

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St., NW, 36th Floor
Atlanta, GA 30303
December 11, 2013
9:00 a.m.

The following Board members were present:

Al McConnell, Chairperson
Tony Moye, Vice-Chairperson
Mike Faulk
Chris Jones
Laird Miller
Bill Prather
Bob Warnock

Staff present:

Tanja Battle, Executive Director
Rick Allen, GDNA
Janet Wray, Senior Assistant Attorney General
Brandi Howell, Business Operations Specialist

Visitors:

Laura Searcy
Jim McNatt
Lara Joiner
Chris Maslankowski
Chris Carpenter
Scott Biddulph
Helen Sloat
Lynda Chapman
Eulet Brown
Leslee Worrell
Wende Adams Moulis
Shawn Williams
Ericka Bankston
Melvin Smith
Lanier Evans
Nirmal Patel

Chairperson McConnell established that a quorum was present and called the meeting to order at 9:08 a.m.

Public Hearing

Chairperson McConnell called the Public Hearing to order at 9:08 a.m.

Rule 480-34-.04 Synthetic Cannabinoids

No comments or written responses were received.

Rule 480-34-.05 Synthetic Cathinones

No comments or written responses were received.

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

Laura Searcy, Coalition of Advanced Practice Registered Nurses, shared comments. Ms. Searcy discussed O.C.G.A. § 43-34-25, which was passed in 2006 and granted prescriptive authority to APRNs. She stated that prescription drug orders generated by electronic medical systems do not comply with

Georgia law. Many of the systems only have one field for the prescriber and do not allow for both the APRN and their delegating physician's names to be identified on the order. In these instances, the delegating physician's name will be the only provider listed on the written prescription and this will result in a lack of information on the prescription about the provider of record and the initiator of the prescription. There are many instances where APRNs may not have any knowledge of the patient's condition or history. Ms. Searcy requested the Board consider action that would require the inclusion of the APRN prescriber's name on all prescriptions and prescription drug labels.

Chairperson McConnell stated that the time limit had been exceeded and accepted Ms. Searcy's written comments.

Rule 480-1-.02 Executive Director

No comments or written responses were received.

Rule 480-10-.20 Required Notifications to the Board

No comments or written responses were received.

Rule 480-11-.02 Compounded Drug Preparations

Dale Coker, Cherokee Custom Script Pharmacy, expressed his concern regarding state vs. federal authority over pharmacy compounding due to new federal legislation. He asked if the State or FDA is going to come in and ask them to register as an outsourcing facility. He stated that Jane Axelrad, FDA, stated that if drugs are compounded without a prescription then the pharmacy must register with the FDA under a new outsourcing facility category.

Mr. Coker suggested the following changes to (1)(a) of the rule:

“Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations that are not commercially available in the marketplace or commercially available as outlined by the restrictions under 12(b).”

Mr. Coker stated that the terms pharmaceuticals, products and preparations are used interchangeably throughout. He suggested that active pharmaceutical ingredients and bulk chemicals should be referred to as pharmaceuticals and finished compounded drug preparations be referred to as preparations.

Mr. Coker stated that (1)(b) and (6)(c) of the rule refers to FDA-approved facilities. He stated that the correct terminology is FDA-registered.

Section (1)(b) of the rule states *“pharmaceuticals that have been made in a FDA-approved facility”*. He suggested changing the wording to *“pharmaceuticals that have been manufactured or repackaged in an FDA-registered facility”* as most pharmaceuticals purchased by compounding pharmacies are purchased from re-packagers.

Mr. Coker suggested the Board clarify which federal law is being referred to by *“applicable federal law”* in section (2)(f) of the rule.

Mr. Coker commented on (2)(i) regarding notification to the Georgia Drugs and Narcotics Agency (GDNA). He asked if this would be a one-time notification and if notification is required for each prescriber? Also, what about offices with multiple prescribers?

Section (2)(j) mentions “institutions”. Mr. Coker stated that this term is not included in the definitions provided under Rule 480-11-.01.

Mr. Coker commended on section (6)(a) and asked why must prescription bulk substances comply with HIPAA?

In section (8) low and medium risk compounded drug preparations are mentioned in relation to USP 795, when in fact, all non-sterile compounded preparations are subject to provisions of USP 795 and all sterile compounded preparations, low, medium, and high risk are subject to USP 797.

Lastly, Mr. Coker suggested several grammatical corrections.

Mr. Coker provided the Board with his written comments as well as written comments from International Academy of Compounding Pharmacists.

Bill Prather responded to Mr. Coker by stating that the Board appreciates his expertise and that a great majority of the issues he mentioned can be addressed. Mr. Prather commented that he is not aware of what the FDA is going to do, but that federal law always trumps state law. He further stated that the purpose of the Board is to protect the safety and welfare of the public. He feels that the Board can pass the rule and then revisit at a later time to address the changes suggested.

