

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St, N.W. 36th Floor
Atlanta, GA 30303
May 13, 2015
9:00 a.m.

The following Board members were present:

Laird Miller, Chairperson
Mike Faulk, Vice-Chairperson
Vicki Arnold
Jim Bracewell
Chris Jones
Tony Moye (*departed @ 2:30 p.m.*)
Bill Prather
Bob Warnock

Staff present:

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

Visitors:

Greg Shuford, Trinity Hospital of Augusta
Ray Solano
Deborah Pears
J. Bernard, Wickliffe Veterinary Pharmacy
Jimmy England, Walgreens
Mary Ann Langford
Scott Lindsay, CAPS
Ed Callis, Omnicare
Katherine Bell, CVS
Kallarin Mackey, GHA
Jennifer Bellis, BSL
Melissa Germain
Mike King, Publix
Ryan Koenig, Roadrunner Pharmacy
Jean-Pierre Edmond, Cold Chain Research
Young Chang, Walgreens
Christine Wheeler, Rite Aid
Sophia Novack, Rite Aid
Sonya Nelson, Walmart
Nirmal Patel, Walmart
Stan Jones, Kaiser, Hemophilia of Georgia

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

Jim Bracewell 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 Vicki Arnold, Jim Bracewell, Mike Faulk, Chris Jones, Laird Miller, Tony Moye, Bill Prather and Bob Warnock.

Executive Session

Appearance

- T.H.A.

Attorney General’s Report – Janet Wray

Ms. Wray presented the following consent orders:

- K.D.
- L.E.

Ms. Wray discussed the following case:

- P.D.S.

Georgia Drugs and Narcotics Agency – Rick Allen

- Online changes by licensed facilities
- Update on training session attended by GDNA

Appearances

- S.C.L.
- W.V.P.

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

Public Rules Hearing

Chairperson Miller called the public hearing to order at 11:30 a.m.

Rule 480-2-.05 Reciprocity.Amended

No comments or written responses were received.

Rule 480-48-.01 Definitions

No comments or written responses were received.

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

Public comments from Jean-Pierre Edmond, Director of Cold Chain Research, were received. Mr. Edmond referred the Board to paragraph (3) of Rule 480-48-.02 states in part *“Pharmacy shall insure integrity of any drug requiring temperature control other than “room temperature storage” that is delivered by mail order by enclosing in each medication’s packaging a USP-recognized method by which the patient can easily detect improper storage or temperature variations”*. Mr. Edmond stated that he has been working with USP for many years and that USP does not have a recognized method by which the patient can easily detect improper storage or temperature variations. He went on to say that chapter 1079 is only a guidance with the sole purpose to provide information and not requirements. He suggested that the Board take this reference out of the rule.

Mr. Edmond discussed his research regarding the storage and transportation of temperature sensitive pharmaceutical products as well as temperature monitoring devices with the Board. Chairperson Miller expressed his concerns by stating he would be skeptical until the Board received some sort of standard set by a governmental agency regarding this matter. Mr. Jones commented that adding a label to the outside of the box stating how long the drug is good for goes a long way. Mr. Jones stated that whether or not the temperature strip is used, he likes the idea better of having a ”beyond use” date on the outside of the box. Mr. Bracewell commented that it should be the mail order shipper’s responsibility to say that

they will take responsibility and be held liable. After further discussion, the Board recommended tabling this rule to allow additional time to research.

Written comments from Jean-Pierre Edmond were received.

Rule 480-48-.03 Delivery by Pharmacy

Public comment from Scott Lindsay, CAPS, was received. He spoke to the Board about delivering their product in validated shipping containers so that they are delivering everything they can in a timely, secured manner. He added they are doing everything they can to get products delivered appropriately and that they do not use temperature strips. Vice-Chairperson Faulk asked who validated their system. Mr. Lindsay responded that it has been reviewed by the FDA and deemed acceptable. Chairperson Miller asked if there was an FDA standard. Mr. Lindsay responded no.

Bill Prather made a motion to adopt Rules 480-2-.05 Reciprocity.Amended, 480-48-.01 Definitions, 480-48-.02 Conditions for Use of Delivery by Mail, and 480-48-.03 Delivery by Pharmacy as posted and requested the Chair appoint a sub-committee of the Board to investigate the temperature strip issue. Discussion was held by Ms. Wray. She stated that the public comments made by Mr. Edmond regarding Rule 480-48-.02 are in the existing rule and not in the amendments. Chairperson Miller responded by stating that based on what Mr. Prather proposed, the Board can certainly appointment a sub-committee to investigate further. There being no further discussion, Mike Faulk seconded and the Board voted unanimously in favor of the motion.

