to a hospital for an intended length of stay of twenty-four (24) hours or longer;.</u>
- (5) "Out-patient." Out patient shall mean means a patient who is not an in-patient, including patients on leave of absence;
- (6) <u>"Remote Location"</u> Remote location shall mean means a location away from the hospital or hospital pharmacy located within the United States where a pharmacist reviews and enters patient specific prescription drug orders for a hospital's patients.
- (7) "Remote Order order Entry entry". Remote order entry shall mean means the entry of information into a hospital's patient record system made by a a pharmacist licensed in this state, who is an employee or contractor of either a pharmacy licensed in this state or a pharmacy that holds a Georgia nonresident pharmacy permit issued pursuant to Code Section 26-4-114.1 Remote Order Entry Pharmacist from a remote location anywhere in the United States indicating that the pharmacist has reviewed the patient specific drug order for a hospital patient, and has approved or disapproved the administration of the drug for to said patient. and has entered the information in the hospital's patient record system.
- (8) "Remote Order Entry Pharmacist". A remote order entry pharmacist shall mean means a pharmacist licensed in this state a pharmacist who is licensed to practice pharmacy in the State of Georgia, who is at a remote location located within the United States, who is an employee or contractor of a pharmacy licensed in this state or a pharmacy that holds a nonresident pharmacy permit issued pursuant to Code Section 26-4-114.1, and who is under contract with or employed by the hospital to review and enter patient specific prescription drug orders for hospital patients when the hospital pharmacy is closed.
- (9) "Standard ward inventory." means a stock of legend drugs kept at one or more locations within the hospital, for which the Director of Pharmacy has established a list of the kind and quantity of legend drugs to be always kept at such location(s). The Director of Pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of legend drugs to be kept at one or more locations at all times within said hospital and such stocks of legend drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy or his/her pharmacist designee. A standard ward inventory may be placed on an emergency vehicle licensed with the State Department of Human Resources. A contract or agreement must be signed between the hospital and the ambulance service and filed with the Department of Human Resources Licensure Division and the Georgia Drugs and Narcotics Agency (GDNA) before any legend drugs may be placed on said licensed vehicle. An agreement can be made with only one hospital.

Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-80, 26-4-83, 26-4-84, 26-4-110.

The Board had discussion on the ongoing issue with the broadness of the current definition of "hospital" and "inpatient" in the regulations related to pharmacy precludes or doesn't adequately cover "Hospital at Home" programs. These programs allow patients to receive hospital-level care in their homes, a model encouraged by CMS (Centers for Medicare & Medicaid Services) which even offers financial incentives for Rural Emergency Hospitals that operate without inpatient beds but provide emergency and observation services. Dr. Azzolin mentioned that Rural Emergency Hospitals need this this redefinition. These are federally designated facilities that do not have inpatient beds but receive significant funding and benefits from CMS. The current definition of "hospital" causes problems for Rural Emergency Hospitals in accessing certain state-level benefits because they don't fit the traditional "hospital" mold.

There is also concern that the definition could allow entities that are not real hospitals (e.g., mental health facilities, detox facilities, or facilities that only want floor stock) to obtain hospital pharmacy permits without necessarily having a pharmacist on-site for 40 hours a week.

Dr. Azzolin commented that DCH's definition is more appropriate, as it is broader in scope. He suggested removing the phrase "and which is classified by the department as a hospital" from Section 1.

The proposed solution involves using an alternate definition, with an additional change to include entities such as rural hospitals and possibly creating subtypes of permits. Changes were made to Rule 480-13-.01 by splitting the permissive and prescriptive language into new rules—480-13-.11 and 480-13-.12—for organizational purposes and are not changes to the rule.

### Rule 480-13-.11 Service of Facilities Under Common Ownership

- (1) The holder of a hospital pharmacy license shall be authorized to service patients of nursing homes, long term care facilities or hospices under the same ownership as the hospital pharmacy.
  - (a) Such entities shall be serviced by the hospital pharmacy subject to the requirements of the rules in Chapter 480-24.
- (2) A hospital pharmacy shall not maintain any standard ward inventory or "floor stock" in any nursing home, long term care facility or hospice.
  - (a) This prohibition shall not apply to the maintenance and supply of emergency kits in such facilities by the hospital pharmacy.

Director Joiner requested the Board review the proposed Rule 480-13-.12, noting its language was extracted from the original definitions section. Director Karnbach then recommended removing the reference to a signed contract or agreement must be filed with the Georgia Drugs and Narcotics Agency (GDNA) from the rule's text.