Public comment from Lara Joiner was received. Ms. Joiner stated that she and Jim McNatt were present to address some of the issues. Specifically, section (1)(c) of the rule regarding “5%”. She asked the Board to clarify what “5%” means. Is this total output of all the compounding they do or what they would do on a specific drug? Laird Miller responded by stating that the view of the Board is that amounts produced greater than 5% would be considered manufacturing or distributing and a license for such would be required. He further stated that the intent is that it is 5% of their production overall.

Written comments from Jim McNatt were received.

Rule 480-6-.02 Nonresident Pharmacy Permit

Public comment from Linda Chapman was received. Ms. Chapman stated that her questions were related to sections (8) and (11) of the rule concerning proof of a valid, unexpired license, permit, or registration. She asked why the Board would want information on every other state that they are dispensing into as it seems like the interest should be with their home state. Rick Allen responded that Georgia does not recognize Verified Internet Pharmacy Practice Sites (VIPPS). Ms. Chapman asked if a non-resident pharmacy wants to do business in Georgia, would Georgia want a copy of its license? She also asked about inspections? Mr. Allen responded by stating that Georgia has the right to inspect. Ms. Chapman stated that the Board should clarify that Georgia has the right to inspect. Bob Warnock responded by stating that he thinks section (21) of the rule addresses the issue.

Written comments from Randy J. Mire, John Sisto, Leigh Knotts, and Allen K. Horne were received.

Rule 480-5-.03 Code of Professional Conduct

No comments or written responses were received.

Rule 480-13-.04 Absence of Pharmacist

No comments or written responses were received.

Rule 480-16-.09 Purchase or Receipt of Drugs by a Pharmacy

No comments or written responses were received.

The hearing was adjourned at 10:13 a.m.

Bill Prather made a motion to approve the rules as written and posted. Chris Jones seconded and the Board voted unanimously in favor of the motion. The Board will consider adoption of these rules at a conference call to be held on 12/19/2013.

Laird Miller made a motion and Chris Jones 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 Al McConnell, Tony Moye, Mike Faulk, Chris Jones, Laird Miller Bill Prather and Bob Warnock.

Executive Session

Appearances

- E.B.
- L.M.W.
- W.S.A.
- N.C.B.
- E.B.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Open Session

Approval of Minutes

Bill Prather made a motion to approve the Public Session minutes for the August 30, 2013 Conference Call, the Public and Executive Session minutes for the November 13, 2013 full Board meeting, and the Public and Executive Session minutes for the November 19, 2013 Conference Call. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Ratifications

Chris Jones made a motion to ratify the list of issued licenses. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver – Savannah Treatment Center and Columbus Metro Treatment Center

Tony Moye made a motion to deny the rule waiver petitions. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance – Primrose Pharmacy, LLC

Laird Miller made a motion to deny the rule variance petition. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – Pamela Cox

Tabled for consideration in Executive Session.

Petition for Rule Waiver – County Line Pharmaceuticals, LLC

Bill Prather made a motion to deny the rule waiver petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance – Jena Madray

Chris Jones made a motion to deny the rule variance petition. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – QOL Meds, LLC

Mike Faulk made a motion to deny the rule waiver petition. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Daniel C. Loper, Pharmaceutical Specialties, Inc.

The Board considered this correspondence. Chris Jones made a motion to direct staff to respond to Dr. Loper by referring him to O.C.G.A. § 16-13-74 Written prescriptions for dangerous drugs; content; signature. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jim Cleghorn, Executive Director, Georgia Board of Nursing

The Board considered this correspondence requesting the Board consider requiring the inclusion of the specific prescriber's name in addition to the delegating physician on all prescription drug labels. Bill Prather made a motion to direct staff to respond by stating that such an amendment would require a legislative change. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Carey Vaughan

The Board considered this correspondence regarding a proposal for a hospice contract. Laird Miller made a motion to direct staff to respond to Dr. Vaughan by stating that they need to submit the information to GDNA. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen reported that he received notice concerning an MPJE law writing workshop. He stated that Ms. Battle should be receiving a request for a board member to assist.

Mr. Allen reported that Tramadol is now classified as a Schedule IV drug.

Miscellaneous

Ms. Battle stated that at the October 16, 2013 meeting, the Board voted to post procedural rules. Our office sent the rules to the Attorney General's office for authority. The Attorney General's office sent them back with some changes. Chris Jones made a motion to repost the following the following rules:

480-39-.01 Scope and Application of These Rules.

The following Rules govern procedure in "contested cases" as that term is defined in the Georgia Administrative Procedure Act (O.C.G.A. 50-13-2(2)) and which are conducted before the Board of Pharmacy. Additional Rules in subsequent chapters may also apply.

480-39-.02 Docket

(1) The Executive Director shall keep a book known as a docket, which shall be arranged by a sequential numbering system for each case or other matter and shall show for each case of matter, as permitted by law, all proceedings, actions and filings.