The hearing adjourned at 12:20 p.m.

Open Session

Chairperson Miller welcomed the visitors.

Appearance

Appearance by Sophia Novack and Christina Wheeler, Rite Aid Licensing Department: Ms. Novack addressed the Board regarding proposed design plan changes to a particular store in Cleveland, Georgia and asked if the proposed changes satisfied board requirements. Ms. Wray expressed her concerns with the proposal. She explained the changes in the law which go into effect on July 1st pertaining to O.C.G.A. § 43-34-26.1.

Chairperson Miller stated that he did not have a problem with the design itself; however, his only concern is the clear glass not providing privacy. The glass could be shaded, but then you run into the issue of supervision of pharmacy technicians. He added that with the current law and rules that are in place, it will be impossible for any store to do immunizations in their work place. He stated that the Board will need to negotiate with the Georgia Composite Medical Board to address some of the encumbrances or pharmacies will have to do the immunizations during specific hours.

In regards to the design plan presented to the Board, Chairperson Miller stated that the plan redesign cannot be approved by the Board. He reiterated that the room itself is fine, but as soon as the pharmacist goes in the room, he/she would be in violation. Mr. Prather added that if the store only has one pharmacist and if he/she has to leave the pharmacy, operations would have to be suspended in order for him/her to do the immunizations. Chairperson Miller directed Director Allen to review the rules regarding this matter to see if they need to be amended so that this issue can be addressed.

Bill Prather made a motion and Vicki Arnold seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and §43-1-2(k) to deliberate and to receive

information on applications, investigative reports and the Assistant Attorney General's report. Voting in favor of the motion were those present who included Vicki Arnold, Jim Bracewell, Mike Faulk, Chris Jones, Laird Miller, Tony Moye, Bill Prather, and Bob Warnock.

Executive Session

Executive Director's Report – Tanja Battle

- C.P.

Applications

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

Cognizant's Report – Mike Faulk

- GDNA Case #B-15-10
- GDNA Case #T-31469
- GDNA Case #B-31325
- GDNA Case #A-31333

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

Open Session

Miscellaneous

Drug Quality and Security Act: Director Allen gave a summary of 503A and 503B facilities. He explained that 503A is any pharmacy in Georgia. Ms. Wray advised that the Georgia Board of Pharmacy needs to take a position on whether it is in favor of this. She added that if the Board does not feel it is a good thing, it should have a position saying so. She stated that she believes California has signed the MOU. She stated that the question is how many pharmacies in the state actually would be shipping out 30% patient specific? This would mean a tremendous amount of more inspections, more reporting to the federal government, etc. Director Allen stated that Alabama and Mississippi are not going to sign the MOU. Ms. Wray stated that the MOU gives you the difference between 5% and 30%. She added that the costs to Georgia from a regulatory standpoint increases. Mr. Warnock asked if Georgia is currently inspecting now. Ms. Wray responded by stating yes, but not at the auditing level the Board would have to.

Director Allen explained that 503B can do office use only. He further stated there could be some sterile compounding while the rest can be non-sterile. The facility must register with the FDA. The facility can ship non-patient specific as much as it wants. He added that the facility can also dispense prescriptions and ship as many as they want. He stated that until the Board can address the matter of license types, the 503B would be licensed as retail and manufacturer. Chairperson Miller asked about pharmacies that supply medications to offices. Ms. Wray responded by stating that cannot be done anymore. It can be done under a wholesaler license.

Rules Discussion: Ms. Wray discussed changes to proposed Rule 480-22-15 Refilling of Ophthalmic Topical Products. The Board recommended tabling this rule for the June meeting.

Bill Prather made a motion to post Rules 480-22-.03 Manner of Issuance of a Controlled Substance Prescription Drug, 480-22-.04 Requirements of a Schedule II (C-II) Controlled Substance Prescription Drug Order, 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, 480-27-.02 Prescription Drug Order Requirements, 480-37-.03 Minimum Requirements, and 480-37-.05 Inspections. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

480-22-.03 Manner of Issuance of a Controlled Substance Prescription Drug Order.

