

GEORGIA BOARD OF PHARMACY
2 MLK Jr. Drive, SE, 11th Floor, East Tower
Atlanta, GA 30334
June 5, 2024
9:00 a.m.

Board Members present:

Mr. Chuck Page, President
Mr. Cecil Cordle, Vice-President
Mr. Michael Azzolin
Mr. Jim Bracewell
Mr. Michael Brinson
Mr. Young Chang
Mr. Dean Stone

Board Staff present:

James Joiner, Executive Director
Itovia Evans, Deputy Director of Licensing
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Rick White, Special Agent, GDNA
Justin Cotton, Assistant Attorney General

Visitors:

Mary Kate Snead, Guardian – LTC
Melissa Reybold, GPHA
Kacy Lee, GHA
Brandon Brooks, Publix
Ben Cowert, Georgia Retailers
Kathleen Bowen
Bryce Carter
Christi Heys, Emory

D. Scott Bass, GPHA
Dawn Sasine
Becca Hallem, GHA
Heather Hughes, Publix
Emily Doppel, Brightspring & McKesson
Julie Mendoza, Walgreens
Jordan Khail, UGA
Donovan Stephens, DCH – Opioid Program

Open Session

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

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

Approval of Minutes

Mr. Stone made a motion to approve the Public and Executive Session minutes from the May 8, 2024, meeting. Vice President Cordle seconded, and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

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

Correspondences

Correspondence from Jennifer Falkenrath: The Board discussed this correspondence seeking guidance relative to the licensing requirement for two adjacent buildings when operated as a single campus. President Page stated that he had some questions about this correspondence and noted that Mrs. Falkenrath was not in attendance. He further stated that while he was not sure the Board would be able to get through all of it today, he asked the Board members for comment. Mr. Stone sought clarification as to what was being asked of the Board. President Page state that his questions were about the device being manufactured and the license sought. He continued stating that the answers to those questions will directly control the answer the Board gives.

Director Troughton added that, in the past, the Board has not licensed medical device manufacturers of devices which do not contain a drug, deliver a drug or are otherwise tied to pharmacy. He also observed that the letter states that they are “looking into two facilities,” and reminded the Board that the Georgia Drugs and Narcotics Agency does not work from hypotheticals, and requires an actual inspectable location to make recommendations.

Mr. Azzolin observed that the correspondent had not yet put in an application, and that they should wait until they were closer to application to seek advice from the Board. Mr. Stone added that he believed it would be prudent for the correspondent to first seek private legal advice to decide on their plan and the type of license they will seek.

President Page stated that the Board needs more information than is before it today to render an opinion.

Director Troughton explained that his Agency cannot work from a hypothetical, and that it wasn't their role to do so. He explained that planning from hypotheticals is the role of legal counsel and consultants. He added that questions of this nature are received by GDNA frequently and this is their response.

Mr. Azzolin proposed that the Board respond stating that the correspondent is welcome to apply for a license when reach that point, and that the Board can address this matter at that time. The Board unanimously approved.

President Page directed Board staff to respond to the correspondent as discussed.

Correspondence from Robert Brennan, Wellstar MCG Hospital at Home Program: The Board discussed this correspondence seeking guidance on behalf of Wellstar Health System regarding establishment of a Hospital at Home program at Wellstar MCG Health. President Page asked Mr. Brennan to give an overview of the program. Mr. Brennan stated that was a hospital at home program which is novel in Georgia, and that the concept is that the patients would be admitted in-patients who are treated at home.

Mr. Brennan introduced the group he had brought with him to answer the Board's questions: Lauren Hopkins, Dr. Phillip Kuhl, and Dr. Richard Burrell. This group then made a presentation to the Board about the program.

