GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
September 17, 2014
9:00 a.m.

The following Board members were present:
Al McConnell, Chairperson
Laird Miller, Vice-Chairperson
Jim Bracewell
Mike Faulk
Chris Jones
Bill Prather
Bob Warnock *(departed @ 1:35 p.m.)*

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

Visitors:
Jimmy England, Walgreens
Chuck Clay
Stacey Karl, Grady
Rondell Jaggers, Grady
Stephanie Kozol, Holland & Knight
John Sisto, ESI
Debbie Wolf, Pro Care Rx
Scott Biddulph, Target
Andy Freeman, GPHA
Joe Adams, NABP
Carmen Catizone, NABP
Ben DiMarco, DaVita
Rebecca Klaus, Briova Rx
David White, Pharmaceutical Specialties
Keith Sledge, Pharmaceutical Specialties
Gary Horlacher, Fresnius MCNA
Joseph R. Koenig, Roadrunner Pharmacy
Robert Stannard, BSL
Jennifer Bellis, BSL
Wendy Bailey, PSHP
David Carver, Curant, Inc.
Spencer Talley, Atlanta Vet
Heather Lindell, UGA
Katherine Bell, CVS Health
Jeff Mesaros, CVS
A. Edge, CVS
Michael Shelnutt, Humana
Lynda Chapman
Scott Lindsay, CAPS
Melvin Smith, CVS
Aman Patel, Walmart
William Hill, Walmart
Brad Borum, Kaiser
Helen Sloat, Kaiser & Hemophilia of GA
Vonda Harrison, Eldercare Pharmacy

Melissa Price, Eldercare Pharmacy
Jennifer Layton, Publix
David Stancil, Dermatran Health Solutions
Stacey Karl, Grady Health System

Chairperson McConnell established that a quorum was present and called the meeting to order at 9:00 a.m.

Administrative Hearing – Olayinka Olaniyi

Ms. Wray stated that the hearing for this individual has been cancelled and there is a proposed settlement for the Board to consider. Ms. Wray stated that she has received a copy of a signed Voluntary Surrender from Ms. Olaniyi. Chris Jones made a motion to accept the signed Voluntary Surrender in lieu of a hearing upon receipt of the original. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Approval of Minutes

Bill Prather made a motion to approve the Public and Executive Session minutes for the August 20, 2014 meeting, the Public Session minutes for the August 28, 2014 conference call and the Public Session minutes for the September 3, 2014 conference call. Bob Warnock 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.

Petition for Rule Variance – Adam Chesler

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

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen introduced Mike Poblet to the Board. Mr. Poblet has been hired as a new agent with GDNA.

Miscellaneous

Ms. Wray briefly discussed additional correspondence received on 09/16/2014 from Josh Belinfante to Andrew Freeman, Georgia Pharmacy Association, regarding recent developments in drug labeling. The request is for the Board to adopt an emergency rule. Ms. Wray asked the Board to postpone consideration of this matter until later in the day to allow the Board time to review.

Administrative Hearing

Administrative Hearing – Regina Harrell

The hearing for Ms. Harrell was called to order at 9:19 a.m. The respondent was not present at this time and the Board proceeded with the hearing.

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. Voting in favor of the motion were those present who included Al McConnell, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Bill Prather and Bob Warnock.

The Board reconvened at 9:35 a.m. as the respondent was now present for the hearing.

Laird Miller made a motion and Bob Warnock 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. Voting in favor of the motion were those present who included Al McConnell, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Bill Prather and Bob Warnock.

The Board reconvened at 10:12 a.m.

Chris Jones made a motion to suspend Ms. Harrell's license and if Ms. Harrell would like the suspension lifted, she would have to present the results of an OMPE that had been performed within thirty days of the date of her petition. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

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

Open Session

Correspondence from Jeff Lurey, GPhA Academy of Independent Pharmacy
The Board recommended deferring this matter until later in the day.

Correspondence from Rosemary Ofume, RPH013910
The Board considered this correspondence from Ms. Ofume requesting to terminate probation. Mr. Allen stated that he spoke with Ms. Wray regarding this request. This was a final decision, so technically there is no petition provision. Laird Miller made a motion to change Ms. Ofume's status from Probation to Active effective immediately. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Correspondence from Bill Maguire, Pharmacy Consultant, Professional Affairs Omnicell/MTS
The Board considered this correspondence from Mr. Maguire requesting a meeting in open session with the Board. Bob Warnock made a motion to approve the request and schedule Mr. Maguire to meet with the Board in November. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Correspondence from Betty Jo Lawson
The Board considered this correspondence from Ms. Lawson requesting clarification of the Georgia Unused Medication regulation. Mike Faulk made a motion to direct staff to refer Ms. Lawson to O.C.G.A. § 49-4-152.3 Reuse of unit dosage drugs for more information. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence regarding notification of FDA recall request to Downing Labs (aka NuVision Pharmacy)
The Board viewed this correspondence for informational purposes only.