(2) The Executive Director shall keep a docket index by both docket number and alphabetical list of the names of the respondents in all proceedings.

480-39-.03 Office Hours

The offices of the Board of Pharmacy shall be open from 8:00 a.m. to 5:00 p.m. each weekday, except State legal holidays.

480-39-.04 Communications

All communications, including correspondence, motions, and pleadings, shall be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303. Copies shall be furnished to all parties of record, including the attorney representing the State. An original of all correspondence, motions, and pleadings shall be filed with the Executive Director and shall comply in all respects with Rule 480-42-.04.

480-39-.05 Date of Filing.

All communications, correspondence, motions and pleadings in any proceedings shall be deemed to be filed or received on the date on which they are actually received by the Executive Director.

480-39-.06 Computation of Time

Computation of any period of time referred to in these rules shall begin with the first day following that on which the act which initiates such period of time occurs. When the last day of the period so computed is a day on which the office of the Board of Pharmacy is closed, the period shall run until the end of the following business day. When such period of time, with the intervening Saturdays, Sundays and legal holidays counted, is seven (7) days or less, the said Saturdays, Sundays and legal holidays shall be excluded from the computation; or otherwise such days shall be included in the computation.

480-39-.07 Extension of Times

It shall be within the discretion of the Board or its designee to extend, for good cause shown, any time limit prescribed or allowed by these rules. All requests for an extension should be made by a motion in accordance with 480-41-.01 and shall indicate therein whether all parties concur. The Board or its designee shall notify all parties of its action upon the motion. Extension shall be granted only when the Board or its designee is satisfied that good cause has been shown and not otherwise.

480-39-.08 Signatures

Every notice, pleading, petition, motion or other document filed by a party, represented by an attorney, shall be signed by at least one attorney of record in his/her individual name. His/her address, e-mail address, telephone number, and representative capacity shall be stated. A party who is not represented by an attorney shall sign his pleading and state his address, e-mail address, and telephone number. Except when otherwise specifically provided by rule or statute, pleadings need not be verified or accompanied by affidavit. The signature of an attorney constitutes a certificate by him/her that s/he has read the pleading, and that it is not interposed for delay.

480-39-.09 Ex-parte Communication

No person not employed by the Board of Pharmacy shall communicate *ex-parte* with any member of the Board of Pharmacy involved in the decisional process with respect to the merits of a contested case. If any *ex-parte* communication is directed to any person in violation of these rules, the Board or its designee and all other parties shall be immediately informed of the substance of the communication and the circumstances of its receipt; provided, that a request for information with respect to the status of a proceeding shall not be prohibited by this section.

480-39-.10 Petition for Promulgation, Amendment, or Repeal of Rules

(1) Form of Petition. Each petition for promulgation, amendment or repeal of rules made pursuant to the Georgia Administrative Procedure Act shall be filed with the Board of Pharmacy. The petition shall be in writing and shall state:

(a) The name and address of the petitioner;

(b) The full text of the rule requested to be amended or repealed, or the full text of the rule desired to be promulgated;

(c) A statement of the reason such rule should be amended, repealed, or promulgated including a statement of all pertinent existing facts which relate to petitioner's interest in the matter;

(d) Citations of legal authority, if any, which authorize, support, or require the action requested by petition. The petition shall be verified under oath by or in proper behalf of; the petitioner.

(2) Proceeding on Petition. Upon receipt of the petition, the Board of Pharmacy shall decide upon the action to be taken. Within thirty days after receipt of the petition, the Board either shall deny the petition in writing (stating its reasons for the denial) or shall initiate rule-making or rule-changing proceedings in accordance with the Georgia Administrative Procedure Act.

480-40-.01 Initial Pleading

(1) The hearing in a contested case shall be commenced by the Board's filing of a notice of hearing directed to the respondent, or respondents.

(2) Every pleading or other paper submitted for filing in a contested case, to the extent possible, shall contain the following:

(a) A title which indicates the nature of the proceeding and the parties involved therein;

(b) The name of the Board;

(c) A short and plain statement of the nature of the pleading (e.g. Answer, Motion for Continuance, etc.);

(d) In addition, the notice of hearing shall, to the extent possible, contain the following:

1. A short and plain statement of the matters asserted or the issues involved;

2. A clear and concise statement of the laws involved;

3. A notice of the rights of the person to whom the notice of hearing is directed;

4. A statement that an answer to the matters asserted is required; and

5. Any other information required by law or deemed appropriate by the Board.

480-40-.02 Answer

The party to whom a notice of hearing is directed must file with the Board an answer within fourteen (14) days after service of the notice of hearing. All allegations contained in the notice of hearing which are not specifically admitted are deemed denied.

480-40-.03 Replies

A reply to the answer shall not be permitted and any new matters asserted in the answer shall be deemed denied.