Dr. Azzolin identified a conflict between Rule 480-24-.04(1) and 480-13-.11. He proposed revising the language in Rule 480-24-.04(1) to state: 'All drugs supplied to a facility must be obtained from a pharmacy holding a retail permit, except as permitted in Rule 480-13-.011'.

### 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. 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.

### Rule 480-13-.01 (Current language)

(i) Standard ward inventory. The Director of Pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of legend drugs to be kept at one or more locations at all times within said hospital and such stocks of legend drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy or his/her pharmacist designee. A standard ward inventory may be placed on an emergency vehicle licensed with the State Department of Human Resources. A contract or agreement must be signed between the hospital and the ambulance service and filed with the Department of Human Resources Licensure Division and the Georgia Drugs and Narcotics Agency (GDNA) (emphasis added) before any legend drugs may be placed on said licensed vehicle. An agreement can be made with only one hospital.

### Rule 480-13-.12 Standard Ward Inventories and Drug Inventories Maintained on Emergency Vehicles

- (1) The Director of Pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of legend drugs to be always kept at one or more locations within said hospital and such stocks of legend drugs shall be known as standard ward inventory.
  - (a) The use of standard ward inventory shall be minimized.
- (2) A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy.
- (3) A standard ward inventory may be placed on an emergency vehicle licensed with the State Department of Public Health.
  - (a) A contract or agreement must be signed between the hospital and the ambulance service and filed with the Department of Public Health and the Georgia State Board of Pharmacy prior to placement of any legend drugs on said licensed vehicle.
  - 1. Such an agreement may be maintained with only a single hospital at any one time.

Dr. Azzolin highlighted an inconsistency: some rules reference areas defined by the Department of Public Health, while others refer to the Department of Community Health or Department of Human Resources. He suggested this would be an opportune time to standardize the language across these rules. Director Joiner concurred, agreeing these are additional areas requiring revision.

Director Karnbach was concerned that Rule 480-13-.06(3)(b) does not adequately address the prescription labeling issue.

### Rule 480-13.06(3)(b)

For use outside the hospital, all drugs dispensed by a hospital pharmacy to patients about to be discharged or on leave of absence shall be labeled with the following information:

The Board discussed possible ways to change the language. Dr. Azzolin suggested modifying the language to state: "For use outside the hospital, all drugs dispensed by hospital pharmacies shall be labeled with the following," or something similar.

The Board agreed that more time is needed to determine the best course of action. Mr. Stone made a motion to table the discussion until the Board can review the wording more closely. Mr. Brinson seconded the motion, and the Board approved the motion.

- **Policy Review**: Evaluation of Board's Fee Schedule. The Board reviewed the current polices and had no changes.
- **Rule Adoption**: Nullification and Voiding of DME License upon relocation Rule 480-7B-.02(5)(d)
  - d. <u>Licenses issued pursuant to this Rule shall immediately become null and void upon</u> written notification to the Board from the Georgia Drugs and Narcotics Agency that upon attempted inspection, routine or otherwise, of an entity licensed under this Rule, GDNA has determined that the licensed entity is not located at its licensed address.
    - 1. Written notification under this section shall be made to the Board's Executive Director, or his or her designated agent, by the Director of the GDNA or his or her designated agent.

Building on the policy articulated by the Board in December, this rule provides its direct translation. The Board has completed its review of the rule's language.

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

- **Rule Adoption**: Clarification of O.C.G.A. § 26-4-80(1) language, re: C-II identification requirement
  - o Relevant statute:

O.C.G.A. § 26-4-80(1)

• "... A pharmacist shall require a person picking up a Schedule II controlled substance prescription to present a government issued photo identification document or such other form of identification which documents legibly the full name of the person taking possession of the Schedule II controlled substance subject to the rules adopted by the board."

The Board pushed this discussion for a later date.

• Rule Adoption & Amendments: Drone Delivery Rule(s) 480-48-.01, 480-48-.02, 480-48-.03

This discussion was continued from conversations at the December 2024 and January 2025 meetings regarding the regulatory structure for drone delivery and edits to the existing rule regarding delivery by pharmacy. A proposed draft of the new rule and rule amendment were presented to the Board.