(1) All controlled substance prescription drug orders issued by the authorized practitioner shall bear the prescribing practitioner's name, address, telephone number and the Drug Enforcement Administration (DEA) permit number assigned to the practitioner for that corresponding address, and each shall be signed and dated on the same day when issued. At the time of dispensing, at a minimum, each shall bear the name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and indications for any refills or zero for none.

(a) A practitioner shall sign a prescription in the same manner as he or she would sign a check or legal document, except as the rules allow regarding the issuance of electronic or facsimile prescriptions. Such controlled substance prescription drug orders shall be written with ink or indelible pencil, pen, typewriter, or printer and shall either be done manually or electronically via computer, as defined by the Board, and signed by the practitioner. Such prescription drug orders may be prepared for the practitioner's signature by the practitioner's authorized agent, but the practitioner is responsible for ensuring that the prescription conforms to all essential respects to the laws and regulations.

(b) A hard copy prescription drug order for any Schedule II controlled substance must be on security paper.

1. If a hard copy of an electronic data prescription drug order for any Schedule II controlled substance is given directly to the patient, the manually signed order must be on security paper.

(2) If a practitioner gives a hard copy of an electronic visual image prescription drug order directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.

(3) Practitioners may electronically transmit prescription drug orders directly to the pharmacy of the patient's choice where the prescription meets the requirements of O.C.G.A. §§16-13-41, 26-4-80, 26-4-80.1, 21 C.F.R. 1306, 21 C.F.R. 1311 and any other applicable state or federal law or regulation for dispensing of a controlled substance prescription drug order transmitted via electronic means.

~~(2)~~(4) Practitioners not registered with the DEA, but affiliated with hospitals or other institutions, shall include the registration number of the hospital or other institutions as well as the special internal code assigned to the authorized practitioner by the hospital or other institution, as provided for in federal regulations 21 CFR 1301.22(c), in lieu of a DEA registration when prescribing or issuing a controlled substance drug order.

(a) Each such hand written prescription drug order shall meet the requirements of Rule 480-22-.04(a) and shall have the name of the practitioner stamped, typed or hand printed on it, as well as the signature

of the practitioner, along with the telephone number where the practitioner can be contacted for verification.

(b) Such prescription drug orders can only be issued by such practitioner for patients treated as a part of his/her duties at such hospital or other institution.

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

(1) A pharmacist or pharmacy intern/extern shall dispense a schedule II Controlled Substance (C-II), as defined by O.C.G.A. § 16-13-26, only pursuant to a ~~written~~ prescription drug order on security paper, except as provided in subparagraphs (1)(a) and (1)(b) and paragraph (3) of this Rule.

(a) A C-II prescription drug order, meeting the requirements of Rule 480-22-.03(1)(a), may be transmitted by the practitioner or the practitioner's agent, to a pharmacy via facsimile machine or equipment. Prior to the practitioner's agent transmitting such schedule II (C-II) prescription via facsimile machine, the C-II prescription drug order, meeting the requirements of Rule 480-22-.03(1)(a), may be transmitted by the practitioner or the practitioner's agent, but not the patient or patient's agent, to a pharmacy via facsimile machine or equipment. The original written, signed prescription drug order must be presented to the pharmacist prior to the actual dispensing of the schedule II (C-II) drug, except as provided in paragraphs (4), (5) or (6) of this section.

(b) A pharmacist may dispense a C-II pursuant to an electronic data prescription drug order where the prescription is transmitted by the practitioner directly to the pharmacy and the prescription otherwise meets the requirements of O.C.G.A. §§16-13-41, 26-4-80, 26-4-80.1, 21 C.F.R. 1306, 21 C.F.R. 1311 or any other applicable state or federal law or regulation for dispensing of a C-II prescription drug order transmitted via electronic means.

(2) Upon dispensing a schedule II (C-II) drug, the pharmacist shall physically sign his or her name on either the face or rear of the schedule II (C-II) prescription drug order in such a manner that the signature does not cover any information required by this chapter. In addition, the pharmacist will ensure that the dispensing date and the serial number for the prescription drug order are indicated on either the face or the back of the C-II prescription drug order.