480-40-.04 Amendments

Any party, including the Board, may amend any pleading or notice without leave until the eighth day prior to the date set for the hearing on the matter. Thereafter a party may amend his pleadings only by leave of the Board or its designee and leave shall be freely given when justice so requires. If an amendment is made to a notice of hearing, the answer to said amended notice shall be filed within seven (7) days after service of the amended notice, unless otherwise ordered by the Board or its designee.

480-41-.01 Motions: Written and Oral

(1) An application to the Board for an order to take any action or to enter any order shall be made by motion which, unless made during the hearing, shall be made in writing, shall state specifically the grounds therefor, and shall set forth the action or order sought. A copy of all written motions shall be served upon the parties in accordance with Chapter 480-42.

(2) A motion for a continuance or an extension of time shall be ruled upon by the Board or its designee forthwith. All other motions shall be ruled upon by the Board or its designee at the outset of the hearing, after an opportunity for argument by the parties; provided, however, that the Board or its designee may establish a hearing schedule and dispose of motions. The Board or its designee may request briefs in support of or in opposition to any motion.

480-41-.02 More Definite Statement

A motion for more definite statement shall be filed and ruled upon pursuant to 480-41-.01.

480-41-.03 General Procedures.

Proceedings before the Board shall be conducted as expeditiously as possible, with due regard to the rights of the parties. In contested cases before the Board of Pharmacy upon issuance of a notice of hearing, the procedures set forth in this chapter and Chapters 480-39 through Chapter 480-48 shall enable the parties to obtain relevant information needed for preparation of the case, to the extent that such disclosure is authorized by law.

480-41-.04 Witness Lists and Respondent Statements.

(1) Should a party seek a list of the names of witnesses, including experts, whom another party expects to call or may call on its behalf, the party seeking the list must communicate the request in writing (by mail, personal service, or electronically) to the other party at least fourteen (14) days prior to the hearing. Such a request must also be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303. The party of whom the information is requested shall, within a reasonable time prior to the commencement of the hearing but at least ten (10) days prior to the hearing, provide such a list to the requester.

(2) The parties may also, within a reasonable period of time prior to the hearing, exchange copies of documents and designate documents already in the possession of the other party which are intended to be introduced as evidence at the hearing. Upon request, the parties shall make available to each other for inspection, copying, testing or sampling any tangible item intended to be introduced as evidence, within a reasonable period of time prior to the hearing. Where a party seeks documents or other evidence already in the possession of the other party which are intended to be introduced as evidence at the hearing, the party seeking the documents must communicate a request for the evidence in writing (by mail, personal service, or electronically) to the other party at least fourteen (14) days prior to the hearing. Such a request must also be filed with the Executive Director, Board of Pharmacy, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303. The party of whom the information is requested shall, within a reasonable time prior to the commencement of the hearing but at least ten (10) days prior to the hearing, provide such evidence to the requester.

(3) If the respondent makes a general or specific written request to the Board for exculpatory, favorable, or arguably favorable evidence that is relative to pending allegations concerning a license, the Board must furnish the requested information, indicate that no such information exists, or refuse to furnish the information requested prior to a hearing.

(a) The Board is not required to furnish information made confidential by state or federal law, until such requested information has been determined to be exculpatory, favorable, or arguably favorable pursuant to the in camera procedure specified in part (b) of this subsection.

(b) Once the Board has furnished exculpatory, favorable, or arguably favorable information, has indicated that no such information exists, or has refused to furnish such information, the respondent may request a prehearing *in camera* inspection of the remainder of the investigative file by the Board or its designee. The Board or its designee shall furnish the respondent with all material that would aid in the respondent's defense that is exculpatory, favorable, or arguably favorable. The Board or its designee shall seal a copy of the entire investigative file in order to preserve it in the event of an appeal.

(4) If any party refuses to or neglects to produce documents, evidence, witness lists or statements in accordance with a request pursuant to 480-41-.04(1) or 480-41-.04(2), the Board or its designee may issue an order compelling production. If a party subsequently refuses to or neglects to produce the requested materials in spite of an order compelling it to do so, the Board or its designee shall have the same rights and powers given the court under the Georgia Civil Practice Act. The Board or its designee may certify the facts to the Superior Court of Fulton County or any county where the offense is committed for appropriate action, including a finding of contempt. The Board or its designee shall have the power to issue writs of fieri facias in order to collect fines imposed for violation of a lawful order of the Board or its designee.

(5) The parties shall be required to confer either in person or by telephone, in reasonable advance of a scheduled hearing date but at least seven (7) days prior to the hearing, in a good-faith attempt to reach an agreement as to the admissibility of any documents or tangible items intended to be offered in evidence

for either side. The parties may stipulate as to any matter of fact and such stipulation will satisfy a party's burden of proving the fact alleged. The parties shall be encouraged to reach pre-hearing stipulations which could facilitate adjudication of the case. The Board or its designee, upon its own motion or upon the request of either party, may schedule a pre-hearing conference to hear and rule on motions or other preliminary matters, or otherwise facilitate adjudication of the case.