Correspondence from Ashley Strait, Quarles & Brady LLP
The Board considered this correspondence from Ms. Strait regarding what type of permit a non-resident outsourcing facility would need in order to ship to Georgia. Bill Prather made a motion to direct staff to respond to Ms. Strait by stating that without seeing a completed application, it would be difficult for the Board to determine what type of permit may be needed. There are two ways for a facility to register. If the facility qualifies as a manufacturer, then it would need to apply as a manufacturer. If it does not qualify as a manufacturer, it would need to apply as a non-resident pharmacy. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Attorney General's Report – Janet Wray

Ms. Wray reported that 187 cases were referred to the Attorney General's office during the last fiscal year. She stated that the five year average for referrals is 68 cases a year. Ms. Wray stated that she will compile a report in writing and send that information to Ms. Battle. Mr. Miller asked Ms. Wray if there are any cases that should be handled administratively. Ms. Wray responded that she is unable to say right now. She stated that there are some cases that she will be bringing back to the Board as it is not unusual for her to do that. Ms. Wray stated if the level of referrals keep up over the next fiscal year, the Board may want to consider SAG (Special Assistant Attorney General) monies in its budget in order to fund an additional staff person to assist with some of the cases.

Executive Director's Report – Tanja Battle

Ms. Battle reported that Pharmacists and Nuclear Pharmacists may now renew. The office is sending reminder notices out to licensees notifying them of this. The number of affidavits being received by mail is increasing as renewals are being initiated by licensees.

Ms. Battle reported that when the Board first transitioned to the Department of Community Health, the Georgia Composite Medical Board graciously allowed the staff of the Boards of Pharmacy and Dentistry to occupy part of its space. The Boards' staff is being relocated to the 6th floor of 2 Peachtree Street, NW but meetings will continue being held in the board room of the 36th floor.

Ms. Battle further reported that the office is also going to implement a decision tree that will give some options on the front end of telephone calls while still allowing customers to speak with a person.

Ms. Battle discussed 2015 meeting dates and stated that potential dates will be presented to the Board next month. She stated that the Board has had discussions about adding an additional date for the practical exam. She asked the Board to consider this matter so that staff can reach out to the schools to find out what dates may be available. Ms. Battle added that the Board has already voted on dates for the January exam. Ms. Battle stated that the Board can talk further about exam content in Executive Session.

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, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Bill Prather and Bob Warnock.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen discussed the following:

- DEA Disposal Rule
- Mixing under USP 797 conditions exemption
- Prescription label changes

Applications

- C.G.F.
- J.D.T.
- S.A.D.
- C.N.M.

- D.V.N.
- K.F.P.
- S.E.P.
- T.J.S.
- J.V.V.
- Z.M.
- M.L.M.
- I.T.I.

Attorney General's Report – Janet Wray
Ms. Wray presented the following consent orders:

- L.M.
- W.
- P.B.
- A.M.
- B.I.I.

Ms. Wray discussed the following cases:

- W.G.
- S.M.

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

Public Hearing

Chairperson McConnell called the Public Hearing to order at 12:05 p.m.

Chairperson McConnell opened the hearing by stating that the Board's primary charge is to protect the public safety, health and welfare of the citizens of the State of Georgia, and one of those ways is through rules. He further stated that the Board feels that the rules being considered today are very important as the Board currently has no oversight over out-of-state pharmacies that ship millions of medications and doses of drugs to Georgia. He stated that the Board feels like the citizens of Georgia should be afforded the same level of protection regardless of whether or not a pharmacy is a non-resident pharmacy or an in-state pharmacy.

Rule 480-48-.01 Definitions
Mr. Bracewell expressed his concern about having a prescription filled on a particular day and not being delivered until the following calendar day. He stated that, perhaps, the Board should have considered defining a day as 24 hours. Chairperson McConnell responded by stating that the Board can go back and address that specific issue in the future.

Mr. Miller stated that his interpretation is that medication would not be on a truck overnight and that it arrives at the destination on the same day it leaves the building.

Public comments from Jimmy England, Walgreens, were received. Mr. England stated that he feels a lot of people are interpreting this to say prescriptions have to be delivered the same day they are filled and

that is what causes concern. If a prescription is filled on Tuesday and they do not want it delivered until Friday, this is not a problem as long as it does not fall under mail order regulation.

Ms. Wray responded by stating that the pharmacy will actually fill it on a particular day, but not dispense until the patient comes to pick it up. She does not think that is going to be treated any differently with these rules. Further, the Board could certainly issue an interpretive statement to clarify any points of confusion.

