GEORGIA BOARD OF PHARMACY 2 Peachtree St., NW, 5th Floor Atlanta, GA 30303 October 12, 2022 9:00 a.m.

The following Board members were present: **Staff present:** Dean Stone, President Eric Lacefield, Executive Director Michael Azzolin, Vice-President Dennis Troughton, Director, GDNA Jim Bracewell Michael Karnbach, Deputy Director, GDNA Emily Lobeck, Special Agent, GDNA Michael Brinson Max Changus, Assistant Attorney General Cecil Cordle **Chuck Page** Kimberly Emm, Assistant Attorney General **Bill Prather** Clint Joiner, Attorney Brandi Howell, Business Support Analyst I Visitors: Stephanie Kirkland, Eldercare Jonathan Marquess, GPhA Melissa Reybold, GPhA Helen Sloat, Nelson Mullins Becca Hallum, GHA Jennifer Duckett, Walgreens Kevin Coggin, Turenne PharMedCo Anthony Carlisle, Turenne PharMedCo Lauren Pollow, EPIC Beth Jarrett, Walmart Dianne Sanders, Kaiser Permanente Christi Heys, Emory Kyle Parrish, GPhA

Public Hearing

Chris Claudius, Emory

President Stone called the public hearing to order at 9:05 a.m.

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

President Stone stated that the purpose of the rule amendment is to remove references to pharmacy benefits managers, which are no longer licensed by the Georgia Board of Pharmacy. He further stated that the main feature of this amendment is the removal of two references to pharmacy benefit managers.

President Stone commented that he has received questions from members of the public regarding this matter. He explained that O.C.G.A. § 26-4-110.1 repealed provisions relating to required licensure as a pharmacy by pharmacy benefits managers engaging in the practice of pharmacy. He added that this change became effective January 1, 2021, and the changes in rule line up with the changes in the law.

No public comments or written responses were received.

Mr. Brinson made a motion to adopt Rule 480-10-.02 Prescription Department, Requirement, Supervision. Mr. Bracewell seconded, and the Board voted unanimously in favor of the motion.

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

President Stone stated that the purpose of the rule amendment is to remove references to pharmacy benefits managers, which are no longer licensed by the Georgia Board of Pharmacy. To eliminate the provision that caused a pharmacy's change in location to void its license, as the Board has determined that there is no basis to void a license solely because a pharmacy has changed locations, and it imposes substantial cost and inconvenience on licensees without significant regulatory benefit. To clarify how changes in ownership and changes in location should be accomplished. He further stated that the main feature of this amendment is the removal of references to pharmacy benefits managers. Elimination of provision causing change in location to void a pharmacy's license. Clarification of how changes in ownership and changes in location should be accomplished through the Board's application process.

No public comments or written responses were received.

Mr. Prather made a motion to adopt Rule 480-10-.06 Licensure, Applications and Display of License and Renewal Certificate. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

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

President Stone commented that a written response was received from Melissa Reybold on behalf of the Georgia Pharmacy Association ("GPhA"). Ms. Reybold, who was present at the hearing, stated that GPhA's comments have nothing to do with the National Provider Identifier. She requested the Board consider removal of the supervising physician information required on e-scripts because it has caused an administrative burden and bottleneck with pharmacies and physician's offices, as well as delays in patient care. Ms. Reybold stated that Mr. Kyle Parish from the Hobgood & Bass law firm was present to answer any questions the Board had. Ms. Reybold continued by stating that GPhA requested outside counsel review the proposed amendment and it is their opinion that it is in the Board's authority to eliminate the requirement of the supervising physician's information from e-scripts.

President Stone stated that the purpose of the rule amendment is to remove the rule's requirement that a prescription drug order contain a National Provider Identifier, as the same is not required by Georgia statutes. He further stated that the main feature of this amendment is elimination of the requirement that a prescription drug order contain a National Provider Identifier.

President Stone stated that, unless the Board has any comments, it would take Ms. Reybold's request under consideration. He explained that if the Board were to delay adoption of this rule, it would impact other rules. President Stone stated that the Board is holding a workshop in November and could put the subject on the agenda for discussion. He further stated that, in a retail pharmacy setting, there are issues with physician's assistants and nurse practitioners working from different locations and e-scripts are received without the location information. He added that he does see where that causes problems. President Stone stated Ms. Reybold's comments.