480-41-.05 Pre-Hearing Discovery

Except as may be expressly authorized by these Rules or by statute, no other forms of prehearing discovery shall be authorized or permitted including, but not limited to, interrogatories and requests for production of documents and other materials.

480-42-.01 By the Board

(1) Service of the notice of hearing, initial decision and final order shall be served personally upon the licensee or applicant or served by certified mail or statutory overnight delivery, return receipt requested, to the last known address of record with the Board.

(2) All other notices, pleadings, orders, motions and other documents shall be personally upon the licensee or applicant or served by certified mail or statutory overnight delivery, return receipt requested, to the last known address of record with the Board.

(3) If such materials are served by certified mail or statutory overnight delivery and are returned marked "unclaimed" or "refused" or is otherwise undeliverable, and if the licensee or applicant cannot, after diligent effort, be located, the Executive Director or his or her designee, shall be deemed the agent of service for such licensee or applicant, and service upon the Executive Director or his or her designee shall be deemed service upon the licensee or applicant.

480-42-.02 Service On All Parties.

A copy of the answer and all other pleadings, notices, motions, briefs, memoranda and other documents filed by any party with the Executive Director shall be served upon all other parties to the proceeding, including counsel for the Board, by personal delivery or by certified mail, return receipt requested.

480-42-.03 To Party's Attorney

Service upon a party's attorney shall be deemed service upon the party.

480-42-.04 Filing of Pleading

(1) A party filing a document or other submission with the Board shall simultaneously serve a copy of the document or submission on each party of record. Service shall be by personal delivery, e-mail as an attachment, first-class mail, certified mail, or statutory overnight delivery, return receipt requested.

(2) A pleading subsequent to the Notice of Hearing shall not be entitled to filing unless accompanied by an Acknowledgement of Service from the person served, by his or her authorized agent for service, or by a certificate of service stating the date, place, and manner of service, as well as the name and address of the person(s) served.

480-43-.01 Intervention

(1) Any person desiring to intervene pursuant to Section 14 of the Georgia Administrative Procedure Act (O.C.G.A. § 50-13-14) shall file a motion in accordance with Rule 480-42-.04.

(a) Such a motion can be made where a statute grants the movant an unconditional right to intervene or when representation of the movant's interest is or may be inadequate to protect that interest.

(b) Such a motion can also be made where a statute grants the person a conditional right to intervene or where the movant's claim or defense and the main action have a question of law or fact in common.

(2) The motion shall state therein the specific grounds for seeking intervention. The Board and any other parties shall have fourteen (14) days from the date of service to file a response to such request.

(3) In considering the motion, the Board or its designee shall consider whether the intervention will unduly delay or prejudice the rights of existing parties.

480-44-.01 Evidence on Hearings

Unless otherwise provided by these rules, in all hearings, the testimony of witnesses shall be taken orally before the Board or its designee and presentation of all documentary and other evidence shall be done before the Board or its designee.

480-44-.02 Evidence on Motions

When a motion is based on facts not appearing of record, the Board or its designee may hear the matter on affidavits presented by the respective parties, but the Board or its designee may direct that the matter be heard wholly or partly on oral testimony.

480-44-.03 Objections and Exceptions

Any objections and exceptions must be made on the record, and at a minimum, must make clear to the Board or its designee the action which s/he desires taken and the grounds therefor.

480-44-.04 Subpoenas.

(1) In contested cases, subpoenas shall be issued without discrimination between public and private parties. At any time after issuance of the Notice of Hearing, and prior to the scheduled date for the hearing, the parties may request the issuance of subpoenas by filing a written request with the Executive Director, in accordance with Rule 480-39-.04, with appropriate service on the opposing party or counsel. Subpoena requests shall state the name and complete address of the person to whom it is directed.

(2) Subpoenas issued pursuant to a request in accordance with Rule 480-44-.04(1) shall not be issued in blank. Every subpoena issued by the Executive Director shall state the name of the Board of Pharmacy and the title of the action, and shall command each person to whom it is directed to attend and give testimony at the hearing at a time and place therein specified, or to produce documents for examination at the hearing, or both.

(3) If such a subpoena is directed to any member, investigator, employee, or other agent or representative of the Board, including experts retained by the Board for purposes of the particular case, production of documentary evidence from the Board or investigative file of the applicant or licensee and the taking of testimony at the hearing from such person or persons shall be governed by applicable provisions in the Pharmacy Practice Act, and by O.C.G.A. §§ 16-13-60, 26-4-28, 26-4-28.1, and 26-4-60.

(3) The party requesting the issuance of the subpoena shall be responsible for serving the same and paying the cost of securing the attendance of witnesses, in the same manner as prescribed by law in civil cases in superior court.