Mr. Bracewell asked for further clarification regarding "local courier". He asked if FedEx or UPS would be considered local couriers. Mr. Miller responded by stating that a local courier would be an agent that you hired and if FedEx did it in the same day, they would qualify as a local courier. Ms. Wray added that FedEx never guarantees same day delivery, so it is generally someone who could do same day delivery.

Public comments from Lynda Chapman were received. Ms. Chapman stated that she thinks the issue comes up with long-term care where doctors' orders are received at five o'clock in the afternoon and a contract courier does not get out until 11 o'clock at night. Some of those orders may not be delivered until after midnight. She stated that technically that is the next day, but you have a contract courier that is filling it in a timely basis. She thinks that might be able to be clarified with some language around the definition.

Chairperson McConnell stated that the Board will clarify the time framing and common carrier and what will be the Board's intent.

Public comments from Ben DiMarco, DaVita, were received. Mr. DiMarco stated that he just wanted to call attention to the fact that their prescriptions actually get furnished to a facility where someone is always receiving them as soon as they are brought there. He stated that same day could be construed as 24 hours and that could occur by FedEx.

Chairperson McConnell stated that the Board will clarify all that in a statement.

Written comments were received from the following:
Stephen Georgeson
Lynda Chapman.

Rule 480-48-.02 Conditions for Use of Delivery by Mail

Public comments from Ryan Koenig, Roadrunner Pharmacy, were received. Mr. Koenig commented on compounding as it relates to the veterinary practice. He asked the Board to respect and understand the distinction between the needs of animals and humans. Mr. Koenig stated that being a veterinary-exclusive compounding pharmacy, he has seen firsthand the ever increasing demand for drugs that are on backorder and being discontinued.

Mr. Faulk responded by asking what distinction does Mr. Koenig want the Board to consider. Mr. Koenig reiterated the distinction between animals and humans.

Mr. Jones asked why Mr. Koenig needs that distinction since the Board is discussing delivery by mail. Mr. Koenig stated that he just came to the meeting today for people to consider the practice of veterinary medicine when making decisions that could impact such. Mr. Faulk responded by stating that what Mr. Koenig is asking the Board to consider appears to be unrelated to what the Board is discussing at the moment. Mr. Koenig agreed and stated that they do plan on following all the rules and regulations as

they always have. Mr. Faulk stated that the Board respects what Mr. Koenig is saying; however, it is unrelated to what the Board is currently considering.

Written comments were received from the following:
David Tucker, Wyatt's Pharmacy
Clayton D. Edwards, Optum Rx
Stephen Georgeson
Kim A. Caldwell, Humana Pharmacy Solutions
Karen Peterson, BriovaRx Specialty Pharmacy
Karen Peterson, Catamaran Mail
John Sisto, Express Scripts
Lynda Chapman

Rule 480-6-.02 Nonresident Pharmacy Permit

Public comments from Jimmy England, Walgreens, were received. Mr. England stated that they would like to see the 72 hours changed to five business days in case it is a holiday weekend. Ms. Wray commented that would require reposting; however, she advised the Board can adopt the rule the way it is currently written and then it can post any changes at a later time. Mr. Miller stated that he feels the Board would support the 72 hours changing to five business days, but feels that the Board should move forward with adopting the rule today and will go back to amend at a later time.

Public comments from Robert Stannard, BSL, were received. Mr. Stannard commented on the five percent rule and asked what Georgia intends to do in terms of determining the line between that compounding and the broader use and distribution from wholesaler. He stated there seems to be some question about that on the federal level. Ms. Wray stated that he is referencing 503b outsourcing facilities.

Mr. Stannard asked if one were to try and distinguish between an out-of-state compounding pharmacy asking for a permit and a wholesale distributor asking for a license, how is that distinction made? Ms. Wray responded by stating that he will need to seek the advice of an attorney in regards to that matter.

Public comments from Carmen Catizone, National Association of Boards of Pharmacy, were received. Mr. Catizone stated that they are in almost weekly conversations with the FDA and the current position is there is no anticipatory compounding. An outsourcing facility under 403b and 503b entities will have to register or voluntarily register with the FDA depending on how the state classifies them. The 503b entities cannot engage in wholesale distribution under the law. Mr. Catizone continued by stating any compounding pharmacy, whether it is in-state or out-of-state, that is compounding in anticipation of a prescription, cannot compound those prescriptions to a pharmacy. They will have to be registered or licensed or operate as an outsourcing facility.

Public comments from Wendy Bailey, Peach State Health Plan, were received. Ms. Bailey stated that her question is concerning the 60 hour per week requirement for pharmacies that are out of state to be open. She asked the Board to clarify whether it means they had to be operating the entire 60 hours, or if they have to have a pharmacist on call to answer questions for patients.