No additional public comments or written responses were received.

Mr. Prather made a motion to adopt 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 seconded, and the Board voted unanimously in favor of the motion.

Rule 480-27-.01 Definitions

President Stone stated that the purpose of the rule amendment is to remove the rule's definition of "NPI", consistent with the Board's elimination of the requirement that a prescription drug order contain a National Practitioner Identifier in its amendments to Rule 480-27-.02. He further stated that the main feature of this amendment is elimination of "NPI" as a defined term.

No public comments or written responses were received.

Mr. Prather made a motion to adopt Rule 480-27-.01 Definitions. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

Rule 480-27-.02 Prescription Drug Order Requirements

President Stone stated that the purpose of the rule amendment is to eliminate the requirement that a prescription drug order contain a National Practitioner Identifier. He further stated that the main feature of this amendment is elimination of the requirement that a prescription drug order contain a National Provider Identifier.

No public comments or written responses were received.

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

Rule 480-27-.04 Use of Facsimile Machine to Transmit or Receive Prescription Drug Order

President Stone stated that the purpose of the rule amendment is to eliminate the requirement that a prescription drug order contain a National Practitioner Identifier. He further stated that the main feature of this amendment is elimination of the requirement that a prescription drug order contain a National Practitioner Identifier with regard to the use of a facsimile machine in processing the order.

Mr. Brinson made a motion to adopt Rule 480-27-.04 Use of Facsimile Machine to Transmit or Receive Prescription Drug Order. Vice-President Azzolin seconded, and the Board voted unanimously in favor of the motion.

Rule 480-27-.05 Record-Keeping When Utilizing an Automated Data Processing System

President Stone stated that the purpose of the rule amendment is to eliminate the requirement that a prescription drug order contain a National Practitioner Identifier. He further stated that the main feature of this amendment is elimination of the requirement that a prescription drug order contain a National Practitioner Identifier with regard to the use of an automated/electronic data processing system in processing the order.

Mr. Brinson made a motion to adopt 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.

The public hearing concluded at 9:14 a.m.

Open Session

President Stone established that a quorum was present and called the meeting to order at 9:14 a.m.

Approval of Minutes

Mr. Bracewell made a motion to approve the Public and Executive Session minutes from the September 14, 2022, meeting. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Mr. Page made a motion to ratify the list of licenses issued. Vice-President Azzolin seconded, and the Board voted unanimously in favor of the motion.

Correspondences

Correspondence from Glenn Kelley, Atrium Health Navicent: The Board considered this correspondence regarding an ACLS course offered by the American Heart Association and if pharmacists could receive credit from the Board for completing the course. The Board directed staff to respond to Mr. Kelly by stating that the provider of the course must complete the "Continuing Education Program Application & Approval Form" located on the Board's website and return it to the Board office for consideration.

Correspondence from Nicole V. Sims, RPH028613: The Board considered this correspondence regarding clarification as to whether a course approved by the North Carolina Board of Pharmacy would be accepted by the Georgia Board of Pharmacy. The Board directed staff to respond to Ms. Sims by stating that the provider of the course must complete the "Continuing Education Program Application & Approval Form" located on the Board's website and return it to the Board office for consideration.

Correspondence from Jessica Comstock, PharmaLogic Holdings Corp: The Board discussed this correspondence regarding a nuclear pharmacy, Essential Isotopes, LLC, located and licensed in Missouri working with Curium Pharma and Essential Isotopes Manufacturing to dispense a clinical trial product into Georgia for phase III trials. In her letter, Ms. Comstock requests an exemption from any potential licensure allowing the pharmacy to dispense to clinical trial sites in Georgia. The Board directed staff to respond to Ms. Comstock by stating that Georgia does not have any exceptions for clinical trials. Additionally, all Georgia shipping, dispensing, labeling, and record keeping laws and rules must be adhered to and all parties must be appropriately licensed and authorized to ship, order, receive, and dispense drugs under Georgia law.

Correspondence from Drew Carlisle, Montgomery Pharmacy: The Board considered this correspondence requesting the Board's permission for a licensed non-resident pharmacy to place a narcotic emergency kit in a Georgia skilled nursing facility. The Board recommended denying the request as it is not permitted by law and directed staff to respond by referring Mr. Carlisle to O.C.G.A. § 26-4-114.1 for more information.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA conducted 623 inspections and received 148 complaints for FY2023.

