GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St, N.W. 5th Floor
Atlanta, GA 30303
October 14, 2015
9:00 a.m.

The following Board members were present:
Laird Miller, President
Mike Faulk, Vice-President
Vicki Arnold
Jim Bracewell
Chris Jones
Bill Prather
Bob Warnock

Staff present:
Tanja Battle, Executive Director
Eric Lacefield, Deputy Executive Director
Rick Allen, GDNA
Janet Wray, Senior Assistant Attorney General
Brandi Howell, Business Operations Specialist

Visitors:
John Milam, Rood & Riddle Vet Pharmacy
Thomas Barrs
Ambria Williams
David White, Pharmaceutical Specialties
Jerel Applewhite, Mercer Univ/Walgreens
Greg Reysold, GPhA
Liza Chapman, Kroger
John Sisto, ESI
Scott Biddulph, Target
Gregg Raduka
John Bringuel

President Miller established that a quorum was present and called the meeting to order at 9:02 a.m.

Bill Prather made a motion and Jim Bracewell 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 Vicki Arnold, Jim Bracewell, Mike Faulk, Chris Jones, Laird Miller, Bill Prather, and Bob Warnock.

Executive Session

Appearances

- M.P.
- M.P.
- R.R.V.P.
- C.W.B.
- T.J.B.
- A.M.W.
- W.C.L.C.M.S.E.

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

President Miller welcomed the visitors.

Appearance

Appearance by Gregg Raduka, Georgia Prescription Drug Abuse Prevention, Initiative Director of Prevention/Intervention, The Council on Alcohol and Drugs: Mr. Raduka thanked the Board for the opportunity to speak to its members. He introduced Mr. John Bringuel, Project Director of the Georgia Prescription Drug Abuse Prevention Initiative. Mr. Raduka spoke to the Board regarding the DEA's disposal of controlled substances rule and requested that the Board adopt this rule. He explained that, to date, forty-seven (47) states have adopted the rule. He stated there is a strong consensus that in concept it is a great rule, but in practice it can be challenging in a number of ways due to the complexity of the rule; however, he feels it would be good for Georgia to adopt it through pilot sites to see how it goes as there are no mandates. Following his presentation to the Board, President Miller asked Mr. Raduka how the Board can help facilitate this other than awareness. Mr. Raduka responded by stating that if the Board would move to adopt the rule so that pharmacies in Georgia would have the option to be collection sites. Ms. Battle commented that staff is currently working to finalize language for the rule and will bring it back to the Board for a vote to post.

Approval of Minutes

Chris Jones made a motion to approve the Public and Executive Session minutes for the September 16, 2015 meeting, and the minutes for the October 8, 2015 Conference Call. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Ratifications

Bob Warnock made a motion to ratify the list of issued licenses. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Portola Pharmaceuticals, Inc., Sarepta Thereapeutics, Inc., Tesaro, Inc., and Otonomy, Inc.

Ms. Wray commented that the Board has on its agenda several rule waivers from facilities that are applying for both a wholesaler and manufacturer permit. Those facilities are Portola Pharmaceuticals, Inc., Sarepta Therapeutics, Inc., Tesaro, Inc., and Otonomy, Inc. Ms. Wray stated that none of these facilities are licensed as manufacturers with the federal government; however, they can be licensed as wholesalers. She added that there have been situations in the past when facilities qualify as 503(b) and under those circumstances, the Board licenses them as manufacturers, but with the facilities she just mentioned, none of them are 503(b) or licensed as manufacturers based on the information provided. Therefore, under current Georgia law, the Board cannot license them as manufacturers. With that said, Ms. Wray stated this brings up the issue of whether or not the Board wants to address legislation on virtual manufacturers. Mr. Prather commented that he would like the Board to pursue legislation regarding such so it has a way of holding these facilities responsible. Ms. Wray responded that it would be great for Ms. Foreman and Director Allen to further research this issue. She stated that right now, the facilities she mentioned only qualify as wholesalers as they do not have the qualifications to be licensed as manufacturers.

Jim Bracewell made a motion to grant rule waiver petitions for the wholesaler applications for Portola Pharmaceuticals, Inc., Sarepta Therapeutics, Inc., Tesaro, Inc., and Otonomy, Inc. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

In the same motion, the Board voted to deny rule waiver petitions for the manufacturer applications for Portola Pharmaceuticals, Inc., Sarepta Therapeutics, Inc., Tesaro, Inc., and Otonomy, Inc. as they

did not provide evidence that they are a 503(b) facility or licensed as a manufacturer with the federal government.