Ms. Wray responded by stating that there have been a lot of questions about the 60 hours. It says a permit holder shall maintain a toll-free telephone number operational during the permit holder's regular hours of operation, but not less than six days per week for a minimum of 60 hours per week that shall be used to provide and facilitate patient counseling. Such toll-free number shall be capable of receiving inbound calls from patients to the permit holder. Ms. Wray stated many comments have been received and people would like for the Board to reduce the hours to 40; however, this is from the law and it

cannot be reduced without a legislative change. Ms. Wray went on to say that she thinks it means it is clearly to facilitate patient counseling and that the toll-free number has to be available the 60 hours per week.

Ms. Wray stated that comments have been received regarding substituting the permit holder pharmacist so that it can be routed out to anybody. She stated that the law says permit holder and the Board copied that verbatim from the law.

Ms. Wray mentioned one other comment spoke to why the pharmacist's name on the label is required. Ms. Wray stated that this is in the law. Per O.C.G.A. § 26-4-80(k) states that the pharmacist who fills an outpatient prescription drug order shall indicate the identity of the dispensing pharmacist on the label of the prescription drug.

Written comments were received from the following:
Stephen Georgeson
Peggy Dietrich, RxDirect
John Sisto, Express Scripts
Allen K. Horne, CVS Health
Lynda Chapman

Rule 480-22-.04 Requirements of a Schedule II (C-II) Controlled Substance Prescription Drug Order

Written comments were received from the following:
Lynda Chapman

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

Public comments from Lynda Chapman were received. Ms. Chapman stated that she thinks it is unclear the way the rule is currently written whether it is the pharmacist who actually filled the prescription to sign the report the next day, or whether it is sufficient to have the pharmacist who comes on the next day. She also asked if the Board is contemplating one person signing on behalf of the team, or each person signing. Chairperson McConnell stated that issue can be covered in a clarifying statement.

Public comments from Jimmy England, Walgreens, were received. Mr. England stated that they are going to have to print out records that are older than 18 months. They contract out the storage of such so they can keep them for the required time. He added that they use a company called Iron Mountain and they have to request the records be sent to them; however, if an investigator is in a pharmacy and wants them right away, they do not have a way to retrieve them unless they keep the paper copies for the additional six months. Ms. Wray commented that she believes the issue has come up before and that a records management system could accommodate the requirement. She suggested speaking to the computer vendor and working with GDNA to make sure that what you have available and what is within your capabilities is in compliance with this rule.

The hearing adjourned at 12:54 p.m.

Chris Jones made a motion to adopt Rule 480-48-.01 Definitions. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to adopt Rule 480-48-.02 Conditions for Use of Delivery by Mail. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Laird Miller made a motion to adopt Rule 480-6-.02 Nonresident Pharmacy Permit. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion to adopt Rule 480-22-.04 Requirements of a Schedule II (C-II) Controlled Substance Prescription Drug Order. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion to adopt Rule 480-27-.05 Record-Keeping When Utilizing An Automated Electronic Data Processing System. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Emergency Rule Hearing

Chairperson McConnell called the Emergency Rule Hearing to order at 12:55 p.m.

Jim Bracewell made a motion to adopt emergency Rule 480-34-0.21-.06 Hydrocodone Combination Products. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

480-34-0.21-.06 Hydrocodone Combination Products.

(1) Effective October 6, 2014, Official Code of Georgia Annotated (O.C.G.A.) §§16-13-27(4)(C), 16-13-27(4)(D) are hereby removed from Schedule III of the Georgia Controlled Substances Act, O.C.G.A. 16-13-25, et. seq. The following language shall be deleted from O.C.G.A. §§16-13-27(4): "(C) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; (D) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts."

(2) Effective October 6, 2014, all Hydrocodone Combination Products (HCPs) in the State of Georgia are Schedule II controlled substances.

(a) Each registrant possessing HCPs must make an actual count inventory of all HCPs as of October 6, 2014 and maintain it with the registrant's biennial DEA inventory.

(b) All HCPs products must be treated as any other Schedule II controlled substance. There can be no oral prescriptions except in the case of an emergency, and all hard-copy HCP prescriptions must be issued on security paper.

(c) For any HCP prescription written and filled before October 6, 2014 with authorized refills, the prescription can be refilled only for the authorized number of refills prior to February 1, 2015.

(3) This rule is based on the following findings of the Board:

(a) that as Schedule III controlled substances, HCPs have an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of HCPs demonstrate that the public is at extreme risk if HCPs are not regulated as Schedule III controlled substances;

(c) that the history and pattern of abuse of HCPs as a Schedule III controlled substance and the scope and significance of that abuse support stricter regulation;

(d) that as a Schedule III controlled substance, there exists an imminent peril to the public health and welfare with regard to the abuse of HCPs;

(e) that HCPs have the same risk to the public health of citizens of the State of Georgia as other Schedule II controlled substances already contained in the Georgia Controlled Substances Act;

(f) that as of October 6, 2014, the U.S. Drug Enforcement Administration has removed all reference to HCPs from Schedule III of 21 CFR 1308.13, which places all HCPs under Schedule II of 21 CFR 1308.12.