Director Troughton introduced GDNA's newest agent, Ms. Emily Lobeck, to the Board. He stated that Special Agent Lobeck started with GDNA on October 1st and was previously with Kroger. He continued by stating that everyone as board members did not realize what the Board did until they became members. Director Troughton stated that, when becoming a Special Agent at GDNA, the individual is giving up practicing in the clinical world and going from the private industry to working for the Government. He explained that once a new agent is hired, it takes about two years before he/she is on their own. He stated that the agents see something different every day and walk into situations that end up coming before the Board. He commended his staff for doing a great job. He further stated that when a new agent starts with GDNA, he/she has really changed his/her life to serve the State of Georgia. Director Troughton stated that he felt Special Agent Lobeck would do a great job and he looked forward to her working with GDNA. Mr. Page commented that GDNA had obtained an outstanding person and agreed that she would do a great job.

Director Troughton reported that his goal was to have three new agents by the end of the fiscal year.

Mr. Brinson welcomed Special Agent Lobeck and commented that, unless one becomes a member of the Board, people have no idea everything the agents do at GDNA. He stated there is a lot of documentation the agent has to prepare and present.

<u> Attorney General's Report – Max Changus</u>

Mr. Changus introduced Ms. Kimberly Emm to the Board. He explained that she previously worked with the Boards of Dentistry and Pharmacy. He stated that she has done a great job with the Attorney General's office and is very knowledgeable when it comes to pharmacy. Mr. Changus stated that he will lean on her going forward to assist the Board.

Executive Director's Report – Eric Lacefield

Continuing Education Report: Mr. Page made a motion to ratify the below continuing education programs approved since the previous meeting. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

| Date of Program | Hours | Sponsoring Group | Program Title | CE Code |
|--------------------|-------|------------------------|--|-----------|
| 09/22/22 | 1 | Kaiser Permanente | Drug Information Resources | 2022-0010 |
| 10/05/2022 | .5 | Atrium Health-Navicent | Pneumococcal Vaccine Inservice | 2022-0011 |
| 10/20/2022 | 1 | Kaiser Permanente | Cabenuva - Role in Management of HIV Infections | 2022-0012 |

Re-Location of Department of Community Health Offices: Mr. Lacefield provided the Board with an update regarding the Department of Community Health relocating its offices in December. He added that staff have begun preparing for the move by boxing up items. He added that the Board will meet in the 5th floor conference room in November.

Renewals: Mr. Lacefield commented that the online portal for pharmacists to renew is now live. He stated that this topic was mentioned in the Board's quarterly newsletter. He encouraged the Board and guests to remind all licensees to renew in a timely manner.

Legal Services – Clint Joiner

DBA's – Single Application for Licensure: Mr. Joiner commented that there have been multiple facility applicants seeking to designate multiple DBAs on a single application for licensure. He stated that, as board staff, he felt this would not be permitted, but wanted to obtain further clarification from the Board regarding such.

President Stone commented that he sees how it could cause confusion if there are multiple DBAs under one license. Mr. Lacefield stated that, in the past, staff have always responded that it was not permitted and a separate license would be needed for that location. Mr. Lacefield further stated he wanted to bring this to the Board's attention as it has come up more frequently as of late. Mr. Lacefield agreed that when looking at the license verification online, multiple DBAs could cause confusion.

Discussion was held by Director Troughton regarding the information reflected on the online verification. He stated that the DBA is what appears on the Georgia license. Vice-President Azzolin discussed a scenario where an entity may have applied for a license without providing the DBA information. Director Troughton responded by stating that if that occurred and a complaint was received, GDNA would conduct an investigation. He continued by stating that with every complaint GDNA verifies the license information and if the DBA information was not provided, GDNA would have the license contact the board office.

Director Troughton stated that when doing investigations, GDNA helps with that process, and if the facility name does not match, it needs to. He added that if the facility name changes, but the license says something else, GDNA would point that out. Director Troughton explained that a facility having numerous DBAs would pose a problem for GDNA. He continued by stating that it would be a record keeping nightmare and there are no rules in place that distinguishes that.

Mr. Cordle inquired if most of the requests were from the retail sector. Mr. Lacefield responded affirmatively by stating that it was mostly retail. There being no further discussion, the Board agreed that multiple DBAs were not acceptable on a single application for licensure.

