

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St., NW, 36th Floor
Atlanta, GA 30303
November 13, 2013
9:00 a.m.

The following Board members were present:

Al McConnell, Chairperson
Tony Moye, Vice-Chairperson (*departed @ 11:59 a.m.*)
Mike Faulk
Chris Jones
Laird Miller
Bill Prather
Ronnie Wallace

Staff present:

Tanja Battle, Executive Director
Rick Allen, GDNA
Janet Wray, Senior Assistant Attorney General
Brandi Howell, Licensure Analyst

Visitors:

Kori Forster
Pauline Badiki
Frances Cullen
Helen Sloat
Robert Robertson
DeRoyce Simmons
Jim Bartling
Anan Khaldi
Robertha Budy
Brian Morris
Scott Biddulph
Andrea Sport
Kelly Huynh
Matt Wilson
Mark Bear
Jon Martin
R. Scott Lindsay
Melvin Smith

Chairperson McConnell established that a quorum was present and called the meeting to order at 9:03 a.m.

Chris Jones made a motion and Bill Prather 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 Ronnie Wallace.

Executive Session

Appearance

- P.M.B.

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

Rule Hearing

Chairperson McConnell called the Rules Hearing to order at 9:35 a.m.

Rule 480-1-.01 Organization of the Board

No comments or written responses were received.

Rule 480-6-.01 Pharmacy Licenses.Amended

No comments or written responses were received.

Rule 480-2-.05 Reciprocity.Amended

No comments or written responses were received.

The hearing was adjourned at 9:37 a.m.

Open Session

Chairperson McConnell declared Open Session at 9:38 a.m.

Bill Prather made a motion to adopt Rule 480-1-.01 Organization of the Board, Rule 480-6-.01 Pharmacy Licenses. Amended and Rule 480-2-.05 Reciprocity. Amended. Tony Moye seconded and the Board voted unanimously in favor of the motion.

Chris Jones made a motion and Laird Miller 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 Ronnie Wallace.

Executive Session

Appearances

- R.R.
- D.D.S.

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

Open Session

Presentation by McKesson

Three representatives from McKesson appeared before the Board to share some of the highlights of the McKesson Pharmacy System and answer any questions the Board had concerning records access. Following the presentation, Laird Miller made a motion to approve the system. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Approval of Minutes

Chris Jones made a motion to approve the Public and Executive Session minutes for the October 16, 2013 full Board meeting. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Tiena Fletcher, Houston Medical Center

The Board considered this correspondence and directed staff to respond to Ms. Fletcher by stating that there is not an exception in the law that would allow someone who is not licensed in Georgia to work in a hospital outside of a military installation, even for training purposes.

Correspondence from Dustin LaValley, The Walman Optical Company

The Board considered this correspondence and directed staff to respond to Mr. LaValley by stating that the law states that a wholesale distributor can only distribute to a licensed person or firm in this state. Given current Georgia law, the Board suggests he review O.C.G.A. § 26-4-113 to determine if the company should be licensed as a wholesale distributor.

Correspondence from Susan DelMonico, CVS Caremark

The Board viewed correspondence that was for informational purposes only.

Correspondence from Loreana Pharmacy and Gifts II, PHRE007919

The Board considered this correspondence from Loreana Pharmacy and Gifts II requesting the Board terminate its probation. Tony Moye made a motion to approve the request. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Maria Losh, Complete Compliance Solutions, LLC

The Board considered this correspondence concerning whether OTC Wholesale Distributors need to be licensed and directed staff to respond to Ms. Losh by referring her to O.C.G.A. Sections 26-4-113, 26-4-115 and Board Rule 480-7-.03.

Correspondence from Jerry W. Hopkins, RPH10084

The Board considered this correspondence from Mr. Hopkins requesting the Board terminate his probation. Tony Moye made a motion to schedule Mr. Hopkins to meet with the Board to discuss his request. Mike Faulk seconded and a majority of the Board voted in favor of the motion. Bill Prather abstained.

Ratifications

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

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen discussed a handout regarding what to do in the case of a robbery.