480-45-.01 Taking of Testimony by Deposition

(1) At anytime during the course of the proceeding, the Board or its designee may, in his discretion, permit the testimony of a witness to be taken by deposition. Application to take testimony by deposition shall be made in writing and shall be filed with the Executive Director of the Board and served upon all parties to the proceedings, including counsel for the Board.

(2) The application shall state the name and address of the witness, the subject matter concerning which the witness is expected to testify, the date, time and place of the proposed deposition, and the reason why the witness cannot appear and testify before the Board. The Board or its designee may, in his, her or its discretion, allow the application where the circumstances are such that the witness to be deposed cannot appear before the Board without substantial hardship to the deponent or to the parties to the case or that testimony by any other method will unduly delay expeditious completion of the proceedings. An application for the taking of testimony by deposition shall not be allowed if the deposition would result in any undue burden to another party or any undue delay of the proceedings. If the application is allowed, the Board or its designee should give notice of the taking of the testimony by deposition to all parties.

480-45-.02 Conduct of the Deposition

(1) Examination and cross-examination of the witness shall proceed as would be permitted at the hearing and under those rules of evidence applicable to proceedings conducted pursuant to the Georgia Administrative Procedure Act. The officer before whom the deposition is to be taken shall put the witness on oath and shall personally record the testimony of the witness. The testimony shall either be taken stenographically and shall be transcribed or shall be taken by video deposition. All objections made at the time of examination to the qualifications of the officer taking the deposition, or to the manner of taking it, or to the evidence presented, or to the conduct of any party, and any other objections to the proceedings, shall be noted by the officer upon the deposition. Evidence objected to shall be taken subject to the objection.

(2) All errors and irregularities in the notice of taking testimony by deposition shall be deemed waived unless written objection thereto is served upon the Board prior to the deposition. Objections to taking testimony by depositions because of disqualification of the officer before whom it is to be taken shall be deemed waived unless made before the deposition begins or as soon thereafter as the disqualification becomes known or could be discovered with reasonable diligence.

(3) Objections to the competency of a witness are not waived by failure to make them before or during the deposition, unless the ground of the objection is one which might have been obviated or removed if presented at that time. Errors and irregularities occurring at the taking of the testimony in the manner of taking the deposition, in the form that the questions are answered, in the oath of affirmation, or in the conduct of the parties, and errors of any kind which might be obviated, removed or cured if properly presented, shall be deemed waived unless reasonable objection thereto is made at the deposition.

(4) Errors and irregularities in the manner in which the testimony is transcribed or the deposition is prepared, certified, sealed, endorsed, transmitted, filed, or otherwise dealt with by the officer taking the testimony are waived unless a motion to suppress the deposition or some part thereof is made with reasonable promptness after such defect is, or with due diligence might have been, ascertained.

(5) The transcript of the deposition or the video deposition must be certified by a court reporter in order to be accepted as evidence upon filing with the Board or its designee.

480-45-.03 Taking of Testimony by Interrogatory

Application to take testimony by interrogatory shall be made and allowed in the same manner as prescribed in Rule 480-45-.01.

480-45-.04 Taking of Testimony by Telephone

Application to take testimony by telephone shall be made and allowed in the same manner as prescribed in Rule 480-45-.01.

480-46-.01 Notice of Hearing

For a hearing held directly before the Board, the Board shall notify all parties of record of the date, time and place of the hearing in the manner as provided by law and these Rules.

480-46-.02 Conduct of the Hearing

(1) The hearing shall be conducted by the Board or an administrative law judge (ALJ) appointed by the Office of State Administrative Hearings (OSAH).

(2) Duties of the Board or its designee. The Board or its designee shall have the authority to do the following: to administer oaths and affirmations; rule upon offers of proofs; regulate the course of the hearing; set the time and place for continued hearings; fix the time for filing briefs and memoranda; dispose of motions; and reprimand or exclude from the hearing any person for any indecorous or improper conduct committed in the presence of the Board or its designee.

(3) Sworn Testimony. All testimony given at the hearing shall be under oath administered by the Board or any person designated by the Board.

(4) Order of Presentation. The State, or in a proper case a moving or complaining party, shall present its evidence or testimony first. Where there is more than one moving or complaining party, the order of

presentation shall be at the discretion of the Board. After all of the evidence and testimony of the State, or the moving or complaining party, has been received, all other parties shall be allowed to present their evidence or testimony. All parties, other than the party introducing the testimony, shall be allowed to cross-examine any witness immediately after his testimony has been received. The State, or the moving or complaining party, shall be allowed to present rebuttal testimony or evidence if it so desires.

480-47-.01 Consolidation

The Board or its designee upon its own motion, or upon motion by a party or other person joined in the proceeding, may order proceedings involving a common question of law or fact to be consolidated for hearing on any or all of the matters at issue in such proceedings.

480-48-.01 Briefs

Briefs may be filed by a party or any interested person either before or during the course of the hearing, or within such time thereafter as the Board or its designee shall designate. Failure to file a brief shall in no way prejudice the rights of any party.