Bill Prather made a motion to post Rule 480-34-.06 Hydrocodone Combination Products. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

480-34-.06 Hydrocodone Combination Products.

(1) Effective October 6, 2014, Official Code of Georgia Annotated (O.C.G.A.) §§16-13-27(4)(C), 16-13-27(4)(D) are hereby removed from Schedule III of the Georgia Controlled Substances Act, O.C.G.A. 16-13-25, et. seq. The following language shall be deleted from O.C.G.A. §§16-13-27(4): "(C) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; (D) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts."

(2) Effective October 6, 2014, all Hydrocodone Combination Products (HCPs) in the State of Georgia are Schedule II controlled substances.

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(c) For any HCP prescription written and filled before October 6, 2014 with authorized refills, the prescription can be refilled only for the authorized number of refills prior to February 1, 2015.

(3) This rule is based on the following findings of the Board:

(a) that as Schedule III controlled substances, HCPs have an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of HCPs demonstrate that the public is at extreme risk if HCPs are not regulated as Schedule III controlled substances;

(c) that the history and pattern of abuse of HCPs as a Schedule III controlled substance and the scope and significance of that abuse support stricter regulation;

(d) that as a Schedule III controlled substance, there exists an imminent peril to the public health and welfare with regard to the abuse of HCPs;

(e) that HCPs have the same risk to the public health of citizens of the State of Georgia as other Schedule II controlled substances already contained in the Georgia Controlled Substances Act;

(f) that as of October 6, 2014, the U.S. Drug Enforcement Administration has removed all reference to HCPs from Schedule III of 21 CFR 1308.13, which places all HCPs under Schedule II of 21 CFR 1308.12.

A motion was made by Laird Miller, seconded by Chris Jones, and the Board voted that the formulation and adoption of these rules 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.

The emergency rule hearing was adjourned at 12:57 p.m.

Appearance

Appearance by Carmen Catizone and Joe Adams, National Association of Boards of Pharmacy (NABP): Mr. Adams, President of NABP, thanked the Board for allowing himself and Mr. Catizone to address the Board. Mr. Catizone thanked the Board and GDNA for the leadership displayed over the years. He stated that one issue that he wanted to discuss is the inspection services in response to the compounding crisis. He stated that NABP has inspected compound pharmacies in New Jersey, Texas and also non-resident pharmacies in states that do not have resources. NABP is in discussion with a number of other states to make sure they are being inspected. He went on to explain that there are pharmacies across the country that have not been inspected in over 20 years that are shipping into Georgia.

Mr. Catizone stated that the NABP is asking the Board and GDNA to work with them and do a cross-walk so they can incorporate what Georgia is requiring. NABP is looking for uniformity with inspections. He stated that Georgia can query information on a non-resident pharmacy anywhere in the United States. He explained that the entire profile for that pharmacy would be in the database. Mr. Catizone stated that they are asking for collaboration and thinks everyone will be better served. He went on to state that if such dialog does not occur, it may result in other pharmacies not being able to practice in other states because the inspection is not comparable.

Mr. Miller responded by stating that it seems like the goal of NABP is to take over licensing and inspections of pharmacies within our state. Mr. Catizone responded by stating that is not the case. He stated that NABP is only as strong as the individual states that participate. He stated revenue has to rest with the states and explained that NABP is not charging for some of the inspections with the states. Inspections are not a revenue generating item for NABP.

Mr. Adams stated that the key focus is providing services to the states. He explained that NABP is there as a support mechanism. Discussion was held regarding uniformity of inspections between GDNA and NABP.

Mr. Catizone and Mr. Adams thanked the Board for allowing them to be placed on the agenda and stated that they will be happy continue the dialogue.

Miscellaneous

Mr. Allen discussed mixing under USP 797 conditions and proposed rule changes for Rule 480-11-.02 Compounded Drug Products and Rule 480-11-.08 Records and Reports. Mr. Allen stated he sent the proposed changes to Anil Foreman, Legal Officer, for her to put into posting format so that the Board may vote on them.

Chairperson McConnell discussed labeling requirements. Ms. Wray referred to a letter sent to the Board on 09/16/2014 requesting the Board consider an emergency rule to mandate that, in addition to identifying the responsible physician, when prescriptions are written by physician's assistants or nurse practitioners, the labels on those prescriptions must also identify the prescribing physician's assistant or nurse practitioner. The Board recommended issuing a clarifying statement that would address this matter. Mr. Allen stated he would draft the statement and send to the Board for review.