Petition for Rule Variance from East Georgia Specialty Pharmacy
Vicki Arnold made a motion to grant the rule variance petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Pharmacyclics, LLC
Bob Warnock made a motion to grant the rule waiver petition. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Kenneth Wells, Oregon Board of Pharmacy
The Board previously considered this correspondence at its meeting on September 16, 2015 regarding a misfill course called Patient Safety and Medication Error Prevention for Pharmacists. At that meeting, the Board voted to table this correspondence to allow time for further review. Mr. Warnock stated that he called the Oregon Board to get more information on the course. He stated that it contains five (5) different components and each component is $200. He stated that the individual can take one specific component or the Board can require him/her to complete them all. Jim Bracewell made a motion to add this course to the Board's list of approved education programs for misfills. Additionally, for misfill policy #1, require the individual to complete two modules of this course (including workflow management and one other of his/her choosing) and for misfill policy #2, the individual must complete all five modules. Bob Warnock seconded and the Board voted unanimously in favor of the motion. In the same motion, the Board voted to review the misfill policy with these amendments at its next scheduled meeting.

Correspondence from Renee Husk, Hunter Pharmacy, Services, Inc.
The Board considered this correspondence regarding remote order processing/telepharmacy laws in the State of Georgia. The Board directed staff to respond to Ms. Husk by referring her to O.C.G.A. §§ 26-4-5 (37.2) and 26-4-80 (c)(7) and Board Rule Chapter 480-13 for more information.

Correspondence from Kurt A. Boesger, RPH015299
The Board considered this correspondence from Mr. Boesger requesting to modify his Public Consent Order #2004-1330 to Private. Mike Faulk made a motion to deny the request. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Timothy Koch
The Board discussed this correspondence from Mr. Koch asking can a licensed pharmacist (who is not licensed in Georgia), who works at a non-resident pharmacy (central fill/processing or mail order pharmacy) licensed by the Georgia Board of Pharmacy, conduct a comprehensive medication review with a patient located in Georgia. The Board directed staff to respond to Mr. Koch by stating that, based on the information provided, the response to his question is yes.

Georgia Drugs and Narcotics Agency Open Session – Rick Allen
No report.

Attorney General's Report Open Session –Janet Wray
No report.

Executive Director's Report Open Session – Tanja Battle
Ms. Battle shared documentation with the Board from Center for Pharmacy Practice Accreditation (CPPA). She stated that there have been presentations in the past regarding accreditation. Ms. Wray

commented that there are two issues with accreditation. One previous presentation was a specialty pharmacy, which is different from the information that Ms. Battle shared. She stated that O.C.G.A. § 26-4-28 states that the Board shall have the authority to approve or recognize accreditation or certification programs for specialty pharmacy practice. After further discussion by the Board, President Miller stated that the Board will continue to discuss this topic at a later time.

Ms. Battle discussed training courses for immunization administration and read the language that is currently on the Board's website as there continues to be some confusion as to what courses are required. The Board voted to amend the language to state the following:

At its meeting on October 14, 2015, the Georgia Board of Pharmacy discussed training courses for immunization administration and confirmed that a pharmacist needs the required training for immunization administration:

- *A one hour ACPE (Accreditation Council for Pharmacy Education) course; and*
- *The previous GPhA course called Pharmacy-Based Immunization Post-Graduate Training Program or the current APhA course*

Although it will not be required as continuing education, the one hour course may also be used as continuing education for renewal.

Ms. Battle discussed the proposed 2016 meeting dates. Bill Prather made a motion to approve the 2016 meeting and exam dates as presented. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Rules Discussion

Ms. Wray commented that Rule 480-34-.07 Hallucinogens was ready for a vote to post. She discussed changes that needed to be made to the following before they can be voted on: Rules 480-7-.01 Manufacturer's Permit, 480-7-0.03 Drug Wholesale Distribution Licensing Requirements, 480-7-.04 Researcher's Permit, 480-7-.05 Reverse Distributors, 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records, and Security, 480-10-.20 Required Notifications to the Board, 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances, 480-28-.02 General Requirements. Amended, 480-30-.02 General Requirements, and Policies for Reduction of Loss or Theft of Records, Drugs, or Controlled Substances. Ms. Wray added that she will draft the changes on the rules and the policy since Ms. Foreman was not present at the meeting.

Chris Jones made a motion to post Rule 480-34-.07 Hallucinogens. Bill Prather seconded and the Board voted unanimously in favor of the motion.