- 1) If someone comes into the pharmacy and announces they are there for money or drugs: *Fully cooperate with them - DO NOT BE A HERO!* No amount of money or drugs is worth risking injury to any employee, much less worth anyone's life. Do not argue with or agitate the person – do as they demand. Don't attempt to fight or pull a weapon on the suspect. Most armed pharmacists reacting to a robbery end with an injury to the pharmacist or another pharmacy employee.
- 2) Stay as calm as possible. Do not attempt to speak to the suspect if they seem overly nervous and agitated. Remember, this may be a prescription drug addict trying to get their next dose of medication. Or it could be street drug addict trying to get drugs to sell to buy the drugs they need. Regardless, the person could be going through withdrawals and DTs and not wanting to engage in conversation.
- 3) Comply with the suspect's demands as quickly as you can, but do not volunteer to do anything unless asked by the suspect. If you are expecting someone (employee) to walk into the pharmacy that might cause them to be alarmed, let the suspect know who it would be. Get the person out of the pharmacy as soon as possible. If the suspect only interacts with a clerk or technician and sends them to

get the drugs or money, develop a code or sign to alert the pharmacist a robbery is taking place. If you are the pharmacist and you've been alerted a robbery is taking place, do not interfere with the clerk or technician – help them get what the suspect demands.

4) Watch everything the robbery suspect does while they're in the pharmacy. Note if they touch anything. Is there someone else with the suspect? What are the suspect's facial features, eye and hair color, what type and color clothes are they wearing? Compare their height to fixtures in the pharmacy – install a height marker in the pharmacy. Write these descriptions down as soon as possible afterwards to give to law enforcement.

5) If a weapon is displayed – what kind is it? A revolver versus a semi-automatic? What color? Anything distinguishable you can remember about it? Write this down along with the suspect description.

6) When the suspect leaves the pharmacy, if possible note where they go and in what direction. Are they walking or in a vehicle? What kind – color, etc.? Do not attempt to chase after them once they leave the pharmacy!

7) Lock the pharmacy down immediately after the suspect leaves and call law enforcement, if not already called, to alert them to the robbery. Arrange beforehand with local law enforcement for a code to alert them to a robbery in progress or one that has just been committed, as well as get guidance from them on how they want you to handle such situations.

8) Immediately after the suspect leaves, each employee should independently write down the facts of what just happened. Use a pre-printed form to help (see GDNA website). Avoid discussing the robbery with other witnesses to avoid contaminating each other's memory of the event. Protect any evidence such a note, anything the suspect touched or left behind. If there is security video of the robbery – ensure it is preserved.

9) Wait for law enforcement to arrive and cooperate fully when they do. They are in charge of a crime scene, aka pharmacy, until they release it back to you. Such as it is, your patients will have to wait for their medications until after law enforcement permits it.

10) Do an inventory of the drugs (or money) taken. To the best of your ability, determine how much of which drugs were taken. Report the theft/loss to GDNA. Call 404.656.5100 or 800.656.6568 to request a DEA 106 Theft Report. Note: If stolen drugs are recovered – even if only after a short while, none of these drugs can be returned to stock. You have no idea what might have happened to them once they left the store. These drugs are considered adulterated and misbranded and must be destroyed.

11) An armed robbery is a very traumatic event. Lives have been threatened, and your safe pharmacy environment has been violated. Look after yourself and your employees. Arrange counseling for all pharmacy employees affected by the robbery, including yourself. If your pharmacy has an Employee Assistance Program, utilize it. If not, ask law enforcement for recommendations of the name of a counselor they use in such situations.

Beforehand:

a) Make a point of contacting your local law enforcement, if they have not already contacted you at your pharmac, and arrange a meeting to discuss what they would like for you to do in case of an armed robbery. Include codes for calling in robberies. Learn how they will respond during an 'in-progress' robbery – avoid a hostage situation. Get to know the people who patrol the area where your pharmacy is located, and the detectives who would investigate robberies and other drug/internal theft.

- b) Install bullet-proof glass in your drive-through windows in case the suspect attempts a robbery pointing a weapon through the glass. Shut the door/gate on the window and immediately lock the pharmacy down – and call law enforcement.
- c) Install video surveillance cameras and recording equipment in the prescription department. The more cameras the better. Have the installers place the cameras at locations which will record faces of potential robbery suspects – and overhead in the Rx drug shelves to help deter internal theft. Most of the larger chain pharmacies have excellent video surveillance systems.