Correspondence from Hunter Odom: Mr. Joiner discussed this correspondence regarding a facility that manufactures methylamine outside of Georgia and has a prospective buyer in Georgia. Mr. Odom's correspondence asks about permitting, restrictions, and other requirements for both buyer and seller. Mr. Joiner explained that methylamine is listed as a List 1 precursor to methamphetamine. After discussion, the Board directed staff to respond to Mr. Odum by stating that the Board determined that for the purely industrial and non-pharmaceutical purpose described, no licensure is required from the Board of Pharmacy for the seller or the buyer. This determination is only relative to licensure from the Georgia Board of Pharmacy and does not speak to whether other permitting or licensure may be required by another state agency or by federal regulation.

Miscellaneous

2023 Proposed Meeting Dates: The Board discussed conflicts with the June 2023 proposed date and suggested considering an alternative date at its November meeting. Mr. Page made a motion to adopt the 2023 meeting dates as presented, with the exception of June. Mr. Cordle seconded, and the Board voted unanimously in favor of the motion.

Maltagon: President Stone thanked Mr. Cordle for attending the meeting on behalf of the Board. Mr. Cordle explained that Maltagon is a professional association for board members for the southern states. He reported that those in attendance viewed presentations from the FDA, FBI and other agencies. He stated that members discussed concerns that overlap into the profession.

National Community Pharmacists Association Meeting: President Stone reported that he recently attended the National Community Pharmacists Association meeting. He explained that board members come together on a quarterly basis with directors to talk about things that are of concern.

November Board Meeting: President Stone stated that November will be a workshop session. He further stated he plans on the meeting being a one day meeting versus a two day meeting. He advised the members to be prepared for a long day.

Upcoming Meetings: Mr. Brinson reported that he will be representing the Board at the Georgia Society of Health-System Pharmacists meeting scheduled for later in October. He stated that he will be speaking about medication errors. Additionally, Mr. Brinson reported that he would be meeting at Georgia Pharmacy Association's office in November to speak with pharmacy technicians.

Public Hearing: Mr. Lacefield reported that a Public Hearing is scheduled for November. He noted that the Board will be considering ten (10) rules for adoption.

Mr. Page made a motion and Vice-President Azzolin 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, Cecil Cordle, Chuck Page, Bill Prather, and Dean Stone.

Executive Session

<u>Georgia Drugs and Narcotics Agency – Dennis Troughton</u> No report

No report.

<u>Cognizant's Report – Michael Azzolin</u>

- GDNA Case # A34448
- GDNA Case # A34075
- GDNA Case # T34465
- GDNA Case # T34463
- GDNA Case # A34415
- GDNA Case # B34371
- GDNA Case # B34368
- GDNA Case # A34419
- GDNA Case # A34413
- GDNA Case # A34424
- GDNA Case # A34423
- GDNA Case # A34400
- GDNA Case # A34390
- GDNA Case # B34181
- GDNA Case # A34352
- GDNA Case # A34353
- GDNA Case # A34354
- GDNA Case # B34388
- GDNA Case # B34407
- GDNA Case # B34406
- GDNA Case # B34361
- GDNA Case # B34376
- GDNA Case # A34493

<u> Attorney General's Report – Max Changus</u>

Mr. Changus presented the following consent orders for acceptance:

- M.P.P.
- K.D.
- C.V.S.
- W.A.A.

Executive Director's Report – Eric Lacefield

No report.

Legal Services

No report.

Applications

- C.N.T.
- M.D.T.B.

- S.B.D.
- A.P.P.
- C.G.M.
- B.M.C.
- C.A.N.
- K.D.D.
- A.C.J.
- C.M.N.
- S.Y.Y.
- C.J.M.
- M.H.P.
- M.Y.R.
- V.E.S.

Correspondences/Requests

- A.S.P.
- F.S.S.P.
- H.V.
- H.V.
- T.H.C.P.
- V.H.P.H.
- D.V.P.
- B.E.T.P.
- H.B.
- A.U.M.C.M.R.P.
- S.K.
- T.B.M.
- E.J.E.
- E.J.K.