480-48-.02 Filing of Documents Subsequent to Hearing

(1) Upon request, the Board or its designee may, for good cause shown, allow the parties to file evidentiary documents of any kind, or exhibits, at a time subsequent to the completion of the hearing, such time to be determined by the Board or its designee. If a request for such subsequent filing is granted, the requesting party shall, on or before the date set for filing, send copies of all documents or exhibits which are the subject of the request to all other parties.

(2) Prior to the admission into evidence of any documents or exhibits filed subsequent to the hearing, the opposing party shall have ten (10) days from the date of service of copies of such proposed documents or exhibits to file any objections to the admission of such evidence.

480-48-.03 Motion to Reopen Hearing

A party may, at any time prior to the rendering of a final decision by the Board, move that the hearing be reopened for the purpose of receiving new evidence. Such motions shall be filed in accordance with the provisions of Rule 480-41-.01 and shall be granted only for good cause shown. The Board shall notify all parties of its action upon the motion. Notwithstanding the above, the Board may at any time prior to the rendering of a decision, reopen the hearing on its own motion.

480-48-.04 Review of Initial Decision

(1) Either the respondent or the Board may seek review of the initial decision of the Board or the administrative law judge (ALJ) pursuant to O.C.G.A. §§ 50-13-17(a), 50-13-41(d). If the respondent files a timely motion for review of the initial decision of the ALJ, the respondent may include therein a statement of the reasons for seeking review and alleged errors made by the ALJ in the initial decision. If the Board files a timely order for review of the initial decision on its own motion, it may include in its order the issues to be considered by the Board at the review hearing.

(2) Upon the filing of a timely motion by the respondent seeking review of the initial decision of the ALJ, or upon the filing of a timely order for review of an initial decision by the Board on its own motion, notice of the date and time for the review shall be served on the respondent or counsel for the respondent and counsel for the Board.

(3) The Board may appoint a hearing officer for review, who shall preside over the review proceedings and control the conduct of the review hearing. In acting as the presiding officer, the hearing officer for review shall rule on all procedural and evidentiary questions that arise during the course of the review. At the direction of the Board, the hearing officer for review shall draft the final decision for the Board.

(4) On review, the Board shall have all the powers it would have in making the initial decision, and in its discretion, shall have the power to take additional testimony or remand the case to the ALJ for such purpose, as provided in the Administrative Procedure Act, O.C.G.A. § 50-13-17 and in accordance with this Rule. Motions, including motions to present additional evidence, shall be filed in accordance with

480-41-.01 and 480-48-.03 and shall be ruled upon within the time period set by the Board but not to exceed thirty (30) days.

(a) Motions to present additional evidence or to remand the case to the ALJ for such purpose shall be granted only if the additional evidence is material, and there was good cause for failing to present such evidence before the ALJ. All motions, including motions for the presentation of additional evidence, shall be ruled on by the Board, prior to oral arguments during the review hearing.

(5) Oral argument up to 30 minutes per side is permitted in the review hearing. Additional time for argument must be requested in writing and docketed at least fourteen (14) days before the date set for the review hearing.

(6) Once the review hearing is concluded, the Board shall deliberate as to the final decision. Neither the hearing officer for review nor the parties nor their counsel shall be present during or participate in the deliberations or voting on the final decision. Provided, however, that during the course of the deliberations the Board may seek or obtain legal advice of its counsel or make an inquiry on the record concerning either procedure or the merits of the case in the presence of all parties.

(a) At the conclusion of the deliberations, the vote and decision of the Board shall be announced in open session, unless the sanction imposed by the decision is made confidential by statute, in which case it shall be announced *in camera* to the respondent and counsel for the parties. The Board may take the matter under advisement and continue the deliberations until a date certain if deemed necessary due to the Board's agenda or the complexity of the issues.

480-48-.05 Rehearing

Any party may file a motion for rehearing of a final decision of the Board within ten (10) days after the date of actual service of such final decision on the respondent or respondent's counsel. Such motion shall be in accordance with Rule 480-41-.01 and, in addition, shall include a statement of all matters alleged to have been erroneously decided and, if applicable, a statement as to any newly discovered matters or circumstances that have arisen subsequent to the final decision. The filing of said motion shall not operate as a stay of the final decision of the Board unless so ordered by the Board.

480-48-.06 Appeals of Final Decisions

All appeals shall be filed in accordance with the Georgia Administrative Procedure Act and must be filed in the Superior Court of Fulton County or superior court of the county of the residence of the petitioner.

Mike Faulk seconded and the Board voted unanimously in favor of the motion.

A motion was made by Chris Jones, seconded by Laird Miller, and the Board voted that the formulation and adoption of these amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rules 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§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Bill Prather made a motion and Jones 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 Al McConnell, Mike Faulk, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Director's Report

- P.N.S.