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

Lastly, Mr. Allen discussed House Bill 605. He stated that the Board will need to consider its position on this bill.

Attorney General's Report – Janet Wray

Ms. Wray discussed highlights of a powerpoint presentation she sent out earlier in the month regarding recusal information for board members, code of ethics for government service, etc.

Executive Director's Report – Tanja Battle

Ms. Battle stated that at the October 16, 2013 meeting the Board voted to table several reciprocity applications. She stated that a determination needs to be made on those applications since the Board voted to adopt the reciprocity rule today. Bill Prather made a motion to move forward with the applications for licensure by reciprocity as they applied before the rule was amended. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Ms. Battle reported on the status of the transition. She stated that licensees now have the capability to print a copy of the pocket card online. Bill Prather stated that he would like to take a moment to commend Ms. Battle and her staff for a job well done as the transition has been challenging.

Ms. Battle stated that online renewals are now functional for the Georgia Board of Dentistry.

Miscellaneous

PointClick Care Presentation: The Board discussed the presentation which was presented to the Board at its 12/2012 meeting. Ms. Wray stated that the powerpoint presentation is fine. The issue is what was discussed during the oral presentation. The oral presentation indicated the nurses would be ordering the drugs prior to the physician ordering the drugs. The physician would then come by and sign off on the order. Ms. Wray stated that this would be in violation of the law. The Board recommended directing staff to respond to the representatives of PointClick Care and state that they must comply with the electronic prescription law found in O.C.G.A. Section 26-4-80.

Rules Discussion: Bill Prather made a motion to post the following rules:

480-11-.01 Definitions.

- (1) "Administer" or "administration" means the provision of a unit dose and/or doses of medication to an individual patient as a result of the order of an authorized practitioner of the healing arts.
- (2) "Barrier Isolator" means an isolator specifically designed for compounding pharmaceutical ingredients or preparations in an aseptic environment.
- (3) "Biological safety cabinet" means a ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

- (4) "Board of Pharmacy" or "Board" means the Georgia State Board of Pharmacy.
- (5) "Class 100 Environment" or "ISO Class 5" means an atmospheric environment which contains fewer than 100 particles 0.5 microns or larger in diameter per cubic meter of air.
- (6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription drug order or initiative based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine and regularly observed prescribing patterns. Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.
- (7) "Component" means any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.
- (8) "Cytotoxic" means a pharmaceutical that has the capability of killing living cells.
- (9) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.
- (10) "Device" means an instrument, apparatus, contrivance, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician" or "Rx Only."
- (11) "Dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient, patient's caregiver, or patient's agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a patient.
- (12) "Distribute" means the delivery of a drug or device other than by administering or dispensing.
- (13) "Drug" means:
- (a) Articles recognized as drugs in any official compendium, or supplement thereto, designated from time to time by the Board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
 - (b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
 - (c) Articles, other than food, intended to affect the structure or any function of the body of humans or animals; and
 - (d) Articles intended for use as a component of any articles specified in subparagraph (a), (b), or (c) of this paragraph but does not include devices.
- (14) Drug regimen review includes but is not limited to the following activities:
- (a) Evaluation of any prescription drug order and patient record for:
 - 1. Known allergies;
 - 2. Rational therapy-contraindications;
 - 3. Reasonable dose and route of administration; and
 - 4. Reasonable directions for use.
 - (b) Evaluation of any prescription drug order and patient record for duplication of therapy;
 - (c) Evaluation of any prescription drug order and patient record for the following interactions:
 - 1. Drug-drug;
 - 2. Drug-food;
 - 3. Drug-disease; and
 - 4. Adverse drug reactions.
 - (d) Evaluation of any prescription drug order and patient record for proper utilization, including over utilization or under utilization, and optimum therapeutic outcomes.
- (15) "Enteral" means within or by way of the intestine.
- (16) "FDA" means the United States Food and Drug Administration.
- ~~(16)~~(17) "GDNA" means the Georgia Drugs and Narcotics Agency.

~~(17)~~(18) "Labeling" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or rule.

~~(18)~~(19) "Nonprescription drug" means a drug which may be sold without a prescription drug order and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and/or the federal government.

