## **GEORGIA BOARD OF PHARMACY**

Conference Call
2 Peachtree Street, NW, 6<sup>th</sup> Floor
Atlanta, GA 30303
July 14, 2021
9:00 a.m.

The following Board members were present:

Michael Brinson, President Dean Stone, Vice-President Carrie Ashbee

Michael Azzolin Young Chang 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

Brandi Howell, Business Support Analyst

**Visitors:** 

Stephanie Kirkland

Jim Richards

Dr. Yolanda Y. Rhetta

Bridget Archer, Exela Pharma Sciences, LLC Rita Boucher, Exela Pharma Sciences, LLC

Shauna Markes-Wilson

## **Open Session**

President Brinson 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.

President Brinson reported that the August meeting will be held in person at the University of Georgia College of Pharmacy.

#### **Approval of Minutes**

Vice-President Stone made a motion to approve the Public and Executive Session minutes from the June 9, 2021, Conference Call. Ms. Ashbee seconded, and the Board voted unanimously in favor of the motion.

## **Report of Licenses Issued**

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

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

Rule Waiver Petition from Bethelview Pharmacy, PHRE010118: The Board recommended tabling this petition pending further discussion in Executive Session.

Rule Waiver Petitions from Kaiser Permanente Southwood Infusion Pharmacy, PHCL000019, Kaiser Permanente Gwinnett Infusion Pharmacy PHCL000016, and Kaiser Permanente **Townpark Infusion Pharmacy, PHCL000018:** Director Troughton discussed the petitions submitted by Kaiser Permanente. He explained that the facility is asking to have shared space between a retail and clinic pharmacy. He stated that it sounds similar to being a hospital retail pharmacy. Director Troughton stated that the Board previously discussed a similar situation and at that time, the Board allowed those spaces to be shared together where the retail pharmacy did not have to have an additional 150 square feet inside the hospital. He explained that when GDNA does an inspection in that type of setting, the facility would have to keep a separate inventory and separate records. He further explained that the retail drugs would be kept separate and secure, and all records would need to be accounted. Director Troughton stated that GDNA would still need to retrace the drugs from purchase to final disposition under the proper license. He stated that with a clinic pharmacy, the Board allows after hours entry into the pharmacy, like a hospital pharmacy. He stated that clinics cannot do refills. He stated they can fill prescriptions for patients to go home with, but they have to be outpatients coming into the clinic. Director Troughton stated they want to have the retail license and do homecare, which would include patients at home and there would be refills for those patients. He stated that it does become more challenging for GDNA to keep up with what the facility is doing. He explained that if they were to coexist in the same space, the facility would still have to meet all requirements of a retail pharmacy such as record keeping.

Mr. Azzolin responded that he interpreted the request differently. He stated that the request is not asking to overlay a retail pharmacy on top of a clinic. He stated that the request is asking to allow the clinic pharmacy to be able to dispense sterile products to outpatients. Mr. Azzolin read section (5) of the petition, which states in part, "This waiver would allow a clinic pharmacy that is capable of providing compounded sterile products to outpatients in the home setting in the same manner as a retail pharmacy permit holder that provides the same services..." Mr. Azzolin stated that it sounds as if the petition is requesting to dispense compounded sterile products under a clinic pharmacy license. President Brinson agreed. Director Troughton responded to Mr. Azzolin by stating they would be doing what is allowed under the retail license. He added that if the rule waiver is the best way to go, there may be several parts of the rule the Board would need to waive to allow them to dispense. He stated that he believes they are asking do refills for patients that are not walking into the clinic. Director Troughton stated that Mr. Azzolin may be correct, but he believes there would be more parts to the rule the Board would need to waive. Mr. Azzolin stated that it may be that they have to have a retail permit in order to dispense those drugs. He inquired if there was anything that would prevent a clinic pharmacy from dispensing drugs outside of the clinic itself. Director Troughton responded by stating it would be the rule itself. He stated the facility is asking to do many different things and believes the Board would have to waive a number of parts of the rule. Mr. Azzolin discussed amending the rule. Discussion ensued.

President Brinson inquired whether a retail pharmacy license could provide home healthcare services. Director Troughton responded by stating they have a clinic license, and they are asking to be able to do all the other things they can do under a retail license. Ms. Emm commented that right now they are limited to the outpatient clinic patients, and cannot do refills at all. Director Troughton commented that the Board would need to either waive parts of the clinic rule or allow them to coexist in same space.