After the presentation, President Page asked Director Troughton whether the virtual beds discussed satisfied, from a rules standpoint, consideration as part of the hospital. Director Troughton responded “yes, and no.” He explained his response, stating that how he looked at it from an enforcement perspective there are things the Board should look at from a drug security perspective. The first was that the patient's address given to the hospital by the patient, may be different from the location to which the patient goes for treatment in the hospital at home program where the drugs and the records will be kept. Knowing where those drugs and drug records are kept is a concern. Director Troughton suggested keeping records of who the person transporting the drugs is, what time they received the package, and what time the package arrived at the patient's location. Director Troughton also suggested signatures be collected upon receipt of the drugs. Director Troughton stated that the hospital pharmacy must be able to identify during a GDNA inspection which patients in their records are hospital-at-home patients.

Director Troughton observed that the presentation proposed bringing unused or expired medications from hospital-at-home patients, back to the hospital pharmacy. He stated that in Georgia, no pharmacy can take back medications unless they are unit dose packed medications from a Medicaid nursing home patient. He stated that this prohibition does not fit with the proposed model. He stated that in his mind, this part of the proposed model would have to be modified.

President Page asked if the drugs used in the program were sent out to patients in unit dose packs, to which the response was affirmative. President Page then asked Director Troughton if that would be sufficient under the Rules, to which Director Troughton responded it would not.

Mr. Azzolin observed that this conversation was like the DEA conversation the Board had a few months ago regarding hospitals taking medications from patients and storing them for the patient. In that instance DEA had determined that because the medications belonged to the patient, turning them over to the hospital constituted illegal distribution. For this reason, the hospital cannot take drugs from a patient even to store on the patient's behalf. Dr. Troughton added that "unit dose" was started in response to the Tylenol scare in the 1980s. He stated that in this case, the drugs are in the home and there is zero control over who does anything with those drugs.

Mr. Azzolin stated that, if they were going to do this, a lot of what would be provided would be IV medications, things that are mixed, et cetera. He asked for clarification as to whether the drugs returned to the pharmacy were being returned for re-use or purely for destruction. The response was that the drugs taken back were purely for destruction. Mr. Azzolin continued, asking if the hospital pharmacy is prevented from taking back those medications, how would the hospital go about "wasting" those drugs? Director Troughton responded that that was something that had to be figured out within the law, but that it was a problem that has plagued nursing homes for a long time.

Director Troughton suggested that the Board should include in its responsive correspondence to Wellstar that drugs cannot be taken back for reuse, and in fact cannot be taken back at all. Mr. Azzolin inquired whether the prohibition on taking drugs back was a Rule that could be waived by the Board, or if the requirement was statutory. Director Troughton responded that this prohibition was in Rule. He also opined that it did not make sense to him to waive that rule.

Mr. Azzolin stated that Rule 480-13-.01 defines an "inpatient" as "a patient who is confined to the hospital" and stated that last month the Board determined that the rules of the Department of Community Health defined a hospital as the four walls at the address of the hospital. He stated that CMS and Federal law are now defining an "inpatient" as a patient at home as well, but that does not cross over in to Georgia law.

Director Troughton then pointed out Rule 480-13-.01(e), which defines an "outpatient" to mean "a patient who is not an inpatient, including patients on leave of absence." He stated that he believes this definition supports Mr. Azzolin's position.

Mr. Azzolin stated that the Board has discussed outpatient dispensing by a hospital pharmacy before, and has concluded that a hospital pharmacy cannot dispense retail prescriptions to an outpatient who has never been an inpatient of the hospital. He continued, stating that the only option then would be the leave of absence part of the rule which would still require that the patient have been an inpatient of the hospital. Mr. Azzolin stated that his question was whether the proposed model would require the waiving of the Georgia definition of "inpatient?"

Director Troughton responded that the Board could entertain a waiver of the inpatient language, but warned of a potential cascade effect where the Board begins waiving that language for every hospital.

Mr. Azzolin clarified that his point was that he did not want to ignore the rule that is there, because other licensees would begin doing to the same thing without waiver. He said, he was pointing out that the correspondents would need to get a waiver if they did move forward.

Director Troughton stated that he believed the waiver question was a legal issue which would need to be addressed by the various legal counsel between the Board and the correspondents.

Mr. Azzolin stated that he thought that what the correspondents were trying to do was “admirable and awesome” and that the waiver route should be available to them or that there should be a rule change.