(3) In the case of an emergency situation, a pharmacist may dispense a schedule II (C-II) controlled substance only upon receiving oral authorization of the prescribing practitioner. For purposes of this paragraph, an emergency situation means a situation in which the prescribing practitioner determines that immediate administration of a schedule II (C-II) controlled drug is necessary, there is no appropriate alternative treatment or drug in a schedule less than CII, and it is not reasonably possible for the practitioner to provide a written prescription drug order for the pharmacist dispensing the drug prior to issuance. Such emergency prescription drug order is permissible provided that:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period must be pursuant to an additional written prescription drug order signed by the prescribing practitioner;

(b) The prescription drug order shall be immediately reduced to writing by the pharmacist or pharmacy intern/extern working under the direct supervision of a licensed pharmacist and shall contain all information required in Rule 480-22-.03, except for the signature of the prescribing practitioner;

(c) If the prescribing practitioner is not known to the pharmacist, the pharmacist must make reasonable effort to determine that the oral authorization came from a licensed practitioner, such effort may include a callback to the prescribing individual using his or her telephone number and/or other good faith efforts to insure the practitioner's identity; and

(d) Within 7 days after authorizing an emergency oral prescription drug order, the prescribing practitioner shall cause a written prescription drug order to be delivered to the dispensing pharmacist for the emergency quantity prescribed. In addition to conforming to the requirements of Rule 480-22-.03, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order.

1. The written prescription drug order shall be delivered to the pharmacist in person or by other means, but if delivered by mail or common carrier it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription drug order to the emergency oral prescription drug order, which had earlier been reduced to writing. The pharmacist shall notify the Georgia Drugs and Narcotics Agency, if the prescribing practitioner fails to deliver a written prescription drug order to the dispensing pharmacist.

(4) A prescription drug order for a terminally ill patient, prepared in accordance with Rule 480-22-.03 written for a Schedule II Controlled Substance as defined by O.C.G.A. §16-13-26, may be transmitted directly by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile machine.

(a) Prior to the prescribing practitioner's agent transmitting such Schedule II Controlled Substance prescription via facsimile machine, the name of the agent and a telephone number for the prescribing practitioner must be included in the face of prescription. The information may be used for verification of the prescription.

(b) The facsimile serves as the original, written prescription drug order for purposes of this paragraph, and it shall be maintained in accordance with Rule 480-22-.04(7) and this chapter. After transmission of the original prescription, the pharmacist should suggest that the practitioner mark "VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical record chart.

(5) A prescription drug order prepared in accordance with Rule 480-22-.04 written for any C-II substance for a resident of Long Term Care Facility (LTCF) may be transmitted directly by the prescribing practitioner or the practitioner's agent, but not the patient or the patient's agent, to the dispensing pharmacy by facsimile machine or equipment.

(a) The practitioner, ~~or~~ practitioner's agent, or pharmacist will note on the prescription drug order that the patient is a LTCF patient by writing "LTCF" on the face of the prescription.

(b) In addition to the term LTCF being noted on the face of the prescription, whenever a practitioner's agent transmits or a pharmacist receives such a prescription, the name of the agent and the practitioner's telephone number or the name and license number of the pharmacist must be included on the face of the prescription. This information may be used for verification of the prescription drug order.

(c) The facsimile serves as the original, written prescription drug order for purposes of this paragraph (c), and it shall be maintained in accordance with Rule 480-22-.04(a) and this chapter. After transmission of the original prescription, the pharmacist should suggest that the practitioner mark "VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical record chart.

(6) A prescription drug order prepared in accordance with Rule 480-22-.03 written for any Schedule II Controlled Substance as defined by O.C.G.A. § 16-13-26, for a patient of a hospice program licensed by the State of Georgia Department of ~~Human Resources~~ Community Health may be directly transmitted by the practitioner or the practitioner's agent, but not the patient or the patient's agent, to the dispensing pharmacy by facsimile machine or equipment.

(a) The practitioner or practitioner's agent will note on the prescription drug order that the patient is a hospice patient by writing "HOSPICE" on the face of the prescription.

(b) In addition to the term "HOSPICE" being noted on the face of the prescription, whenever a practitioner's agent transmits such prescription, the name of the agent and the practitioner's telephone number must be included on the face of the prescription. This information may be used for verification of the prescription drug order.

(c) The facsimile serves as the original, written prescription drug order for purposes of this paragraph, and it shall be maintained in accordance with Rule 480-22-.04(a) and this chapter. After transmission of the original prescription drug order, the pharmacist should suggest that the practitioner mark "VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical chart.