~~(19)~~(20) "Parenteral" means an injectable sterile preparation of drugs for administration by any other means than through the gastrointestinal tract.

~~(20)~~(21) "Patient counseling" means the oral communication by the pharmacist of information, as defined in the law and the rules of the Board, to the patient, patient's caregiver, or patient's agent, in order to improve therapy by ensuring proper use of drugs and devices.

~~(22)~~ "Pharmaceutical" means a compound to be used as a medicinal drug.

~~(21)~~(23) "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy. This recognizes a pharmacist as a learned professional who is authorized to provide patient services and pharmacy care.

~~(22)~~(24) "Pharmacist in charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of such pharmacy and personnel.

~~(23)~~(25) "Pharmacy" means any place licensed in accordance with the laws and rules of this state wherein the possessing, displaying, compounding, dispensing, or selling of drugs may be conducted, including any and all portions of the building or structure leased, used, or controlled by the licensee in the conduct of the business or profession licensed by the Board at the address for which the license was issued.

~~(26)~~ "Practitioner" or "practitioner of the healing arts" means a physician, dentist, podiatrist, or veterinarian and shall include any other person licensed under the laws of this state to use, mix, prepare, dispense, prescribe, and administer drugs in connection with medical treatment to the extent provided by the laws of this state.

~~(24)~~(27) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient.

~~(25)~~(28) "Prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the law and the rules of the Board, prior to dispensing the drug as part of a drug regimen review.

~~(26)~~(29) "Sterile pharmaceutical" means any dosage form devoid of viable microorganisms, or any other contaminant including, but not limited to, parenterals, injectables, and ophthalmics.

~~(27)~~(30) "Sterile Preparations" are those as defined by USP 797.

~~(31)~~ "USP-NF" means the United States Pharmacopeia and National Formulary.

480-38-.01 Definitions

For purposes of this chapter of the Rules and Regulations, the following definitions apply:

(a) "Board" shall mean the Georgia Board of Pharmacy.

(b) "Delivery by Mail" or "delivered by mail" shall mean delivery to a patient by the United States postal service or a commercial common carrier. It is not considered to be delivery by mail when a pharmacy uses its own employees or employs a local courier service to deliver filled prescriptions in the same day from the pharmacy to a patient.

(c) "Pharmacy" means a pharmacy holding a current Board issued license or permit to operate a pharmacy in Georgia and shall include pharmacy benefit managers licensed pursuant to O.C.G.A. Section 26-4-110 and 26-4-110.1.

(d) “Regularly employ” or “regularly use” means when a pharmacy routinely, on a monthly or quarterly basis, employs or uses the U.S. Postal Service or a common commercial carrier to deliver an entire prescribed quantity of a filled prescription to a single patient as requested by the patient.

480-38-.02 Conditions for Use of Delivery by Mail

(1) Any pharmacy can regularly employ the U.S. Postal Service or a common commercial carrier to deliver a drug which requires a prescription to a patient only after the patient has requested that a pharmacy use this method of delivery for his/her filled prescription drugs.

(2) A pharmacy must document in writing a patient’s request for delivery by mail of his/her filled prescription drugs. Such documentation must be maintained for at least two years after the last delivery by mail.

(3) Any pharmacy regularly using delivery by mail to deliver dispensed prescription drugs shall comply with the following conditions:

(a) The pharmacy shall provide an electronic, telephonic, or written communications mechanism which provides a proof of delivery which records when the medications delivered by mail were received by the patient or their designee.

(b) The pharmacy shall ensure that the mail service will not leave medications unattended and will hold the medications for pickup by the patient or his/her designee.

(c) A pharmacy that regularly employs delivery by mail must provide a method, including a local or toll-free telephone number, for the patient to call and speak with a pharmacist at the pharmacy if the patient has any questions regarding their medication and to allow the pharmacist or pharmacy intern under the supervision of the pharmacist to offer counseling on each filled prescription drug in accordance with and obligated by Code Section 26-4-85, unless the patient refuses such consultation or counseling and such refusal is documented.

(d) The pharmacy shall utilize, in accordance with standards of the manufacturer, United States Pharmacopeia and National Formulary, Federal Drug Administration and other standards, temperature tags, time temperature strips, insulated packaging, or a combination of these which protect the integrity of and indicate when the integrity of any drug which has been delivered by mail order has been compromised.