Mr. Hector Clarke, who was on the call, spoke to the Board regarding the request. He explained that what they are trying to accomplish is allow the clinic license to hold a home care permit as well. He stated the clinic pharmacy is already built and functions as a sterile compounded pharmacy with engineering, mechanical and environmental infrastructures. Mr. Clarke stated they cannot apply for a retail pharmacy permit, which requires an additional 150 square foot of space. He further stated the waiver would allow a clinic pharmacy that is capable of providing compounded sterile products

to outpatients in the home setting in the same manner as a retail pharmacy permit holder that provides the same services.

After further discussion, Vice-President Stone made a motion to table the three (3) petitions until the August meeting to allow additional time for GDNA to inspect the facility. Mr. Azzolin seconded, and the Board voted unanimously in favor of the motion.

#### **Correspondence from Johnny D. Thornton**

The Board considered this correspondence requesting clarification as to whether or not the Georgia Boards of Dentistry and Pharmacy have any fees for or regulatory oversight over marijuana cultivated and bulk manufactured by the U.S. Government under the legal auspices of the Drug Enforcement Administration. Additionally, Mr. Thornton inquired if the Georgia Boards of Dentistry and Pharmacy have an application policy, or any other fee requirements for a U.S. Government sanctioned business that is bulk drug manufacturing cannabis, and/or its derivatives, for medical efficacy or varied research. Ms. Emm stated that Mr. Thornton wants to start growing marijuana, not low TCH or hemp. She stated that there is a DEA program that allows it to be grown for research purposes. Ms. Emm explained that she does not know anything about the program. She further explained that she provided information on Georgia law. Director Troughton responded that he has never seen a research program for growing marijuana. He stated that the response to both of Mr. Thornton's questions would be "no". Mr. Azzolin inquired as to whether a researcher permit would be required for the research mentioned in the correspondence. After further discussion, the Board directed staff to respond "no" to both questions; however, also refer Mr. Thornton to Rule 480-7-.04 for additional information.

## Georgia Drugs and Narcotics Agency - Dennis Troughton

Director Troughton reported that GDNA has conducted 2621 inspections and received 414 complaints for FY2021.

Deputy Director Karnbach reported that he recently attended a PDMP Advisory Committee meeting. He stated that Ms. Ashbee was in attendance as well. Deputy Director Karnbach stated that substance abuse was on the rise during the Covid-19 pandemic. Additionally, the prescribing of opioids had decreased during the pandemic, but now they are starting to see an uptick. He reported that there has been an increase in fentanyl overdoses and the Department of Public Health will start a media campaign related to fentanyl overdoses. Deputy Director Karnbach stated that they are also starting a pain clinic closure protocol, which will provide information to patients as to when a pain clinic closes. He explained that it will be a multi-agency effort. PDMP is currently sharing with 20 other states.

President Brinson discussed House Bill 367. He explained that Epidiolex was taken off of Schedule V status and is no longer a controlled drug.

Director Troughton reported that he attended the GSHP meeting last weekend. He stated that it was a great way for the Board and members of GDNA to interact with members of the public.

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

No report.

#### **Executive Director's Report – Eric Lacefield**

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

Date of Program	Hours	<b>Sponsoring Group</b>	Program Title	CE Code
07/27/2021	1	Kaiser Permanente	2021-2022 Preceptor Development	2021-0006

**Executive Order 06.30.21.02:** Mr. Lacefield reported that Executive Order 06.30.21.02 is effective and still allows for the following: temporary licenses to pharmacists currently licensed in another state; computer-based processing of prescriptions in alternate locations; pharmacists to continue administering the covid vaccine with or without a protocol agreement; and a pharmacist to directly supervise more than one (1) intern. He stated that this order is set to expire July 30, 2021.

**August Board Meeting:** Mr. Lacefield reported that the August meeting will be held in-person at the University of Georgia. He explained there will be no Microsoft Teams or call-in information provided. He stated that if there are any protocols required for guests, that information will be included on the agenda posted on the board's website.

#### **Legal Services – Kimberly Emm**

**Correspondence from Tina Posey:** Ms. Emm discussed this correspondence received asking if the Board is accepting the FDA's non-binding guidance that manufacturers and wholesalers be allowed to dispense drug samples directly to patients. The Board directed staff to respond by directing Ms. Posey to O.C.G.A. § 26-4-113.