A motion was made by Mike Faulk, seconded by Vicki Arnold, and the Board voted that the formulation and adoption of this rule does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board 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§ 50-13-9 16 5 9 4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this rule will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Discussion Topics

Temporary Licensure: President Miller stated this topic stems from the short cycle and not being able to get residents in on exam dates so that they can begin rotations on July 1st. He added that this would extend to military applicants as well. He asked how the Board can accommodate these individuals. Ms. Wray responded that it would require a change in the law to grant temporary licensure. Mr. Prather commented on alternatives for reciprocity applicants and asked if the Board could find a competency test that it could substitute for the Board's practical examination. President Miller responded that the only concern he has about that is that it would that make applicants go to another state and reciprocate into Georgia and taking that competency test instead of the Board's practical. Mr. Prather responded that if the Board had the right competency test that covers compounding and calculating, that would lessen the list of exam candidates. President Miller commented that he is afraid if the Board does that it undermines the test. Ms. Wray commented that the Board may run into issues with Equal Protection and stated that a compromise may be to give those applicants a temporary permit for no more than six months and issue a license once they pass the examination. She added that if the individual fails, the temporary permit would no longer be valid. President Miller asked if this would only be for residents or for anyone. Ms. Wray responded that it would be for reciprocity and out of state applicants. President Miller stated that it would be nice to have legislation that would allow the Board to issue a temporary license and then develop a policy regarding such. The Board discussed amending the law pertaining to pharmacy interns to say applicants that have graduated within the past six months. Ms. Wray stated the Board could go back to its current temporary license provision amend it to say the Board can grant a temporary licensure for up to six months as this is in the current law. This would apply to applicants that have met all requirements for licensure except for passing the practical examination. She added that O.C.G.A. § 26-4-43 could be amended to say "shall be valid no longer than six months from the date of issuance" and that this could cover military and residency applicants.

Registration of DMEs (Durable Medical Equipment): President Miller stated that this topic came up earlier this past year. It was initially proposed to fall under the Pharmacy Board, but then it was shifted to the Georgia Composite Medical Board; however, the bill did not pass. He stated that this issue is still up for consideration. He added that the Board's language gives pharmacy some control. Ms. Wray stated that it is not currently in our law because it is not prescriptive. She stated that the question is whether or not the Board wants to include this in its statute or not. She asked if the Board wants to exempt from registration requirements those pharmacies that already do it as they are already a highly regulated area. President Miller stated that he feels if this issue is brought up again, the Board needs to be prepared to take it on. Director Allen commented that GDNA would need additional agents to go and inspect. Mr. Biddulph asked who would regulate DMEs, if they were not going to be overseen by the Board of Pharmacy. President Miller reiterated that it would likely be the Medical Board. Mr. Biddulph commented that if the DMEs are mostly sold through pharmacies, he wondered if the Board of Pharmacy really would want the Medical Board regulating the pharmacies selling the DMEs. President Miller stated that was his point and that this is really a jurisdictional issue. He added that the Board will continue to work on this topic and have a contingency plan.

Intern Hours: At the Board's April 15, 2015 meeting, this was discussed as part of someone's correspondence to the Board regarding accruing internship hours for licensure. The individual requested approval to be allowed to work at Pfizer (or gain hours at Pfizer). The position would be considered a non-conventional setting. The individual requested full accreditation or at least 75% of hours that will be worked and the Board approved two (2) for one (1). At that meeting, the Board requested this topic be a subject of discussion "how many hours have to be directly pharmacy and how many have to be indirect". Chairperson Miller stated that usually if someone works in a drug information service that is not typically pharmacy. As pharmacies change, not everyone works at a dispensing function. He asked what would constitute legitimate hours. Mr. Warnock responded by

stating that the Board needs to figure out a way that would be "clinical pharmacy" work. He stated that he does not know if drug information fits that category and as a board member, he would say it did. He stated that he feels giving them one (1) hour of credit for every two (2) hours of work would be discouraging. Mr. Prather stated that he does not recall the Board every turning down someone working in a pharmacy arena by giving them two (2) for one (1). He stated that typically what the Board runs into is someone requesting full hours for research study on semi-permeable membranes and what the Board based that on is when it gives someone a pharmacy license, the Board is not giving them a pharmacy license for a special area. Mr. Warnock replied that he understands the way of thinking; however, the practice of pharmacy has changed vastly. President Miller commented that his impression since he has been on the Board is the two (2) for one (1) is mainly implied if the person is doing research and did not really involve the practice of pharmacy. Mr. Jones stated that he feels the Board needs to consider this on a case by case basis. He added that the Board may need to start realigning the way it thinks as there are many ways for a pharmacist to practice. President Miller discussed traditional and non-traditional and stated that the Board needs to define what is non-traditional. Mr. Warnock stated that if it is something that the company has the pharmacist doing, that is a reasonable one (1) for one (1). He added that if it is not in the field of pharmacy or drug related, it would be two (2) for one (1). Ms. Wray discussed qualifying experience for internship credit hours as outlined in Rule 480-2-.03(4)(d), which reads:

(a) Any intern wishing to obtain internship credit for work in a research and /or industrial program must first submit a request for approval of the program to the Board along with an outline of the program from the individual who will supervise the intern in this program. If approved by the Board, the maximum number of hours that will be awarded is one (1) hour of credit for every two (2) hours worked, not to exceed a maximum of 200 hours credit. An intern will not be granted approval or credit for participation in more than one research/industrial program.
(b) At the discretion of the Board, credit may be given for serving in the Armed Services and working under the direct supervision of a registered pharmacist. Documentation of experience must be signed by a registered pharmacist.
(c) The Board may give internship credit to an applicant that has demonstrated to the satisfaction of the Board that such applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements.

Ms. Wray added that if the Board is doing something inconsistent with the rule, it would need to go back and amend the language.

Accreditation for Specialty Pharmacies: The Board recommended tabling this subject.

Biosimilars: The Board recommending tabling this subject.

Auto Injection/Epinephrine: Ms. Wray stated she conducted research on this topic. She stated there was one law about schools, but it was amended to add facilities. The person who designates facilities is the Department of Public Health (DPH) by rule. She added that they have until January 2016 to come up with a rule, so the Board will have to wait until that time. Ms. Wray stated that Ms. Battle can reach out to DPH and ask them to let the Board know when it adopts its rule.

RAMS: Ms. Wray stated that she thought the Board had already voted to have RAMS renewal date to mirror the facility. Mr. Warnock asked if each one has a license does the company only have one fee. President Miller responded by stating that he thought if it was a licensed pharmacy it needs to have its own fee. Ms. Wray stated that the rule is supposed to clarify that. The Board recommended placing this subject on next month's agenda so the Board can vote to post the rule.

Vaccination/Immunization/Direct Supervision of Pharmacy Technicians: President Miller stated that this topic stems from the new immunization bill. He stated that the requirement is that the technicians should be under direct supervision at all times; however, the pharmacist should be allowed to leave the pharmacy for a brief time. Ms. Wray commented that she understands there may be existing pharmacies are bringing patients into the pharmacy with the pharmacist behind the counter. Ms. Wray stated that the Board will need to address video observation and does this comply with supervision of the technician. She stated that obviously the standard of review before it goes out the door cannot be done by video supervision. She stated that the Board has that issue and the issue with the immunization law and privacy concern. The Board has to address what can be done by the technician if the pharmacist is outside the pharmacy for an unlimited amount of time. Mr. Miller clarified that he is talking about what is going on in the existing pharmacy such as stepping out to do a flu shot or over-the-counter recommendation. Mr. Warnock commented that we have a structure set up now in which pharmacists/technicians are responsible. There is good information out there that shows technicians are better than pharmacists at filling prescriptions. He added that by utilizing technicians, the Board is not endangering the public. He asked how the Board can free up the pharmacist. He added that it may not be reasonable to say a pharmacist cannot ever leave the prescription counter. Mr. Jones commented that it is concerning when you have an unnamed chain bringing patients into a secure setting where drugs are at. He added that it works better for the pharmacist to walk outside and give the flu shot. President Miller responded by stating that under our existing rules, that cannot be done. Ms. Wray stated that O.C.G.A. § 26-4-88(c) reads, "*Nothing in this Code section shall prohibit any person from assisting any duly licensed pharmacist or practitioner, provided that such duly licensed pharmacist or practitioner shall be physically present in the prescription area and actually observing the actions of such person performing such tasks; provided, further, that no prescription shall be given to the person requesting the same unless the contents and the label thereof shall have been verified by a licensed pharmacist or practitioner."* Additionally, O.C.G.A. § 26-4-82(c)(2) states that the pharmacist shall be present and personally supervising the activities of the pharmacy technician at all times. She went on to state that O.C.G.A. § 26-4-110 states that every pharmacy licensed under this chapter, except those located within and owned and operated by a duly licensed and accredited hospital, nursing home, or college of pharmacy or a pharmacy complying with subsection (j) of this Code section, shall have a prescription department open for business at all times that the business establishment is open to the public, except that during temporary absences of any licensed pharmacist not to exceed three hours daily or more than one and one-half hours at any one time the prescription department shall be closed and no prescription shall be filled or dispensed. With that said, she stated that there is anticipation of temporary absences and those are the issues that you are increasingly coming up against. President Miller stated that for the short term, the Board is going to try and change the code section now to allow the pharmacist to take a short excursion from the pharmacy department. Ms. Wray stated that the Board would be defining normal prescription area. She added that prescription department is defined in the law, but not prescription area. She further added that the Board can put a timeframe such as "no longer than x amount of minutes". President Miller directed Director Allen to work on this proposed language.