(e) The pharmacy shall provide information to the patient on the procedure the patient should follow if any prescription drug does not arrive in a timely manner, or if the integrity of the packaging or medication has been compromised during shipment and delivery by mail.

(f) Any pharmacy utilizing delivery by mail shall immediately replace any prescriptions drugs that are compromised during shipment and delivery by mail or that do not arrive in a timely manner.

(g) A pharmacy using delivery by mail shall document in its records when the prescription drug was sent to the patient and received by the patient or his/her designee, and such records shall be maintained for the same time period and in the same method as when a patient is delivered the medication in person or by courier.

(h) A pharmacy using delivery by mail shall document instances when prescription drugs have been compromised during shipment and delivery by mail or when drugs do not arrive in a timely manner, and shall maintain such documentation for two (2) years.

(4) The following drugs may not be delivered by mail:

(a) Schedule II controlled substances;

(b) Prescription drugs that require refrigeration;

(c) Chemotherapy drugs deemed by the federal Environmental Protection Agency as dangerous; and

(d) Medications in suppository form;

(e) Quantity of C3-C4 30 day supply or 180 tabs

(6) A pharmacy or a pharmacist shall refuse to deliver by mail a prescription drug which, in the professional opinion of the pharmacy or pharmacist, may be clinically compromised by delivery by mail.

Ronnie Wallace seconded and the Board voted unanimously in favor of the motion.

A motion was made by Ronnie Wallace, seconded by Chris Jones, 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.

Chairperson McConnell reported hydrocodone with acetaminophen is being reformulated and, in the future, will not have more than 325 mg of acetaminophen in any formulation. Mr. McConnell shared this information with the Executive Director of the Composite Medical Board.

Ms. Wray stated that the Pharmacy Board may also want to notify the Medical Board that Tramadol may go to a Schedule IV drug.

Ms. Wray stated that the wording concerning the existence of a public board order needs to be revised as we need to make sure this information is accurate.

Chris Jones made a motion and Ronnie Wallace 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 Ronnie Wallace.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

Discussed latest PDMP reports.

Cognizant's Report – Laird Miller

- GDNA Case #A-30827
- GDNA Case #A-30813
- GDNA Case #T13-62
- GDNA Case #B13-55
- GDNA Case #A13-63
- GDNA Case #A13-67
- GDNA Case #A13-66
- GDNA Case #A-30746
- GDNA Case #A-30747
- GDNA Case #B-30768
- GDNA Case #B-30810
- GDNA Case #A-30815
- GDNA Case #B-30872
- GDNA Case #B-30888
- GDNA Case #A-30510-97
- GDNA Case #A-30510-87
- GDNA Case #A-30510-88

- GDNA Case #A-30510-89

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders for acceptance:

- A.B.
- K.J.G.
- A.L.H.
- J.N.

Executive Director's Report – Tanja Battle

Ms. Battle presented the following consent order for acceptance:

- J.D.B.

Applications

- D.D.S.
- S.S.M.
- R.L.A.
- M.L.S.
- H.D.P.
- J.L.M.
- A.L.S.
- K.E.D.
- T.A.M.
- T.P.
- J.A.W.
- L.S.
- A.N.N.
- M.S.W.
- R.U.K.
- D.M.P.
- M.I.
- C.L.
- A.
- S.N.
- L.P.
- A.P.H.
- D.Z.H.
- S.D.D.
- S.M.C.
- W.E.C.
- R.K.D.
- S.P.T.
- E.M.

Correspondences/Requests

- C.E.C.
- H.S.A.H.
- M.H.
- U.P.S.S.C.S.

- X.G.P.
- C.K.
- K.W.A.
- J.F.R.
- T.H.A.

Miscellaneous

- G.D.N.A. #B-30765

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

Open Session

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

Appearances

- P.M.B. Approve with public consent order
- R.R. Denial overturned and application approved
- D.D.S. Approve with private consent order

Georgia Drugs and Narcotics Agency – Rick Allen

- Discussion of PDMP reports. No action taken.