Mr. Joiner added that this would be his suggestion, for the Board to look at changing the Rule as opposed to granting waivers. He stated that the issue with a waiver is that it must be based on a unique hardship, and the simple fact that a rule does not allow one to do as one proposes to do, is not a hardship.

Mr. Azzolin stated that he believes that the correspondent’s inability to treat those patients does pose a hardship.

Director Troughton stated that his last question related to drug labeling. The hospital rules have specific requirements for the labeling, essentially a retail label, that must be affixed to drugs that are intended to be used outside the hospital and he stated that compliance with those requirements are what his agents would be looking for during an inspection.

Mr. Azzolin suggested that the hospital pharmacy in this instance could get a retail permit.

Mr. Brinson added that he believed this proposal was a great idea that would be highly beneficial to patients in Georgia.

The Board discussed several hypothetical scenarios of drug diversion.

Respondents clarified that when medications are self-administered by patients it is done over a video call wherein a nurse verifies who the patient is, what medication they will be taking, and witnesses the patient take the medication.

President Page summarized the discussion, stating that it appeared that there were two things at play: a possible rule waiver to address the inpatient and outpatient part of the issue, and the second item is whether it would be feasible for the correspondents to show Director Troughton and the Georgia Drugs and Narcotics Agency the necessary paperwork and procedures to satisfy their concerns.

Director Troughton stated that what the Georgia Drugs and Narcotics Agency needs, is for the Board to set up in its communications with the correspondents fixed definitions for anything which is not clearly defined at present.

Mr. Farmer inquired whether he was correct in understanding that any patient on a new controlled substance medication would be excluded from this program. The correspondents confirmed this was correct.

Mr. Farmer further inquired about whether the correspondents had considered a model wherein the destruction of medication occurred at home for the patient. The Correspondents responded that they had considered that option at one time but elected against it due to the complications surrounding home destruction and the inappropriateness of some drugs for disposal in household trash.

Director Troughton stated that it was important that all of these practices be included in the hospital policies, and that these policies were among the documents reviewed by Georgia Drugs and Narcotics, as well as other agencies, when they conduct an inspection.

Mr. Azzolin stated, to him, the correspondents are a hospital pharmacy, operating under a hospital pharmacy license, and there are hospital pharmacy rules to follow. One of those rules allows for leave of absence dispensing. To him, looking at the rules, in everything that has been discussed about logistics, they have not touched upon this leave of absence dispensing. It is a concern, that they are doing the same thing

as leave of absence dispensing but with a slightly different system because of what CMS allows. The correspondents are proposing to do more volume, but it is the same thing as what has always been allowed. The only issues he sees with their proposal is what he discussed earlier relating to inpatient language and the destruction mechanism also discussed earlier. Mr. Azzolin further stated that he understands both of these issues to be board waivable.

Mr. Farmer inquired about what happens if the patient has to change locations, is that allowed? The correspondents responded that it could occur without the patient having to be moved back to the hospital, and would require that the hospital-at-home program conduct a new inspection of the new site and approve before relocating the patient.

Mr. Stone stated that he agreed with Mr. Azzolin that the Board needed to consider whether this type of program required new rules to effectively implement.

President Page stated that from his understanding it appeared that the first step for this program would be to seek the rule waivers as required. He also added that the Board would send correspondence back to the correspondents detailing the Board recommendations and what the Georgia Drugs and Narcotics Agency would like to see before an inspection of the program.

Mr. Stone added that the Board should research how hospital-at-home programs like this one are handled in other states.

President Page directed Board staff to respond to the correspondent as discussed.

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

Director Troughton introduced Special Agents Emily Lobeck and Rick White to the Board.

Special Agent White stated that he currently covers Gwinnett and Rockdale counties, and that he has been with GDNA since 2010.

Special Agent Lobeck stated that she currently covers Cobb and Paulding counties, and the City of Alpharetta, and that she has been with GDNA since 2022.

Director Troughton stated Agents Lobeck and White do a great job for GDNA.

Director Troughton reported that GDNA conducted 3,104 inspections with 11 agents. He also stated that each time they add an agent they increase their capability about 10%. He further stated that they have conducted 496 investigations for through the end of May.