Temperature Controls for Delivery by Mail: During the public hearing at the Board's May 13, 2015 meeting, the Board received public comments from Jean Pierre Edmond concerning Rule 480-48-.02 Conditions for Use of Delivery by Mail. His comments were about using "USP" in paragraph (3) of the rule. He stated that USP does not have a recognized method. The Board adopted the rule as written, but was going to investigate the USP issue further. After further discussion by the Board, it recommended removing the language referenced in Board Rule 480-48-.02.

Prescription Drug Order Requirements: The Board recommended tabling this subject.

3PL Pharmacy License: At the Board's June 10, 2015 meeting, discussion was held on creating a 3PL pharmacy license. Director Allen responded that he has drafted language for a law amendment to make the current statute consistent with the federal law.

Institutional Pharmacy License: Mr. Warnock stated that there are a number of issues (controlled drug script, electronic medication cabinets, pharmacy physical requirements, etc.) where institutional pharmacies more appropriately resemble hospitals, and other areas where they resemble retail pharmacies. He stated that he wanted to propose the Board assign a task force to work with LTC pharmacy providers to develop separate rules that may address these differences and bring these rules back to the Board for discussion and possible approval. He added that this may reduce the continued need to try to fit change institutional practice issues into a retail mold, making it easier to address both site locations as the Board adopts future rules. President Miller responded that most of the Board does not know the dynamic of what goes on in such a facility. Ms. Wray stated that a law change would not be required and it would only be a rule to create another category of licensure. President Miller asked Mr. Warnock to contact the group and request they send correspondence to the Board regarding this matter.

Clinical Pharmacy Services Across State Lines: Mr. Warnock stated that this service would entail a clinical pharmacist in a location who is reaching out to a patient in the state of Georgia and advising them on his/her drugs. Ms. Wray responded that an individual offering services across state lines is the Board's issue, but it would need to be researched further. Mr. Warnock stated it would be medication therapy management for an insurance company. She stated that her initial response is that licensure would be required in this state. She requested Mr. Warnock email Ms. Battle and define what medication therapy management is and Ms. Battle can forward it to her.

Clinical Pharmacist Collaborative Practices: Mr. Warnock stated that they frequently have physicians that want to enter into practice with them for Coumadin dosing. Ms. Wray responded by stating that is in the law. She added that those collaborative practice agreements are filed with the Board. Mr. Warnock stated that there is a new set of regulations that require the pharmacist/pharmacy to be looking at anti-biograms. Ms. Wray advised Mr. Warnock to review the rules pertaining to this matter. She stated that collaborative pharmacy agreement is in both the pharmacy and medical practice acts. She added that at the point you extend beyond what you are delegated to, you are getting into unlicensed practice.

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

Appearances

• M.P.	Non-Resident Pharmacy	Approve pending receipt of additional information
• M.P.	Manufacturing Pharmacy Renewal	Deny renewal
• R.R.V.P.	Denied Non-Resident Pharmacy	Overturn denial and approve registration
• C.W.B.	Denied Pharmacist Applicant	Uphold denial
• T.J.B.	Request to reinstate license	Request approved
• A.M.W.	Denied Pharmacy Technician	Overturn denial and approve pending receipt of additional information
• W.C.L.C.M.S.E.	Denied Wholesaler Pharmacy	Uphold denial

Chris Jones seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 5:37 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Thursday, October 15, 2015 at 8:00 a.m. at 254 Washington Street, SW, Ground Floor, Atlanta, GA 30334.

Minutes recorded by Brandi P. Howell, Business Operations Specialist
Minutes edited by Tanja D. Battle, Executive Director