Due to the multifaceted nature of the proposed rule drafts and amendments, the board reviewed them and opted to establish a subcommittee. This subcommittee will delve into the complexities of the various areas requiring consideration. Additionally, it will be tasked with researching regulations in other states and obtaining updates from those with existing drone prescription delivery pilot programs.

Mr. Page and Mr. Farmer agreed to review the material further and will present their suggestions and updates to the Board.

### Discussion: Remote entry work for Pharmacy Technicians

The Board discussed recent Pharmacy Technician applications, including a meeting with an applicant to clarify the specifics of remote Pharmacy Technician duties.

The Board acknowledged that this initiative is driven by the desire to streamline workflow, reduce patient therapy delays, and significantly improve patient safety. However, the Board does have concerns about how these advancements would be achieved while still maintaining direct pharmacist supervision and a final verification step.

To address these concerns, the Board agreed that reviewing existing regulations and researching how other states manage similar arrangements would be necessary. President Cordle noted that this is an initial discussion, and the most effective way to proceed would be to establish a committee to thoroughly explore and potentially implement this concept. Mr. Stone and Dr. Azzolin have committed to investigating the issue further.

Rule Amendment: Repeal of Central Fill Signage Rule 480-10A-.08
 Following the board's discussion and decision from the previous meeting, Director Joiner revised this rule, eliminating the signage requirement when central fill is used.

### Rule 480-10A-.08. Notification to Patients [Repealed]

An originating pharmacy that utilizes central filling services must, prior to outsourcing the prescription, notify patients that prescription filing may be outsourced to another pharmacy. The patient shall have the choice to not have the prescription outsourced.

Notification may be provided through the use of a sign located in the originating pharmacy which is clearly visible to and readable by the public.

Authority: O.C.G.A. § 26-4-60.

Dr. Azzolin made a motion to post the Rule. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

Mr. Stone made a motion and Mr. Brinson 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 in 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.

President Cordle and Mr. Brinson thanked the visitors for their patience, as the meeting ran longer than usual. President Cordle also reminded everyone to sign in and provide their NABP e-Profile number to receive credit for attending, which counts towards the live continuing education requirement.

President Cordle asked if anyone had any questions or comments. President Cordle reminded everyone that the next scheduled meeting of the Georgia State Board of Pharmacy will also include an agency review which will be held on Wednesday, June 18, 2025 at 9:00 a.m. at the Board's office located at 2 Martin Luther King Jr Drive SE, East Tower, 11<sup>th</sup> floor, Atlanta, GA 30334.

He requested that any department or member of the public that wishes to be added to an upcoming meeting must submit the information prior to the Wednesday before the scheduled meeting to be considered for the agenda. He thanked the public for their attendance and participation.

Mr. Bracewell 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**

**Appearances:** A.J.W. M.K.D

Georgia Drugs and Narcotics Agency - Mr. Michael Karnbach

Cognizant's Report – Mr. Young Chang

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A35718	B35464	B35567	B35570	B35605
B35666	B35645	B35763	B35616	B35522
B35574	B35578	B35579	B35598	B35599
B35614	B35646	B35656	B35548	

Attorney General's Report - Mr. Dowlin Ryals, Assistant Attorney General

### Mr. Ryals presented the following consent orders for acceptance:

B.H.P.	C.I.	M.L.D.	A.H.D.	A.R.L.
C.D.	M.C.P.	E.M.L.	W.G.	C.C.P.

**Status Open Cases** 

C.P.S.	E.H.	R.C.P.	E.S.P.	A.H.	P.A.J.
V.P.L.	P.S.I.	B.T.Y.	W.P.	C.H.E.D.L.	R.C.P.
C.C.P.	W.P.	C.P.	C.P.		

### **Executive Director's Report** – Mr. Clint Joiner

No Report.

### Legal Services - Mr. Clint Joiner

No Report.

**Applications** 

L.J.	H.B.	S.J.	H.S.	C.F.	J.D.O.
C.H.	M.M.	L.N.	M.B.	J.W.S.	N.N.
A.R.	T.T.	M.D.	B.S.	J.M.	N.S.
L.K.	T.J.	T.G.L.	D.C.S.		

### Correspondences/Requests

C.E.	K.B.	C.B.	G.H.	R.H.	K.J.
K.K.	C.C.	R.M.	S.E.	A.S.	J.H.
B.G.	M.M.				