Emergency Rules: Mr. Changus discussed the emergency rules that were passed to meet the needs of the public health emergency. He stated that when the emergency ended, those rules expired. He inquired as to whether the Board wanted to reinstitute those rules. Mr. Changus stated that Georgia is now under another State of Emergency, which is a post-pandemic recovery order. He explained that in the order, many things were continued, but a number of those rules were not included in the new order. He stated that he was unsure if the Board had a desire to revisit the emergency rules. Ms. Emm stated the rules Mr. Changus was referencing were Rule 480-48-0.43-.04 Delivery by Mail, Rule 480-36-0.42-.08 Remote Order Verification for Retail Pharmacy Permits, Rule 480-22-0.44-.16 Emergency Schedule II Prescription Drug Order, and Rule 480-15-0.40-.07 Temporary Pharmacy Technician Registration. The Board agreed to not extend these rules; however, requested to discuss them further for the long-term at the October meeting.

#### Miscellaneous

Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel: Mr. Prather made a motion to post Rule 480-15-.03. Use of Registered Pharmacy Technicians and Other Pharmacy Personnel as amended. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

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

- (a) In dispensing drugs, no individual other than a licensed pharmacist, intern or extern working under direct supervision of a licensed pharmacist shall perform or conduct those duties or functions which require professional judgment. It shall be the responsibility of the supervising pharmacist to ensure that no other employee of the pharmacy, excluding pharmacy interns or externs, performs or conducts those duties or functions which require professional judgment.
- (b) For all prescription drug orders, it shall be the responsibility of the Pharmacist on duty at a facility to ensure that only a pharmacist or a pharmacy intern and/or extern under the direct supervision of a registered pharmacist provides professional consultation and counseling with patients or other licensed health care professionals and that only a pharmacist or a pharmacy intern or an extern under the direct supervision of a registered pharmacist accepts

- telephoned oral prescription drug orders or provides or receives information in any manner relative to prescriptions or prescription drugs.
- (c) Registered pharmacy technicians and other pharmacy personnel, i.e., clerks, cashiers, observers, etc., in the prescription department shall be easily identifiable by use of a name badge or other similar means which prominently displays their name and the job function in which the personnel are engaging at that time. Any pharmacy personnel or other person present in the pharmacy department must be under the direct supervision of a licensed pharmacist.
- (d) In the dispensing of all prescription drug orders:
  - (1.) The pharmacist shall be responsible for all activities of any registered pharmacy technician in the preparation of the drug for delivery to the patient.
  - (2.) The pharmacist shall be present and personally supervising the activities of any registered pharmacy technician at all times.
  - (3.) When electronic systems are employed within the pharmacy, registered pharmacy technicians may enter information into the system and prepare labels; provided, however, that it shall be the responsibility of the pharmacist to verify the accuracy if the information entered and the label produced in conjunction with the prescription drug order.
  - (4<u>.</u>) When a prescription drug order is presented for filling or refilling, it shall be the responsibility of the pharmacist to review all appropriate information and make the determination as to whether to fill the prescription drug order, and
  - (5.) Any other function deemed by the Board to require professional judgment.
- (e) The pharmacist to registered pharmacy technician ratio shall not exceed one pharmacist providing direct supervision of three-four registered pharmacy technicians in accordance with the certification requirements below. One of the three technicians must:
  - 1. Any time during which a pharmacist is directly supervising one or two technicians, no certification is required.
  - 2. Any time during which a pharmacist is directly supervising three technicians, at least one must be certified as outlined below in subsections i-iii.
  - 3. Any time during which a pharmacist is directly supervising four technicians, at least two must be certified as outlined below in subsections i-iii.
  - (1)—(i) Have successfully passed a certification program approved by the Board of Pharmacy;
  - (2)—(ii) Have successfully passed an employer's training and assessment program which has been approved by the Board of Pharmacy; or
- (f) Have been certified by the Pharmacy <u>\*Technician Certification Board.</u>
  In addition to the utilization of <u>three (3) four (4) registered pharmacy technicians as outlined in subsection (e), if one is certified, a pharmacist may be assisted by and directly supervise at the same time one (1) pharmacy intern, as well as one (1) pharmacy extern, and one (1) pharmacy observer.</u>
- (g) The board may consider and approve an application to increase the ratio in a pharmacy located in a licensed hospital. Such application must be made in writing and may be submitted to the Board by the pharmacist in charge of a specific hospital pharmacy in this state.
- (h) No completed prescription drug order shall be given to the patient requesting <u>the</u> same unless the contents and <del>the</del> label thereof <del>shall</del> have been verified by a <del>registered</del> pharmacist.
- (i) The Board of Pharmacy may revoke or suspend the registration of a pharmacy technician for any of the grounds set forth in O.C.G.A. Sections 43-1-19 or 26-40-60. The revocation or suspension of the registration of a pharmacy technician is not a contested case under the Georgia Administrative Procedures Act, O.C.G.A.T. 50, Ch.13, and the technician is not entitled to a hearing, but the technician may be entitled to an appearance before the Board.