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

Open Session

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

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

<u>Cognizant's Report – Michael Azzolin</u>

- GDNA Case # A34448
 Accept Private Interim Consent Order
- GDNA Case # A34075 Accept Private Interim Consent Order
- GDNA Case # T34465 Accept Voluntary Surrender
- GDNA Case # T34463 Accept Voluntary Surrender
- GDNA Case # A34415 Refer to the Department of Law
- GDNA Case # B34371 Misfill Policy #1
- GDNA Case # B34368 Misfill Policy #1
- GDNA Case # A34419 Letter of concern to PIC/Refer to the Department of Law for pharmacy
- GDNA Case # A34413 Refer to the Department of Law

- GDNA Case # A34424 Null and void permit
 - GDNA Case # A34423 Null and void permit
- GDNA Case # A34400 Null and void permit
- GDNA Case # A34390 Refer to the Department of Law
- GDNA Case # B34181 Schedule respondent for an appearance, disapproved as a preceptor; send letter to three schools involved notifying them that the individual has been disapproved as a preceptor.
- GDNA Case # A34352 Refer to the Department of Law
- GDNA Case # A34353 Refer to the Department of Law
- GDNA Case # A34354 Refer to the Department of Law
- GDNA Case # B34388 Close with no action
- GDNA Case # B34407 Close with no action
- GDNA Case # B34406 Close with no action
- GDNA Case # B34361 Close with no action
- GDNA Case # B34376 Close with no action
- GDNA Case # A34493 Refer to the Department of Law

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- M.P.P. Public Consent Order accepted
- K.D. Public Consent Order accepted
- C.V.S. Private Consent Order accepted
- W.A.A. Private Consent Order accepted

Executive Director's Report – Eric Lacefield

No report.

Legal Services

No report.

Applications

| • C.N.T. | Pharmacy Technician | Approved for registration |
|------------|---------------------------------|---|
| • M.D.T.B. | Pharmacy Technician | Approved for registration |
| • S.B.D. | Pharmacy Technician | Table pending receipt of additional information |
| • A.P.P. | Pharmacist Intern | Approved extension thru 09/30/2023 |
| • C.G.M. | Pharmacist Intern | Approved extension thru 03/31/2023 |
| • B.M.C. | Pharmacist Intern | Approved application |
| • C.A.N. | Pharmacist Intern | Approved application |
| • K.D.D. | Pharmacist Intern | Approved application |
| • A.C.J. | Nuclear Pharmacist | Approved application |
| • C.M.N. | Nuclear Pharmacist | Approved application |
| • S.Y.Y. | Nuclear Pharmacist | Approved application |
| • C.J.M. | Reciprocity Applicant | Approved application |
| • M.H.P. | Pharmacist Certification of DTM | Approved application |
| • M.Y.R. | Pharmacist Certification of DTM | Approved application |
| • V.E.S. | Pharmacist Certification of DTM | Approved application |

Correspondences/Requests

| orrespondences/Request | LS | |
|------------------------|--|---|
| • A.S.P. | Notice of Discipline | No action |
| • F.S.S.P. | Notice of Discipline | No action |
| • H.V. | Notice of Discipline | No action |
| • H.V. | Notice of Discipline | No action |
| • T.H.C.P. | Notice of Discipline | No action |
| • V.H.P.H. | Notice of Discipline | No action |
| • D.V.P. | Notice of Discipline | No action |
| • B.E.T.P. | Notice of Discipline | No action |
| • H.B. | Notice of Discipline | No action |
| • A.U.M.C.M.R.P. | Correspondence | Board directed GDNA to contact |
| • S.K. | Request for 4 th attempt to retake NAPLEX | Approved request |
| • T.B.M. | Request for 4 th attempt to retake NAPLEX | Approved request |
| • E.J.E. | Correspondence | The Board viewed this correspondence for informational purposes only. |
| • E.J.K. | Correspondence | The Board viewed this correspondence for informational purposes only. |

Mr. Brinson seconded, and the Board voted in favor of the motion, with the exception of Mr. Page, who recused himself from the vote regarding K.D., and Mr. Cordle, who recused himself from the vote regarding C.V.S.P.

President Stone reminded the board members that the November meeting will be held in person at the Department of Community Health offices in Atlanta. He added that the plan is to have a one day meeting.

There being no further business to discuss, the meeting was adjourned at 12:52 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, November 16, 2022, at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5th Floor, Atlanta, GA 30303.

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