At the close of the Executive Session, President Cordle declared the meeting to be back in Open

### **Open Session**

Mr. Page made a motion for the Board to take the following action:

Cognizant's Report

GDNA	Licensee	Recommendation
Case #		
A35718	M.A. / J.D.M. / V.H.Q.	Referral to AG's Office for Private Consent Order
B35464	C.P. / S.W.R.	Letter of Concern to Pharmacist
B35567	W.G. / T.A.T.P.	Misfill Guidance #1A
B35570	B.B.B. / A.M.S.C.O.	Cease & Desist; Flag application for consideration of sanction
B35570	R.H.B. / S.L.V.	Close & refer the case to Composite Medical & Nursing Board
B35605	S.D.C.I. / M.P.L. / L.M.G.	Letter of Concern to Pharmacist
B35666	V.R.D. / C.H.B. / E/T/R/	Referral to AG's Office for Private Consent Order
B35645	W.G. / S.N.E. / L.B.H,	Misfill Guidance #1A
B35763	F.E.C.M.C./ T.K.T. / N.W.	Close and refer case to Composite Medical Board
	/ J.W.	
B35616	J.J.M.	Referral to AG's Office for Private Consent Order and approve
		application after
B35522	C.P.	Close
B35535	K.P.S.M.O.P.	Close
B35574	G.P.A.	Close
B35578	W.G.	Close
B35579	P.P.	Close
B35598	W.P.	Close
B35599	C.P	Close
B35614	C.P.	Close
B35646	C.P.	Close
B35656	T.A.B.	Close
B35548	N.F.P. / M.E.	Close
A35783	A.M.R.I.	Immediate License Suspension

All proposed orders were approved for docketing and no formal counterproposals were submitted.

**Applications** 

Applicant	Type of License	Status
L.J.	Pharmacy Technician	Approve
H.B.	Pharmacy Technician	Approve
S.J.	Pharmacy Technician	Approve
H.S.	Pharmacy Technician	Approve
C.F.	Pharmacy Technician	Approve
J.D.O.	Pharmacy Technician	Approve
C.H.	Pharmacy Technician	Approve with conditions
M.M.	Pharmacy Technician	Approve
L.N.	Pharmacy Technician	Approve
M.B.	Pharmacy Technician	Approve
J.W.S.	Pharmacy Technician	Approve
N.N.	Pharmacist	Approve
A.R.	Pharmacist	Approve
T.T.	Pharmacist	Approve
M.D.	Pharmacist	Approve

B.S.	Pharmacist	Approve
J.M.	Pharmacist	Tabled – Additional Information is Needed
N.S.	Pharmacist Certification of DTM	Approve
L.K.	Nuclear Pharmacist	Approve
T.J.	Nuclear Pharmacist	Approve
T.G.L.	Durable Medical Equipment	Approve
D.C.S.	Research Application	Approve

**Notices of Discipline:** The Board reviewed the notices and agreed that these notices are for information only and that no further action is necessary at this time

O.I.S.	C.P.	T.I.	P.C.I.	S.C.
E.S.P.	W.G.	O.P	H.O.C.	O.R.
S.S.S.	P.P.S.	T.M.	A.I.S.	S.D.C.
Q.C.R.	S.C.S.	E.P.	T.S.L.	

Correspondences/Requests

Licensee	Request	Decision
C.E.	Request for Application Extension	Approve
K.B.	Request to take MPJE for the 4 <sup>th</sup> attempt	Approve
C.B.	Self-Report Arrest	Approve
G.H.	Scope of work for remodel	Take as information
R.H.	Request to take MPJE for 4 <sup>th</sup> attempt	Approve
K.J.	Request for Application Extension	Approve
K.K.	Request for Application Extension	Approve
C.C.	Requesting Appearance for Reinstatement	Approve to Appear
R.M.	Requesting Appearance for Reinstatement	Approve to Appear
S.E.	Requesting Appearance for Application Denial	Tabled for additional information
A.S.	Requesting Appearance for Reinstatement	Approve to Appear
J.H.	Request for Reconsideration of Appearance	Approve to Appear
	Denial	
B.G.	Response to Board's Denial	No Action
M.M.	Request to Terminate Probation	Approve

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

There being no further business to discuss, the meeting was adjourned at 2:56 p.m. The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, June 18, 2025, at 9:00 a.m. at the Board's office located at 2 Martin Luther King Jr Drive SE, East Tower, 11<sup>th</sup> floor, Atlanta, GA 30334

Minutes recorded by Angela Johnson, Board Administrative Secretary Edited by J. Clinton Joiner, II, Executive Director