**Rule 480-9-.03 Conditions:** Vice-President Stone made a motion to post Rule 480-9-.03 Conditions. Mr. Azzolin seconded, and the Board voted unanimously in favor of the motion. Rule 480-9-.03. Conditions

The conditions for allowing Multi-drug Single-dosing containers shall be as follows:

- (a) The number of drugs placed in one package cannot exceed the capacity of the container in order to prevent damage to the individual dosage forms;
- (b) The total quantity of drugs dispensed may not be more than a thirty-four (34) ninety-six (96) day supply;
- (c) The labels must be of sufficient size to properly and clearly label each container of a thirty-four (34) ninety-six (96) days or less drug supply with all information required by state and federal law and rules;
- (d) The integrity of each individual multi-drug single-dosing container shall be maintained until the last drug dose is administered to or taken by the patient;
- (e) Once a multi-drug single-dosing container has been properly labeled and dispensed to a patient, and this same container is returned to the pharmacy, the drugs packaged in such container are considered adulterated and may not be returned to the pharmacy stock. Drugs may be redispensed only under the following conditions:
  - 1. Drugs repackaged for and redispensed only to the same patient to which the drugs were originally dispensed or;
  - 2. Whenever a patient has an allergic reaction to any drug contained in a multi-drug single-dosing container and this drug is discontinued from the patient's treatment, a pharmacy cannot repackage and redispense any drug(s) which were packaged with the discontinued drug in the single-dosing container, because any such drug is then considered to be adulterated as defined under O.C.G.A. 26-3.
  - 3. Unopened unit-dose drugs packaged only by the original drug manufacturer dispensed to and returned only by a Long Term Care facility patient for Medicaid credit;
  - 4. A multi-drug single-dosing container must be tamper evident in such a manner to prevent the container from being either reclosed or designed to show evidence of having been opened;
- (f) Whenever a drug(s) in such a container previously dispensed to a patient has/have been discontinued, the remaining container(s) must be returned to the dispensing pharmacy for the removal of the discontinued drug(s) from the container for destruction. Except as provided for in paragraph 480-9-.03(5)(a)1, once the discontinued drug(s) has/have been removed, the pharmacy may repackage the drug(s) to be continued and once again only dispense them to the patient to whom they were originally dispensed. Under no circumstances may any of the renmaining or discontinued drug(s) be returned to the drug stock of the pharmacy or dispensed to any patient other than the patient to whom the drugs were originally dispensed, as specified in 480-9-.03(5), (6) and (7).
- (g) At the time of administration, nothing in this rule is meant to prevent a nurse or a patient specified caregiver from removing a discontinued drug(s) from a container to be wasted as directed by a pharmacist or from retaining up to a 72-hour supply of the continued drug(s) in the original container in order to maintain a patient on his or her continuing drug administration schedule:
- (h) Any pharmacist or pharmacy using multi-drug single-dosing container must implement policies and procedures which will exclude any drug(s) which have the following characteristics from being utilized in such packaging:
  - 1. The USP-DI monograph or official labeling requires dispensing in the original container;
  - 2. The drugs are incompatible with packaging components or each other;

3. The drugs require special packaging.

**Rule 480-34-.15 Repealed:** Vice-President Stone made a motion to post Rule 480-34-.15 Repealed. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

#### Rule 480-34-.15. Additional Compounds under Schedule V-Repealed

- (1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places an additional compound as specifically identified here under Schedule V of the Georgia Controlled Substances Act, Section 16-13-29 as follows:
- (1.5) Epidiolex: A drug product in finished dosage formulation in its original container that has been approved by and labelled in compliance with the U.S. Food and Drug Administration (FDA) that contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.
- (2) This rule is based on the following findings of the Board:
  - (a) that the FDA approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is an oral solution that contains CBD extracted from the cannabis plant.
  - (b) that the U.S. Drug Enforcement Administration (DEA) did seek a medical and scientific evaluation or scheduling recommendation from the U.S. Department of Health and Human Services (HHS) with respect to the Epidiolex formulation. In responding to that request, HHS advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and therefore, recommended that if DEA concluded that control of the drug was required under the Single Convention, Epidiolex should be placed in Schedule V of the Federal Controlled Substance Act (CSA).
  - (c) that the Board has considered, based on available information, the potential for abuse; scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; and the potential of the drug to produce psychic or physiological dependence liability.