(7) Record keeping for Schedule II Controlled Substances shall be as follows:

(a) Original and all other hard copy schedule II (C-II) prescription drug orders shall be maintained in a separate file from all other prescription drug orders.

(b) Whenever a pharmacy utilizes a computerized record keeping system in addition to hard copies to record the dispensing of prescription drug orders for C-II drugs, such records shall be immediately retrievable without delay in a printout form by the prescribing practitioner's name, patient's name, drug name or date of dispensing upon a verbal request from a representative of the Georgia Drugs and Narcotics Agency (GDNA), and/or one of its agents.

(8) Whenever a pharmacist receives a prescription for a C-II controlled substance, and either the quantity of the drug to be dispensed or the strength of the drug to be dispensed has not been included by the prescribing practitioner, or when the strength of the prescribed drug is not immediately available, in order to dispense this drug, the pharmacist must perform the following:

(a) Contact and speak directly with the practitioner, not with an agent for the practitioner, and inform the practitioner of the missing information on the face of the prescription, or the problem with the prescription in question by:

1. Determining the quantity of the drug the practitioner intended to be dispensed; or
2. Determining the strength of the drug the practitioner intended to be dispensed; or
3. Informing the practitioner the drug in the strength prescribed is not immediately available, but another strength of the prescribed drug is available.

(b) Regarding the information provided by the practitioner, the pharmacist must write the missing quantity, the missing strength, or the changed quantity and strength of the prescribed drug on the face of the prescription along with the initials of the pharmacist.

(c) On the back of the prescription, the pharmacist must write the date and time the pharmacist spoke with the practitioner, along with a brief explanation of the situation and how it was resolved.

(d) Nothing in this rule is intended to require a pharmacist in a hospice or LTCF setting to obtain a new prescription drug order when changes are made to a patient's dosing requirements. This action may be taken as long as the pharmacist verifies the change(s) with the practitioner and makes a notation of the change(s) along with the date of the change(s) on the original hardcopy prescription drug order.

(9) A Schedule II narcotic controlled substance prescription prepared in accordance with Rule 480-22-.03 and as defined by O.C.G.A. § 16-13-26, to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with this rule and state and federal law.

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.

(1) Under O.C.G.A. § 43-34-103(e.1), a physician's assistant (PA) licensed by the Georgia Composite Medical Board is permitted to issue a prescription drug order or orders for any dangerous drugs, as defined in O.C.G.A. § 16-13-71, or for any Schedule III, IV, or V controlled substance without the co-signature of a supervising physician under the following conditions:-

(a) The supervising physician has delegated the authority to prescribe dangerous drugs and/or controlled substances in the PA's job description on file with the Georgia Composite Medical Board.

(b) If the prescription is for controlled substances, the PA has a DEA number.

(c) If the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.

~~(e)~~(d) The prescription drug order must be on security paper and include the following:

- (i) The name, address, and telephone number of the supervising physician and the PA;
- (ii) The patient's name and address;
- (iii) The drug name, strength and quantity prescribed;
- (iv) The directions to the patient with regard to taking the drug;