Jim Bracewell 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, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones and Bill Prather.

Executive Session

Attorney General's Report – Janet Wray
Ms. Wray discussed the following cases:

- M.P.
- C.P.I.
- G.D.
- W.E.D.P.
- C.P.

Cognizant's Report – Laird Miller

- GDNA Case #A13-43B
- GDNA Case #A13-43A
- GDNA Case #A14-31
- GDNA Case #A14-33
- GDNA Case #T31227
- GDNA Case #T31151
- GDNA Case #T31025
- GDNA Case #B31054
- GDNA Case #A30972
- GDNA Case #A31134
- GDNA Case #A30711
- GDNA Case #A31061
- GDNA Case #B31081
- GDNA Case #B31102
- GDNA Case #B31139
- GDNA Case #B31132
- GDNA Case #B29543
- GDNA Case #B31148
- GDNA Case #A14-34

Miscellaneous
Eric Lacefield, Deputy Director, discussed the August examination and the upcoming January examination with the Board.

Applications

- A.P.I.
- I.T.L.
- P.P.I.
- P.D.S.L.
- R.M.I.

Correspondences/Requests

- D.W.W.
- M.N.
- K.I.
- C.K.L.
- N.M.

- K.R.S.
- J.Z.M.

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

Open Session

Miscellaneous

Bill Prather made a motion to post Rule 480-11-.02 Compounded Drug Preparations and Rule 480-11-.08 Records and Reports. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

480-11-.02 Compounded Drug Preparations

(1) Compounded drug preparations –Pharmacist/Patient/Prescriber Relationship.
(a) 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 in the place as outlined by the restrictions under 12(b). Dispensing of pharmaceutical products shall be consistent with the provisions of O.C.G.A. T. 16, Ch. 13 and T. 26, Ch. 4 relating to the issuance of prescriptions and the dispensing of drugs.
(b) Pharmacists shall receive, store, or use pharmaceuticals that have been manufactured or repackaged in a FDA-registered facility. Pharmacists shall also receive, store, or use pharmaceuticals in compounding preparations that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.
(c) Pharmacists may compound pharmaceuticals prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such preparations compounded at the pharmacy. Preparations compounded in anticipation of a valid prescription drug order shall be properly labeled to include the name of the compounded pharmaceutical, date of compounding, and beyond-use date. The distribution of compounded preparations, for office use by a practitioner, shall not exceed 5% of production of compounded preparation in a calendar year by that pharmacy. Amounts produced greater than
5% shall be considered manufacturing and will require separate licensure as a manufacturer. Pharmacists must maintain a separate compounding log for each compounded preparation that includes the quantity and amount of each pharmaceutical that is compounded. Pharmacists shall label all compounded preparations that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. T. 16, Ch. 13 and O.C.G.A. T. 26, Chs. 3 and 4, and Board rules and regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.
(d) All compounded preparations labeled in accordance with Board rules and regulations regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of O.C.G.A. T. 16, Ch. 13, and T. 26, Chs. 3 and 4.
(2) Compounded drug preparations – Pharmacist for Distribution to Practitioner
(a) Only a pharmacy licensed or registered by the Board may distribute compounded preparations to practitioners licensed in this state for administration to their patients in the course of their professional practice, either personally or by an authorized person under their direct and immediate supervision.
(b) A practitioner shall make a request to the pharmacy for a compounded preparation in the same manner as ordering products from a wholesale pharmaceutical distributor or manufacturer and not by using a prescription drug order.

(c) A pharmacy receiving an order from a practitioner for a compounded preparation shall maintain such order with its compounding records as required in Rule 480-11-.08 and other rules and regulations of the Board.
(d) Pharmacists shall label all compounded preparations distributed to practitioners for administration to their patients with the following:

1. "By purchase order, Not by prescription",
2. "For Office Use Administration Only – Not for resale",
3. The name of the active ingredients and strengths contained in the compounded preparation,
4. The lot number or identification of the compounded preparation,
5. The pharmacy's name, address and telephone number,
6. The initials of the pharmacist verifying the finished compounded preparation and the date verified,
7. The quantity, amount, size, or weight of the compounded preparation in the container,
8. An appropriate beyond-use (expiration) date of the compounded preparation as determined by the pharmacist in compliance with Board rule and USP-NF standards for pharmacy compounding, and
9. Appropriate ancillary instructions such as storage instructions or cautionary statements, and where appropriate, hazardous drug warning labels.