A motion was made by Vice-President Stone, seconded by Mr. Page, 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 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 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 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.

Request from James Flanigan, Flanigan's Counseling and Evaluation Services: The Board reconsidered this request to be a board-approved treatment facility. Vice-President Stone made a motion to approve the request. Mr. Page seconded and the Board voted unanimously in favor of the motion.

**Low THC Specialty Dispensing Rules:** Ms. Emm directed the Board to O.C.G.A. § 16-12-206. She stated the Board needs to review this information when considering rules related to this matter. She discussed O.C.G.A. § 16-12-206(a)(1), which states, "Upon request by a licensed pharmacy in this state, the State Board of Pharmacy shall be authorized to develop an annual, nontransferable

specialty dispensing license for an independent pharmacy with a registered office located within this state to dispense low THC oil and products to registered patients. The State Board of Pharmacy shall develop rules and regulations regarding dispensing pharmacies in this state in accordance with the requirements contained in subsection (b) of this Code section." Mr. Azzolin commented that "independent pharmacy" should be defined as someone may think it means something different than what is intended. Ms. Emm commented that O.C.G.A. § 16-12-206 is the only place where the term, "independent pharmacy" is utilized. Mr. Azzolin inquired as to whether or not the Board is allowed to clarify the meaning in its rules. Mr. Changus responded by stating since this particular code section is the only place it is utilized and is not defined, and agreed that the Board should proceed with defining it in the rules. Mr. Azzolin inquired as to whether or not the Board can keep the definition of "independent pharmacy" relative to this particular code section. Ms. Emm responded affirmatively and stated the Board would need to create a new rule chapter for Low THC, which would include definitions.

Mr. Prather suggested the Board proceed with posting the draft so that comments from the public could be received. Ms. Emm responded that Mr. Prather provided a good starting place; however, O.C.G.A. § 16-12-206 requires the board to include things beyond what is currently in the draft. She added that there are items the Board needs to first discuss because right now the rule is not in compliance with what the law allows. President Brinson suggested Mr. Changus and Ms. Emm review the document and the law and bring back suggested changes to the Board. Mr. Lacefield commented that a lot of the information needs to come from the Board and suggested the members review the document provided by Ms. Emm and provide her with guidance on how to proceed.

**FDA Memorandum of Understanding (MOU):** President Brinson reported that the Board can request a two-year extension and that may be something the Board wishes to consider. He directed the Board to two (2) correspondences on Sharepoint regarding the MOU. President Brinson stated that in the correspondence from Mr. John Finley, he is requesting the Board sign the MOU. President Brinson thanked Mr. Finley for providing comments to the Board. Mr. Page responded that he agrees with the Board requesting an extension.

Mr. Greg Reybold, GPhA, was on the call and spoke to the Board regarding the MOU. Mr. Reybold stated that he has spoken with several compounders throughout the state that do ship out of state and the overwhelming response is they think the state should enter into the MOU. He further stated that he has not assessed the extension and what the implications would be. He offered to provide input on the matter if the Board requests such. Mr. Reybold commented that the consensus seems to be for the Board to put it off as long as it can and then enter into it so there is no action from the court to join. He added that he does not know what the implications are with the extension in terms of pharmacies shipping out of state, but knows there is concern from pharmacies that do so. President Brinson thanked Mr. Reybold for his input. President Brinson suggested the Board bring back additional information and discuss this matter further at its August meeting. Mr. Changus commented that one item mentioned was the ramifications of signing an extension. He added that one of the things worth exploring is the extension and what that entails going forward. He explained that there are legal, practical, and resource impediments to signing it. Mr. Changus stated that it would be interesting to see the states that have already signed the MOU and what the impact has been.

Director Troughton stated that the biggest impact will be on GDNA. He stated that he can provide information on what the impact could be today or next month. He stated that he does not want to inhibit anyone's business, but this is essentially opening up a new area of enforcement if the Board would like that input. President Brinson agreed and stated that it would really increase GDNA's workload. He further stated there is no way they can do that in addition to what they already do for the Board. Director Troughton stated that one section of the MOU states, "By signing this MOU,

the Board of Pharmacy affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU..." Director Troughton discussed that it requires investigating serious drug adverse reactions. He stated that has not ever been required by legislature unless it was part of a complaint. He added that the FDA's MedWatch system received over 1.2 million serious drug adverse reaction complaints last year. Director Troughton commented that there is potential the FDA could start forwarding those to GDNA to determine if any were from compounded drugs that were shipped out of state. He stated that he wants the Board to understand the implications.