Attorney General's Report – Mr. Justin Cotton

Mr. Cotton introduced new staff in the Attorney General's office, who were with him to observe the meeting. These were Ms. Zoe Elridge, an intern from UGA; and Mr. Craig Bank, a new attorney in the AG's office.

Executive Director's Report – Mr. James Joiner

No Report.

Legal Services – Mr. James Joiner

No Report.

Miscellaneous

USP-800 Memo: The Board discussed this legal memorandum from Mr. Scott Bass, regarding enforcement of USP-800 in Georgia.

President Page thanked Mr. Bass for his memo, stating that it was very well done. He continued, saying that he understands there to be two sides to this issue: First, whether the Board should and enforce USP exactly as it is written, or whether the Board has some discretion in the application of its provisions.

President Page continued, stating that unfortunately for this meeting today, after discussion with Mr. Cotton, the Attorney General's office still has this matter under consideration in their office and is still researching parts of it. He advised that he was unable to say whether the Board would resolve anything today, but would discuss the matter if Mr. Bass had any comments.

Mr. Bass discussed the content of his memo.

Mr. Bass concluded that the Board had authority to exercise discretion in its application of USP-800 and that such an exercise of discretion would not require a legislative change.

Mr. Azzolin stated that in his opinion USP has gone too far in its oversight of compounding, and the Board should pay attention when it has the opportunity either legislatively or through the rules to control how those USP standards will be enforced in Georgia in certain settings. Mr Azzolin acknowledged that this issue was still under consideration by the Attorney General's office. He suggested formation of a sub-committee to review the USP to study what the Board wants to keep in place and what the Board does not want to keep, to then move that through the rule making process for vetting by the AG's office.

Mr. Farmer stated that he agrees with Mr. Azzolin's suggestion and believes that such a committee would take some of the burden off of the AG's office.

Mr. Stone stated that he also agreed with Mr. Azzolin's suggestion.

President Page thanked Mr. Azzolin for his suggestion, stating he thought it was a great idea and that the Board would circle back to it once it had received advice from the Attorney General's office.

Mr. Brinson inquired about what happens when other regulatory agencies come in to Georgia licensed facilities for inspections and those facilities are compliant with Georgia rules and not those of the other agency. Mr. Cotton responded that he would have to research this issue and report back.

Mr Azzolin added, that if you are seeking accreditation by a particular agency, you will still need to comply with the rules of that agency for the purpose of that accreditation, even if Georgia regulations would allow a more relaxed compliance.

Mr. Stone made a motion and Vice-President Cordle 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

Georgia Drugs and Narcotics Agency
A.P.I.

Cognizant's Report – Mr. Cecil Cordle

- GDNA Case #T35281
- GDNA Case # T35315
- GDNA Case # B35239
- GDNA Case # A35276
- GDNA Case # A35301
- GDNA Case # A35300
- GDNA Case # B35242
- GDNA Case # A35283
- GDNA Case # B35267
- GDNA Case # B35269
- GDNA Case # B35179
- GDNA Case # B35286
- GDNA Case # B35251
- GDNA Case # B35250
- GDNA Case # B35240
- GDNA Case # B35217

Attorney General's Report – Mr. Justin Cotton

Mr. Cotton presented the following consent orders for acceptance:

- C.C.B.H.C.C.
- C.R.R
- C.P.
- L.C.C.S.
- T.T.C.
- W.R.P.C.
- L.C.P. /C.A.V. / C.A.V.
- P.S.K.
- S.L.M.
- W.P.
- A.C.P.
- C.H.P.
- C.C.O.

Mr. Cotton discussed the following:

- O.O.A.
- P.S.M.
- P.J.
- R.P.P.I.

Executive Director's Report – Mr. James Joiner
W.R.S.I.

Legal Services – Mr. James Joiner
No report.

Applications

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

Correspondences/Requests

- I.C.
- T.R.
- S.2.L.
- C.W.
- D.Y.
- H.D.
- J.A.
- L.S.
- N.H.
- N.A.
- S.P.
- S.L.