- (v) The number of authorized refills, if any;
 - (vi) A NPI number; and
 - (vii) If applicable, the DEA permit number of the PA.
- (d) If the prescription is transmitted by facsimile or computer, the prescription shall include:
- (i) The complete name and address of the supervising physician and the PA;
 - (ii) In the case of a prescription drug order for a controlled substance, the DEA registration number of the PA;
 - (iii) The telephone number of the PA for verbal confirmation;
 - (iv) The name and address of the patient;
 - (v) The time and date of the transmission;
 - (vi) The full name of the person transmitting the order; and
 - (vii) The drug name, strength and quantity prescribed;
 - (viii) The directions to the patient with regard to taking the drug;
 - (ix) The number of authorized refills, if any;
 - (x) A NPI number; and
 - (xi) The signature of the PA as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.
- (e) No prescription drug order issued by a PA can be used to authorized refills more than twelve (12) months past the date of the original drug order.
- (2) Under O.C.G.A. § 43-34-25, an advanced practice registered nurse (APRN) who is recognized by the Georgia Board of Nursing as having met the requirements to engage in advanced nursing practice, and whose registered nurse license and advanced practice registered nurse license are in good standing with the Georgia Board of Nursing, is permitted to issue a prescription drug order or orders for any dangerous drugs, O.C.G.A. § 16-13-71 except for drugs intended to cause an abortion to occur pharmacologically, or for any Schedule III, IV, or V controlled substance without the co-signature of a delegating physician under the following conditions:
- (a) The APRN has been delegated the authority to issue prescription for the dangerous drugs and controlled substances by a physician licensed by the Georgia Composite Medical Board in a nurse protocol agreement and that agreement has been filed with the Georgia Composite Medical Board.
 - (b) If the prescription is for controlled substances, the APRN has a DEA number.
 - (c) If the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.
- ~~(e)(d)~~ (d) The prescription drug order must be on security paper and include the following:
- (i) The name, address, and telephone number of the delegating physician and the APRN;
 - (ii) The patient's name and address;
 - (iii) The drug name, strength and quantity prescribed;
 - (iv) The directions to the patient with regard to taking the drug;
 - (v) The number of authorized refills, if any;
 - (vi) A NPI number; and
 - (vii) If applicable, the DEA permit number of the APRN.
- (d) If the prescription is transmitted by facsimile or computer, the prescription shall include:
- (i) The complete name and address of the delegating physician and the APRN;
 - (ii) In the case of a prescription drug order for a controlled substance, the DEA registration number of the APRN;
 - (iii) The telephone number of the APRN for verbal confirmation;
 - (iv) The name and address of the patient;
 - (v) The time and date of the transmission;
 - (vi) The full name of the person transmitting the order; and
 - (vii) The drug name, strength and quantity prescribed;
 - (viii) The directions to the patient with regard to taking the drug;

- (ix) The number of authorized refills, if any;
 - (x) A NPI number; and
 - (xi) The signature of the APRN as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.
- (e) No prescription drug order issued by a APRN can be used to authorize refills more than twelve (12) months past the date of the original drug order unless the prescription drug order is for oral contraceptives, hormone replacement, or prenatal vitamins. Oral contraceptives, hormone replacement and prenatal vitamins may be refilled up to twenty-four (24) months from the date of the original drug order.
- (3) Nothing in this Rule, Title 16, Chapter 13 or Title 43, Chapter 34, shall be construed to create a presumption of liability, either civil or criminal, on the part of a pharmacist who in good faith fills a prescription drug order presented by a patient that had been issued by a PA or an APRN consistent with this Rule.
- (a) A pharmacist shall presume that a prescription drug order issued by a PA or APRN was issued by a PA or APRN duly licensed and qualified under Title 43, Chapter 34 to prescribe pharmaceutical agents.
- (b) A pharmacist shall presume that the drug prescribed by the PA is a drug approved by the supervising physician in the PA's job description and that the drug prescribed by an APRN is a drug authorized by the delegating physician in the APRN's nurse protocol agreement, unless the pharmacist has actual or constructive knowledge to the contrary.
- (4) Any prescription drug order form containing less information than that described in this Rule shall not be offered to or accepted by any pharmacist.

480-27-.02 Prescription Drug Order Requirements.

- (1) Prescription drug orders shall include, but not be limited to, the following information:
- (a) Date of issue;
 - (b) Name and address of patient (or patient location if in an institution):
 - (c) Name and address of prescriber, telephone number, and NPI as assigned under federal law;
 - (d) DEA registration number of the prescriber in the case of controlled substances;
 - (e) Name, strength, dosage form and quantity of drug prescribed;
 - (f) Number of authorized refills;
 - (g) Directions for use by patient;
 - (h) If a written prescription drug order, the signature of the prescribing practitioner; and
 - (i) Any cautionary statements as may be required or necessary.
- (2) Electronically transmitted prescription drug orders shall contain all information required for written prescriptions above and required by state and federal law including the prescriber's name, address, and phone number, except the signature may be an electronic signature as provided below and the electronically transmitted prescription must include the time and date of transmission. ~~Such electronically transmitted prescription may not be for controlled substances except as may be allowed by federal law.~~
- (a) Electronically transmitted prescription drug orders transmitted from the practitioner and received by a pharmacy via facsimile must contain either an electronically reproduced visual image signature or original signature of the practitioner.
 - (b) Electronically generated prescription drug orders transmitted from the practitioner and received by a pharmacy as e-mails must contain an electronic data signature of the practitioner.
 - (c) All electronic prescription drug orders generated by a practitioner containing an electronically reproduced visual image signature or an electronic data signature must bear wording that appears on the face of the prescription which indicates the signature was electronically generated.
- (3) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists ~~is~~are

entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from an intervening electronic formatter that comply with this rule.