Georgia Drugs and Narcotics Agency – Rick Allen

Discussed latest PDMP reports.

Attorney General's Report – Reagan Dean for Janet Wray

Mr. Dean presented the following consent orders for acceptance:

- L.A.
- D.R.P.
- J.C.
- S.R.
- T.W.
- W.P.
- C.V.S.

Mr. Dean presented the following Inactive Status application for consideration:

- R.M.N.

Applications

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

Correspondences/Requests

- I.P.
- J.W.C.
- P.M.
- D.W.M.
- C.H.
- D.W.W.
- R.M.B.
- H.D.S.W.D.C.
- M.J.O.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Open Session

Chairperson McConnell stated that the Board needs to nominate officers for the upcoming year. Bill Prather made a motion to nominate Al McConnell as President. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Chris Jones made a motion to nominate Laird Miller as Cognizant and Vice-Chairperson. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Chris Jones made a motion to approve all recommendations based on deliberations in Executive Session as follows:

Appearances

- E.B. Uphold denial
- L.M.W. Uphold denial
- W.S.A. Table and place on January agenda for consideration
- N.C.B. Denial overturned and approved for registration
- E.B. Denial overturned and approved for registration

Executive Director's Report

- P.N.S. Manufacturing Pharmacy Renew application once late renewal fee has been received.

Georgia Drugs and Narcotics Agency – Rick Allen

Discussion of PDMP reports. No action taken.

Attorney General's Report – Reagan Dean for Janet Wray

Mr. Dean presented the following consent orders for acceptance:

- L.A. Public Consent Order accepted
- D.R.P. Public Consent Order accepted
- J.C. Public Consent Order accepted
- S.R. Private Consent Order accepted
- T.W. Private Consent Order accepted
- W.P. Private Consent Order to be accepted and signed with express permission upon receipt.

- C.V.S. Private Consent Order accepted

Mr. Dean presented the following Inactive Status application for consideration:

- R.M.N. Application accepted

Applications

- | | | |
|----------|------------------------|--------------------------------------------------------------------------------|
| • S.L.B. | Pharmacy Technician | Denial overturned and approved for registration |
| • P.C. | Pharmacy Technician | Denied registration |
| • T.L.R. | Pharmacy Technician | Denied registration |
| • D.L.S. | Pharmacy Technician | Denied registration |
| • A.J.M. | Pharmacy Technician | Denied registration |
| • G.K.L. | Pharmacy Technician | Denied registration |
| • D.W. | Pharmacy Technician | Denied registration |
| • K.T.R. | Pharmacy Technician | Denied registration |
| • E.S.B. | Pharmacist Intern | Approved application |
| • J.J.C. | Pharmacist Intern | Denied application |
| • M.E.D. | Pharmacist Intern | Approved application |
| • V.S.C. | Pharmacist Intern | Approved application |
| • T.S. | Pharmacist Intern | Approved application |
| • D.L.S. | Pharmacist Intern | Approved application |
| • N.K.M. | Pharmacist Reciprocity | Approved application |
| • S.K. | Pharmacist Applicant | Allow 4 th attempt at MPJE after completion of a law review course. |
| • T.M.B. | Pharmacist Reciprocity | Approved application |
| • R.E.L. | Pharmacist Renewal | Approved renewal |
| • Y.G.G. | Pharmacist Reciprocity | Approved application |
| • M.O.H. | Pharmacist Reciprocity | Approved application |
| • J.S.M. | Pharmacist Reciprocity | Denied application |
| • T.C.K. | Pharmacist Reciprocity | Denied application |
| • P.J.M. | Pharmacist Applicant | Allow applicant to apply by reciprocity |
| • P.L.I. | Wholesaler Pharmacy | Table and place on January agenda for consideration |
| • C.L. | Wholesaler Pharmacy | Approved application |

Correspondences/Requests

- | | | |
|--------------|-----------------------------------------|---------------------------------------------|
| • I.P. | Revision to pharmacy drive-thrus | Schedule for an appearance before the Board |
| • J.W.C. | Request to modify no PIC limitation | Approved request |
| • P.M. | Request to lift supervision restriction | Approved request |
| • D.W.M. | MPJE exam extension request | Approved 3 month extension |
| • C.H. | Request to lift supervision restriction | Approved request |
| • D.W.W. | Appearance request | Approved request |
| • R.M.B. | Self-report | No action taken |
| • H.S.W.D.C. | Notice of disciplinary action | No action taken |
| • M.J.O. | Self-report | No action taken |

Bill Prather seconded and the Board voted in favor of the motion, with the exception of Tony Moye, who recused himself from the vote regarding P.M.

In the same motion, the Board voted to deny a rule waiver petition for Pamela Cox.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, January 22, 2014, at 9:00 a.m. at Mercer University College of Pharmacy, 3001 Mercer University Drive, Atlanta, GA 30341.

The Board meeting adjourned at 3:12 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director