Cognizant’s Report – Laird Miller

- GDNA Case #A-30827 Refer to the Attorney General’s office for discipline
- GDNA Case #A-30813 Refer to the Attorney General’s office for discipline
- GDNA Case #T13-62 Revoke technician registration
- GDNA Case #B13-55 Refer to the Attorney General’s office for discipline
- GDNA Case #A13-63 Refer to the Attorney General’s office for discipline
- GDNA Case #A13-67 Accept Consent Order
- GDNA Case #A13-66 Refer to the Attorney General’s office for discipline
- GDNA Case #A-30746 Schedule Investigative Interview
- GDNA Case #A-30747 Schedule Investigative Interview
- GDNA Case #B-30768 Close with Letter of Concern
- GDNA Case #B-30810 Refer to the Attorney General’s office for discipline
- GDNA Case #A-30815 Refer to the Attorney General’s office for discipline
- GDNA Case #B-30872 Close with no action
- GDNA Case #B-30888 Close with Letter of Concern
- GDNA Case #A-30510-97 Refer to the Attorney General’s office for discipline
- GDNA Case #A-30510-87 Refer to the Attorney General’s office for discipline
- GDNA Case #A-30510-88 Refer to the Attorney General’s office for discipline
- GDNA Case #A-30510-89 Refer to the Attorney General’s office for discipline

Attorney General’s Report – Janet Wray

Ms. Wray presented the following consent orders for acceptance:

- A.B. OMPE
- K.J.G. Private Consent Order accepted

- A.L.H. Private Consent Order accepted
- J.N. Private Consent Order accepted

Executive Director's Report – Tanja Battle

Ms. Battle presented the following consent order for acceptance:

- J.D.B. Private Consent Order accepted

Applications

- | | | |
|----------|--------------------------|---|
| • D.D.S. | Pharmacy Technician | Approved for registration |
| • S.S.M. | Pharmacy Technician | Approved for registration |
| • R.L.A. | Pharmacy Technician | Approved for registration |
| • M.L.S. | Pharmacy Technician | Refer to the Attorney General's office |
| • H.D.P. | Pharmacy Technician | Approved for registration |
| • J.L.M. | Pharmacy Technician | Denied registration |
| • A.L.S. | Pharmacy Technician | Approved for registration |
| • K.E.D. | Pharmacy Technician | Approved for registration |
| • T.A.M. | Pharmacy Technician | Approved for registration |
| • T.P. | Pharmacy Technician | Table pending receipt of additional information |
| • J.A.W. | Pharmacy Technician | Denied registration |
| • L.S. | Pharmacy Technician | Denied registration |
| • A.N.N. | Pharmacy Technician | Approved for registration |
| • M.S.W. | Pharmacist Reinstatement | Approved application |
| • R.U.K. | Pharmacist Reinstatement | Denied application |
| • D.M.P. | Pharmacist Reciprocity | Approved application |
| • M.I. | Wholesaler Pharmacy | Refer to the Attorney General's office for discipline |
| • C.L. | Wholesaler Pharmacy | Table and place on December agenda for consideration |
| • A. | Wholesaler Pharmacy | Approved application |
| • S.N. | Wholesaler Pharmacy | Approved application |
| • L.P. | Wholesaler Pharmacy | Refer to the Attorney General's office for discipline |
| • A.P.H. | Pharmacist Intern | Approved application |
| • D.Z.H. | Pharmacist Intern | Approved application |
| • S.D.D. | Pharmacist Intern | Approved application |
| • S.M.C. | Pharmacist Intern | Approved application |
| • W.E.C. | Pharmacist Intern | Approved application with letter of concern |
| • R.K.D. | Pharmacist Intern | Approved application |
| • S.P.T. | Pharmacist Intern | Hours approved |
| • E.M. | Manufacturing Pharmacy | Table pending receipt of additional information |

Correspondences/Requests

- | | | |
|----------------|------------------------|---|
| • C.E.C. | Appearance request | Approved request |
| • H.S.A.H. | Pharmacy Wholesaler | No action taken |
| • M.H. | Pharmacist Intern | Table pending receipt of additional information |
| • U.P.S.S.C.S. | Pharmacy Wholesaler | No action taken |
| • X.G.P. | Manufacturing Pharmacy | Letter of concern |
| • C.K. | Correspondence | Send response indicating there is no law under the Pharmacy Practice Act that addresses such. |
| • K.W.A. | Appearance request | Approved request |