(e) Pharmacists shall enter into a written agreement with a practitioner for the practitioner's use of the compounded preparation before providing any compounded preparation to the practitioner. The written agreement shall provide the following information:
1. The name and address of the practitioner, license number and contact information.
2. An agreement by the practitioner that the compounded preparation may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity.
3. An agreement by the practitioner to include on the patient's chart, or medication administration record the lot number and beyond-use date of the compounded preparation administered to the patient.
4. The procedures for a patient to report an adverse reaction or to submit a complaint about a compounded preparation.
5. The procedure to be used when the pharmacy has to recall a batch of compounded preparation. (f) When pharmacists are compounding sterile preparations to be provided to practitioners for use in patient care or when pharmacists are altering or repackaging such products for practitioners to use in patient care in the practitioner's office, the sterile compounding shall be conducted as allowed by applicable federal law and Board rules and shall be in compliance with USP-NF standards for sterile compounding.
(g) Sterile compounded preparations may be dispensed to practitioners in quantities no more than 100 individual dosage containers and must have a beyond-use date no more than one week.
(h) Pharmacist may not compound Schedule II, III, IV or V controlled substances, as defined in Article 2 of Chapter 13 of Title 16 without a patient specific prescription drug order.
(i) Prior to any pharmacy engaging in the practice of compounding preparations for use in the practitioner's office, the pharmacy must notify the Georgia Drugs and Narcotic Agency ("GDNA") of its practice, and must maintain on file the written acknowledgement of receipt of the notice from GDNA.
(j) Nothing in this paragraph shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners employed by an institution or its affiliated entities; provided, however, pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to the other rules and regulations of the Board governing the compounding of pharmaceuticals.
(3) Pharmacists must maintain documentation of proof that the beyond-use date on compounded pharmaceuticals is valid.

(4) Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final verification check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

(5) Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.
(6) Pharmacists may use prescription bulk substances in compounding when such bulk substances:
(a) Comply with the standards of an applicable USP-NF monograph, if such monograph exists, including the testing requirements, and the Board rules on pharmaceutical compounding; or are substances that are components of pharmaceuticals approved by the FDA for use in the United States; or otherwise approved by the FDA;
(b) Are manufactured by an establishment that is registered by the FDA; and
(c) Are distributed by a wholesale distributor licensed by the Board and registered by the FDA to distribute bulk substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.
(7) Pharmacists shall maintain records of all compounded pharmaceutical products. Pharmacist shall maintain a complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail when such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.
(a) This recording keeping requirement does not apply when FDA approved and labeled sterile injectable drug products, produced by registered pharmaceutical manufacturers, are reconstituted under conditions as allowed by USP 797, and each such sterile drug product must be administered within 24 hours of being reconstituted.
(8) Pharmacists engaged in the compounding of pharmaceuticals shall operate in conformance with Georgia laws and regulations. Non-sterile compounded preparations shall be subject to USP 795. All sterile compounded preparations shall be subject to USP 797.
(9) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.
(10) Special precaution preparations. If drug preparations with special precautions for contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross- contamination.
(11) Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved.
(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet or an appropriate barrier isolator. Other preparations should not be compounded in this cabinet.
(b) Personnel compounding cytotoxic drugs shall wear protective apparel as outlined in the National Institute of Occupation Hazards (NIOSH.) in addition to appropriate compounding attire as described in USP 797.
(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations.
(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.
(e) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.
(f) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and delivered in a manner to minimize the risk of accidental rupture of the primary container.
(g) Disposal of cytotoxic and/or hazardous wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of cytotoxic and/or infectious waste in a manner so as not to endanger the public health.
(12) Pharmacists shall not engage in the following:
(a) The compounding for human use of a pharmaceutical product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe.

(b) The compounding of any pharmaceutical products that are essentially copies of commercially available pharmaceutical products. However, this prohibition shall not include:
1. The compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,
2. The compounding of a commercially available manufactured pharmaceutical during times when the product is not available from the manufacturer or wholesale distributor,
3. The compounding of a commercially manufactured pharmaceutical that appears on the drug shortages list, or
4. The mixing of two or more commercially available products of which the end product is a commercially available product.
(13) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. Section 26-4-130 shall comply with all the provisions of this rule and other applicable Board laws, rules and regulations.

480-11-.08 Records and Reports.
(1) Any procedures or other records required to be maintained in compliance with this chapter shall be retained for the same period of time as required in chapter 480-10 of the Board Rules for the retention of prescription files.
(2) All records required to be retained under this chapter or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.
(3) Records required under this chapter may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, electronic files or other accurate reproductions of the original records. All records or reports must be producible immediately if requested by the Board or an agent of the GDNA or within forty-eight (48) hours if maintained in a central database.
(4) In addition to standard record and reporting requirements, the following records and reports must be maintained for sterile pharmaceuticals:
(a) A policy and procedure manual, including policies and procedures for cytotoxic and/or infectious waste, if applicable; and
(b) Lot numbers and expiration dates of all the components used in compounding sterile prescription drug orders.
(c) This recording keeping requirement does not apply when FDA approved and labeled sterile injectable drug products, produced by registered pharmaceutical manufacturers, are reconstituted under conditions as allowed by USP 797, and each such sterile drug product must be administered within 24 hours of being reconstituted.