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

Open Session

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

Georgia Drugs and Narcotics Agency

A.P.I.

Approve application and issue license

Cognizant's Report – Mr. Cecil Cordle

- GDNA Case #T35281
- GDNA Case # T35315
- GDNA Case # B35239
- GDNA Case # A35276
- GDNA Case # A35301
- GDNA Case # A35300
- GDNA Case # B35242
- GDNA Case # A35283
- GDNA Case # B35267
- GDNA Case # B35269
- GDNA Case # B35179

Revoke registration
Accept signed voluntary surrender
Misfill Guidance #1A
Null and void the license
Public Order and Fine
Public Order
Misfill Guidance #1A
Investigative Interview
Close no action
Close no action
Close no action

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|----------------------|-----------------|
| • GDNA Case # B35286 | Close no action |
| • GDNA Case # B35251 | Close no action |
| • GDNA Case # B35250 | Close no action |
| • GDNA Case # B35240 | Close no action |
| • GDNA Case # B35217 | Close no action |

Attorney General's Report – Mr. Justin Cotton

Mr. Cotton presented the following consent orders for acceptance:

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|---------------------------|--------------------------------------|
| • C.C.B.H.C.C. | Accept Private Consent Order |
| • C.R.R | Accept Public Consent Order |
| • C.P. | Accept Private Consent Order |
| • L.C.C.S. | Accept Private Consent Order |
| • T.T.C. | Accept Signed Voluntary C & D |
| • W.R.P.C. | Accept Private Consent Order |
| • L.C.P. /C.A.V. / C.A.V. | Accept Public Consent Orders |
| • P.S.K. | Accept Private Consent Order |
| • S.L.M. | Accept Public Consent Order |
| • W.P. | Accept Private Consent Oder |
| • A.C.P. | Accept Consent Order counterproposal |
| • C.H.P. | Deny Consent Order counterproposal |
| • C.C.O. | Deny Consent Order counterproposal |

Mr. Cotton discussed the following:

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| • O.O.A. | AG's office will proceed with Consent Order |
| • P.S.M. | |
| • P.J. | AG's office will proceed with Consent Order |
| • R.P.P.I. | AG's office will proceed with Consent Order |

Executive Director's Report – Mr. James Joiner

W.R.S.I.	Deny application and render license Null and Void
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Legal Services – Mr. James Joiner

No report.

Applications

- | | | |
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| • T.A.S. | Pharmacy Technician | Issue Registration |
| • B.H. | Pharmacy Technician | Issue Registration |
| • E.J. | Pharmacy Technician | Issue Registration |
| • J.C. | Pharmacy Technician | Issue Registration |
| • B.R. | Pharmacy Technician | Issue Registration |
| • S.G. | Pharmacy Technician | Deny |
| • T.M. | Pharmacy Technician | Issue Registration |
| • K.V. | Pharmacist | Approved Application |
| • R.W. | Pharmacist | Approved Application |
| • S.P. | RPH Certification DTM | Approved Application |

- S.M. RPH Certification DTM Approved Application

Correspondences/Requests

- | | | |
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| • I.C. | Notice of Discipline | Take as Information |
| • T.R. | Notice of Discipline | Take as Information |
| • S.2.L. | Notice of Discipline | Take as Information |
| • C.W. | Request to extend Intern license | Approved |
| • D.Y. | Request to extend Intern license | Approved |
| • H.D. | Request for 4th MPJE attempt | Approved |
| • J.A. | Request to extend Intern license | Approved |
| • L.S. | Request to extend Intern license | Approved |
| • N.H. | Request for 4 th MPJE attempt | Approved |
| • N.A. | Request to extend Application | Approved |
| • S.P. | Request to extend Application | Approved |
| • S.L. | Request for 4 th NAPLEX attempt | Approved |

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

There being no further business to discuss, the meeting was adjourned at 1:31 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, July 17, 2024, at 9:00 a.m. at University of Georgia School of Pharmacy, 250 W Green Street, Athens, GA 30602.

Minutes edited by J. Clinton Joiner, II, Executive Director