- J.F.R. Request to terminate probation Approved request
- T.H.A. Remote order entry Table pending receipt of additional information

Miscellaneous

- G.D.N.A. #B-30765 Close case and refer to the Georgia Composite Medical Board

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

Ronnie Wallace made a motion to post the following rules:

480-34-.04 Synthetic Cannabinoids.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places newly identified compounds, including any material, compound, mixture, or preparation which contains these substances or their isomers, halogens, analogues, and/or homologues, collectively known as Synthetic Cannabinoids, under Schedule I, of the Georgia Controlled Substances Act, Code Section 16-13-25 (12) as follows:

- (M) (1-Pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl) methanone (UR-144)
- (N) [1-(5-fluoropentyl)indole-3yl]-(2,2,3,3-tetramethylcyclopropyl) methanone (XLR11)
- (O) [1,1'-biphenyl]-3-yl-carbamic acid, cyclohexyl ester (URB602)
- (P) [1-(2-morpholin-4-ylethyl)-1H-indol-3-yl]-(2,2,3,3-tetramethylcyclopropyl) methanone (A-796,260)
- (Q) [3-(3-carbamoylphenyl)phenyl] N-cyclohexylcarbamate (URB597).
- (R) 6-methyl-2-[(4-methylphenyl)amino]-1-benzoxazin-4-one (URB754)
- (S) 1-pentyl-N-tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indazole-3-carboxamide (AKB48)
- (T) 1-pentyl-3-(1-adamantylamido)indole (2NE1)
- (U) 1-(5-fluoropentyl)-N-tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3-carboxamide (STS-135)
- (V) 1-naphthalenyl[4-(pentyl)-1-naphthalenyl]-methanone (CB-13)
- (W) 1-(5-chloropentyl)indol-3-yl(2,2,3,3-tetramethylcyclopropyl)methanone (5-Chloro-UR-144)
- (X) 1-(5-bromopentyl)indol-3-yl(2,2,3,3-tetramethylcyclopropyl)methanone (5-Bromo-UR-144)
- (Y) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indole-3-carboxamide (ADBICA)
- (Z) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5-Fluoro-ADBICA)

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

- (a) that Synthetic Cannabinoids have an extremely high potential for abuse;
- (b) that scientific evidence and scientific knowledge of the pharmacological effects of these compounds demonstrate that the public is at extreme risk if they are not regulated as controlled substances;
- (c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;
- (d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;
- (e) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act;
- (f) that these compounds have no known precursor already scheduled under the Act; and
- (g) that the DEA encourages all states to add these compounds to their respective Controlled Substances Acts while DEA follows its procedures to add such compounds to the Federal Controlled Substances Act under Schedule I.

480-34-.05 Synthetic Cathinones

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places an additional newly identified compound, including any material, compound, mixture, or preparation which contains these substances or their isomers, halogens, analogues, and/or homologues, collectively known

as a Synthetic Cathinone, under Schedule I, of the Georgia Controlled Substances Act, Code Section 16-13-25 (12) as follows:

(aa) N-acetyl-3,4-methylenedioxymethcathinone

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

(a) that Synthetic Cathinones have an extremely high potential for abuse;

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

(c) that the pattern of abuse of these compounds and the scope and significance of that abuse support regulation;

(d) that there exists an imminent peril to the public health and welfare with regard to the abuse of these compounds;

(e) that these compounds have the same risk to the public health of citizens of the State of Georgia as other substances already contained in Schedule I under the Controlled Substances Act;

(f) that these compounds have no known precursor already scheduled under the Act; and

(g) that the DEA encourages all states to add these compounds to their respective Controlled Substances Acts while DEA follows its procedures to add such compounds to the Federal Controlled Substances Act under Schedule I.

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

A motion was made by Ronnie Wallace, seconded by Chris Jones, 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.

Laird Miller stated that he spoke with the Dean at the University of Georgia concerning the examination and the maximum number of applicants that can be seen per day. Mr. Miller recommended appointing a committee at the first of the year to oversee this matter.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, December 11, 2013, at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 3:18 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director