A motion was made by Chris Jones, seconded by Jim Bracewell, and the Board voted that the formulation and adoption of these rules 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 for the Board to take the following actions:

Georgia Drugs and Narcotics Agency – Rick Allen
Mr. Allen discussed the following:

- DEA Disposal Rule: No action taken
- Mixing under USP 797 conditions exemption
- Prescription label changes

Applications

• Crystal G. Flagg	Pharmacy Technician	Approved registration
• J.D.T.	Pharmacy Technician	Denied registration
• S.A.D.	Pharmacy Technician	Denied registration
• Chelsea N. McAfee	Pharmacy Technician	Approved registration
• D.V.N.	Pharmacist Reciprocity	Allow to sit for MPJE
• Kristen F. Peebles	Pharmacist Reciprocity	Approved application
• Sarah E. Poole	Pharmacist Intern	Approved application
• Tiffany J. Somerville	Pharmacist Intern	Approved application
• James V. Valkenburg	Pharmacist Intern	Approved application
• Zabiullah Mohsini	Pharmacist Intern	Approved application
• M.L.M.	Pharmacist Certification of DTM	Approve pending receipt of additional information
• I.T.I.	Manufacturing Pharmacy	Approve with letter of concern

Attorney General's Report – Janet Wray
Ms. Wray presented the following consent orders:

• L.M.	Private Consent Order accepted
• Walgreens #5446	Public Consent Order to be accepted and signed with express permission upon receipt of the original
• Pauline Badiki	Public Consent Order accepted
• A.M.	Private Consent Order to be accepted and signed with express permission upon receipt of the original
• B.I.I.	Private Consent Order accepted

Ms. Wray discussed the following cases:

• W.G.	Close case with letter of concern
• S.M.	Close case with letter of concern

Attorney General's Report – Janet Wray
Ms. Wray discussed the following cases:

• M.P.	Refer to the Attorney General's office for discipline
• C.P.I.	Close case and deny manufacturer application
• G.D.	No action taken
• W.E.D.P.	No action taken
• C.P.	No action taken

Cognizant's Report – Laird Miller

- GDNA Case #A13-43B Refer to the Attorney General's office for discipline

- GDNA Case #A13-43A Refer to the Attorney General's office for discipline
- GDNA Case #A14-31 Accept Voluntary Surrender
- GDNA Case #A14-33 Accept Private Interim Consent Order for Assessment
- GDNA Case #T31227 Accept Voluntary Surrender
- GDNA Case #T31151 Revoke technician registration
- GDNA Case #T31025 Revoke technician registration
- GDNA Case #B31054 Close case with letter of concern
- GDNA Case #A30972 Refer to the Attorney General's office for discipline
- GDNA Case #A31134 Refer to the Attorney General's office
- GDNA Case #A30711 Refer to the Attorney General's office
- GDNA Case #A31061 Refer to the Attorney General's office for discipline
- GDNA Case #B31081 Close with no action
- GDNA Case #B31102 Close with no action
- GDNA Case #B31139 Close with letter of concern
- GDNA Case #B31132 Close with letter of concern
- GDNA Case #B29543 Close with no action
- GDNA Case #B31148 Close with no action
- GDNA Case #A14-34 Accept Interim Consent Order

Miscellaneous

Eric Lacefield, Deputy Director, discussed the August examination and the upcoming January examination with the Board. No action taken.

Applications

• Areva Pharmaceuticals, Inc.	Wholesaler Pharmacy	Approved application
• INO Therapeutics, LLC	Wholesaler Pharmacy	Approved application
• P.P.I.	Wholesaler Pharmacy	Refer to the Attorney General's office for discipline
• P.D.S.L.	Wholesaler Pharmacy	Letter of Concern
• R.M.I.	Wholesaler Pharmacy	Schedule for an appearance with the Board

Correspondences/Requests

• D.W.W.	Request to amend Consent Order	Approved request
• M.N.	Drive thru inspection	Approved
• K.I.	Correspondence	Apply with NABP for licensure by reciprocity and pay necessary fee. Waive $500 fee that will accompany application to Board office.
• C.K.L.	Request to reinstate registration	Request denied
• N.M.	Request for telephonic appearance	Request denied
• K.R.S.	Request for 500 hours of supervised practice restriction be lifted	Request approved
• J.Z.M.	Seeking guidance regarding reciprocity	Allow individual to take MPJE and reciprociate

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

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, October 22, 2014, at 9:00 a.m. at Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 5:12 p.m.

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