Mr. John Finley was on the call and spoke to the Board about the MOU. Mr. Finley thanked the Board for allowing him to speak. He stated that he would be willing to assist the Board in any way to help it understand the components of the MOU and the impacts. He further stated that he thinks a lot of states that have signed it, with North Carolina being the most recent, do not know how it will impact every state. Mr. Finely stated that the state always has the choice to not sign the MOU. Relative to the level of work, he stated the states have the flexibility to implement this in a way that makes sense within the states' current rules and capabilities. He added that the FDA is not going to be sending a quarter million complaints; however, if Georgia received a complaint about a serious adverse event, Georgia would collect that information as the FDA does not have the legal, technical authority to collect the information and that is why they are trying to partner with the state. Mr. Finley added that many states are asking for the extension and thinks it makes sense to request such. He stated that the National Association of Boards of Pharmacy (NABP) have done good work in assisting the states and could be helpful to Georgia in understanding what the obligations are. President Brinson thanked Mr. Finley for his comments and recommended the Board discussing this matter further at its August meeting.

Mr. Page made a motion and Ms. Ashbee seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and § 43-1-2(k) 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 Carrie Ashbee, Michael Azzolin, Michael Brinson, Young Chang, Chuck Page, Bill Prather, and Dean Stone.

#### **Executive Session**

#### **Appearances**

- R.T.K.
- G.S.R.

#### Georgia Drugs and Narcotics Agency – Dennis Troughton

- W.C.M.
- C.V.S.H.

#### Cognizant's Report – Dean Stone

- GDNA Case # A33788
- GDNA Case # A33589
- GDNA Case # A33671
- GDNA Case # A33627
- GDNA Case # A33694
- GDNA Case # A33747
- GDNA Case # A33748
- GDNA Case # B33707

- GDNA Case # B33710
- GDNA Case # B33663
- GDNA Case # B33688
- GDNA Case # B33660
- GDNA Case # B33668
- GDNA Case # B33680
- GDNA Case # A33778
- GDNA Case # B33740
- GDNA Case # B33703
- GDNA Case # B33731
- GDNA Case # B33737
- GDNA Case # B33664
- GDNA Case # B33766
- GDNA Case # B33587
- GDNA Case # B33665
- GDNA Case # B33678
- GDNA Case # B33696GDNA Case # B33724

# Attorney General's Report – Max Changus

Mr. Changus discussed the following cases:

- J.A.S.
- E.P.
- R.D.C.
- R.B./J.P.
- P.P./H.P./J.E.T.

## Executive Director's Report – Eric Lacefield

No report.

#### **Legal Services – Kimberly Emm**

Correspondence regarding Virtual Verification System

#### **Applications**

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

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

- A.H.I.I.
- A.H.I.I.
- A.H.I.I.
- A.H.I.I.
- C.P.S.I.
- M.S.D.
- M.S.D.
- M.S.D.
- M.S.D.
- B.
- B.
- M.M.S.I.
- M.M.S.I.
- M.M.S.I.
- M.M.S.I.
- M.M.S.M.S.I.
- M.M.S.G.S.
- M.M.S.I.
- M.M.S.I.
- M.M.S.I.
- S.D.I.
- C.H.A.
- A.H.G.I.
- B.C.H.S.I.
- J.W.H.
- K.B.

## **Correspondences/Requests**

- W.S.C.P.
- C.V.S.P.
- E.P.S.
- C.H.
- C.B.
- S.R.V.
- K.R.W.
- Q.A.H.
- T.G.H.
- S.C.P.
- P.S.H.

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

## **Open Session**

## **Miscellaneous**

Human Trafficking: Vice-President Stone made a motion for the Board to post the below statement on its website. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

"The State of Georgia is moving swiftly and comprehensively to eliminate human trafficking and slavery as a threat to people in every corner of Georgia. The Georgia Board of Pharmacy urges all pharmacists, technicians, and staff to learn to identify any signs of human trafficking; how to respond in cases where they suspect someone is a victim and how to protect children and others from this horrific crime. To access the voluntary statewide Human Trafficking Awareness Training, please click here."

Know the signs. Speak up. Make a difference. http://doas.ga.gov/human-resources-administration/human-trafficking-awareness.

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

Rule Waiver Petition from Bethelview Pharmacy, PHRE010118: Mr. Prather made a motion to deny the rule waiver petition. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Vice-President Stone made a motion for the Board to take the following actions:

#### **Appearances**

• R.T.K.	Request to Reinstate Pharmacist License	Denied request
• G.S.R.	<b>Denied Pharmacist Examination</b>	Overturn denial and grant
		5 <sup>th</sup> attempt at NAPLEX

#### Georgia Drugs and Narcotics Agency - Dennis Troughton

•	W.C.M.	Request regarding supervising pharmacist	Denied request
•	C.V.S.H.	Correspondence	Schedule to meet with
			the Board

## Cognizant's Report - Dean Stone

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•	GDNA Case # A33788	Accept Private Interim Consent Order
•	GDNA Case # A33589	Refer to the Department of Law
•	GDNA Case # A33671	Refer to the Department of Law
•	GDNA Case # A33627	Refer to the Department of Law
•	GDNA Case # A33694	Null and void DME supplier permit
•	GDNA Case # A33747	Refer to the Department of Law
•	GDNA Case # A33748	Refer to the Department of Law
•	GDNA Case # B33707	Misfill Policy #1
•	GDNA Case # B33710	Misfill Policy #1
•	GDNA Case # B33663	Close with no action/Share investigation with the California,
		Virginia, and Texas Boards of Pharmacy
•	GDNA Case # B33688	Misfill Policy #1
•	GDNA Case # B33660	Refer to the Department of Law
•	GDNA Case # B33668	Close with letter of concern
•	GDNA Case # B33680	Misfill Policy #1
•	GDNA Case # A33778	Refer to the Department of Law
•	GDNA Case # B33740	Close with no action/renew pharmacist's license
•	GDNA Case # B33703	Close with no action
•	GDNA Case # B33731	Close with no action
•	GDNA Case # B33737	Close with no action
•	GDNA Case # B33664	Close with no action
•	GDNA Case # B33766	Close with no action

•	GDNA Case # B33587	Close with no action
•	GDNA Case # B33665	Close with no action
•	GDNA Case # B33678	Close with no action
•	GDNA Case # B33696	Close with no action
•	GDNA Case # B33724	Close with no action

## Attorney General's Report - Max Changus

Mr. Changus discussed the following cases:

• J.A.S. Close case and approve application for inactive status

• E.P. Refer to the Department of Law

R.D.C. Deny counterproposal
 R.B./J.P. Accept counterproposal
 P.P./H.P./J.E.T. Close with no action

## **Executive Director's Report - Eric Lacefield**

No report.

## **Legal Services – Kimberly Emm**

M.A.H.

J.D.F.

Correspondence regarding Virtual Verification System

Refer to GDNA

<b>Applications</b>		
• S.K.G.	Pharmacy Technician	Approved for renewal
• R.H.	Pharmacy Technician	Approved for renewal
• B.C.R.	Pharmacy Technician	Approved for renewal
• T.A.F.	Pharmacy Technician	Approved for renewal
• D.A.S.	Pharmacy Technician	Approved for renewal
• G.E.A.	Pharmacy Technician	Approved for renewal
• T.A.L.	Pharmacy Technician	Approved for renewal
• A.M.H.	Pharmacy Technician	Approved for renewal
• L.A.V.	Pharmacy Technician	Approved for renewal
• K.M.S.	Pharmacy Technician	Tabled pending receipt of additional information
• M.L.A.	Pharmacy Technician	Approved for renewal
• R.M.M.	Pharmacy Technician	Approved for renewal
• J.M.S.	Pharmacy Technician	Approved for renewal
• M.B.J.	Pharmacy Technician	Approved for registration
• M.J.S.	Pharmacy Technician	Tabled pending receipt of additional information
• J.L.H.	Pharmacy Technician	Denied application
• O.Y.B.A.	Pharmacy Technician	Approved for registration
• B.S.R.	Pharmacy Technician	Approved for registration
• E.M.O.	Pharmacy Technician	Approved for registration
• S.A.D.	Pharmacy Technician	Approved for registration
• B.U.V.	Pharmacist Intern	Approved application
• F.M.F.	Pharmacist Intern	Approved application
• A.D.D.	Pharmacist Reciprocity	Approved application
• A.R.S.	Pharmacist Reciprocity	Approved application

Pharmacist Reciprocity

Pharmacist Reinstatement

Approved application

Denied request for

fee(s) and reduction of internship requirements/Policy 3A Denied request for B.I.A. Pharmacist Reinstatement waiver of reinstatement fee(s) I.R.S.P. Approved for renewal Non-Resident Pharmacy E.S. Non-Resident Pharmacy Approved for renewal A.H.G.I. Non-Resident Pharmacy Approved for renewal Non-Resident Pharmacy A.H.G.I. Approved for renewal A.H.G.I. Non-Resident Pharmacy Approved for renewal C.C.V.S.S.I.S. Non-Resident Pharmacy Approved for renewal M.C.P.S.I. Non-Resident Pharmacy Approved for renewal Non-Resident Pharmacy Approved for renewal C. U.S.C.I. Non-Resident Pharmacy Approved for renewal V.S.H.D. Non-Resident Pharmacy Approved for renewal M.C.P. Non-Resident Pharmacy Approved for renewal C.P.S.I. Non-Resident Pharmacy Approved for renewal G.R. Non-Resident Pharmacy Approved for renewal C.V.S.C. Non-Resident Pharmacy Approved for renewal P.C.P. Non-Resident Pharmacy Approved for renewal A.H.I.I. Non-Resident Pharmacy Approved for renewal A.H.I.I. Non-Resident Pharmacy Approved for renewal A.H.I.I. Non-Resident Pharmacy Approved for renewal M.D.P.D. Non-Resident Pharmacy Approved for renewal I.R.S.P. Non-Resident Pharmacy Approved for renewal Z.H. Non-Resident Pharmacy Approved for renewal N.V.P. Non-Resident Pharmacy Approved for renewal U.B.C.P. Non-Resident Pharmacy Approved for renewal P.P.S. Non-Resident Pharmacy Approved for renewal S.P. Non-Resident Pharmacy Approved for renewal T.M.R. Non-Resident Pharmacy Approved for renewal U.S.C.I. Manufacturing Pharmacy Approved for renewal H.C. Wholesaler Pharmacy Approved for renewal H.C. Wholesaler Pharmacy Approved for renewal H.C. Wholesaler Pharmacy Approved for renewal A.H.I.I. Approved for renewal Wholesaler Pharmacy A.H.I.I. Wholesaler Pharmacy Approved for renewal C.P.S.I. Approved for renewal Wholesaler Pharmacy

waiver of reinstatement

•	M.S.D.	Wholesaler Pharmacy	Approved for renewal
•	M.S.D.	Wholesaler Pharmacy	Approved for renewal
•	M.S.D.	Wholesaler Pharmacy	Approved for renewal
•	M.S.D.	Wholesaler Pharmacy	Approved for renewal
•	B.	Wholesaler Pharmacy	Approved for renewal
•	В.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.I.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.I.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.I.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.I.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.M.S.I.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.G.S.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.I.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.I.	Wholesaler Pharmacy	Approved for renewal
•	M.M.S.I.	Wholesaler Pharmacy	Approved for renewal
•	S.D.I.	Durable Medical Equipment Supplier	Denied application
•	C.H.A.	Reverse Distributor Pharmacy	Approved for renewal
•	A.H.G.I.	Retail Pharmacy	Approved for renewal
•	B.C.H.S.I.	Retail Pharmacy	Approved for renewal
•	J.W.H.	Pharmacist Certification of DTM	Approved application
•	K.B.	Pharmacist Certification of DTM	Approved application

## Correspondences/Requests

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•	W.S.C.P.	Notice of Discipline	No action
•	C.V.S.P.	Notice of Discipline	No action
•	E.P.S.	Notice of Discipline	No action
•	C.H.	Appearance request	Tabled pending receipt of additional information
•	C.B.	Request to Terminate Consent Order	Approved request
•	S.R.V.	Request to Terminate Consent Order	Approved request effective 08/10/2021
•	K.R.W.	Request for extension of intern license	Approved request
•	Q.A.H.	Request for extension of intern license	Approved request
•	T.G.H.	Request for extension of intern license	Approved request
•	S.C.P.	Correspondence	The Board viewed this correspondence for informational purposes only.
•	P.S.H.	Request regarding consent order	Board directed staff to respond by stating that it would permit the individual to volunteer only if the individual is working as a pharmacist under the supervision of a pharmacist approved by the Board. Additionally, the employer must comply with the reporting requirement.

Ms. Ashbee seconded, and the Board voted unanimously in favor of the motion.

President Brinson reminded the members that the August meeting will be held in person at the University of Georgia College of Pharmacy.

There being no further business to discuss, the meeting was adjourned at 4:35 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, August 18, 2021, at 9:00 a.m., at the University of Georgia College of Pharmacy located at 250 W Green St, Athens, GA 30602.

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