(4) An electronic visual image prescription drug order that bears an electronic reproduction of the visual image of the practitioner's signature and is given directly to the patient must be printed on security paper. Electronically generated drug orders presented to a patient by a practitioner must be printed on security paper, and must contain either an electronically reproduced visual image signature of the practitioner with the wording that indicates the signature was electronically generated, or the original signature of the practitioner.

(a) Every hard copy prescription drug order for any Schedule II controlled substance written in this state by a practitioner shall be written on security paper. If a hard copy of an electronic data prescription drug order for any Schedule II controlled substance is given directly to the patient, the manually signed hard copy prescription drug order must be on security paper.

(5) Pharmacies are prohibited from receiving electronic data from intervening electronic formatters that do not meet all of the following requirements:

(a) Utilize recognized encrypted technology and secure servers.

(b) Maintain HIPAA compliance.

(c) Maintain a combination of technical and administrative security measures, such as, but not limited to those listed in Security Standards for the Protection of Electronic Protected Health Information (HIPAA), to ensure a reasonable and appropriate level of:

1. Practitioner and dispenser authentication;

2. Content integrity; and

3. Confidentiality.

(d) Refrain from collecting and disseminating patient and/or prescriber data to sources other than the originating prescriber and the receiving pharmacy.

480-37-.03 Minimum Requirements

Minimum Requirements. A pharmacy may use a RAMS provided that:

(a) The pharmacy has a policy and procedure manual at the skilled nursing facility or hospice that includes:

1) The type or name of each RAMS including a serial number or other identifying nomenclature.

2) A method to ensure security of a RAMS to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (including, but not limited to optic scanning or fingerprint) or other coded identification. If the RAMS is compromised or an attempt is made to compromise a RAMS, a real time verifiable communication must be sent to the PIC immediately. This compromise or attempted compromise must reported to GDNA within 72 hours via a verifiable method.

3) A process of filling and stocking a RAMS with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.

4) Documentation of inventory procedures including removal of any discontinued/out-dated medications.

5) Compliance with a Continuous Quality Improvement Program.

6) A method to ensure that patient confidentiality is maintained.

(b) No more than a 30 day supply of each individual medication may be stocked in a RAMS at one time.

(c) All drugs in a RAMS must inventoried no less than once every 30 days and documentation must be maintained of the inventories including the removal of any discontinued/out of date medications.

(d) All the registered pharmacists, licensed pharmacy interns or registered pharmacy technicians involved in the process of stocking, entering information into RAMS, or inventorying the RAMS must be identified. No person shall be permitted to perform a function related to the machine that they are not authorized to do in the pharmacy. Specifically, where direct supervision is required in the pharmacy, such supervision must occur in duties related to the RAMS.

(e) Patient confidentiality must be maintained.

- (f) The PIC, or a pharmacist designated by the PIC, must be able to revoke, add, or change access to RAMS at any time.
- (g) Only a Georgia registered nurses or a Georgia licensed practical nurse may be assigned access to and remove dangerous drugs from a RAMS.
- (h) Only a Georgia registered nurse may access and remove a controlled substances from a RAMS.
- (i) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.
- (j) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, or registered pharmacy technicians involved in the processing of the prescription order.
- (k) A RAMS shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.
- (l) The stocking or restocking of a dangerous drug or controlled substances into a RAMS shall only be completed by a Georgia licensed pharmacist or a Georgia-licensed pharmacy intern/extern under the direct ~~on-site~~ supervision of a Georgia licensed pharmacist. The stocking or restocking of a dangerous drug or controlled substance into a RAMS by a certified registered pharmacy technician must be done in strict compliance with O.C.G.A. § 26-4-28 (a)(12.1)(B).
- (m) A RAMS must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from a RAMS.
- (o) All medication shall be packaged and labeled in compliance with Board rules and laws for patient specific labeled medication and/or unit of use medication.
- (p) The licensed pharmacist or Georgia-licensed intern under the direct supervision of a Georgia-licensed pharmacist responsible for filling, verifying, ~~or~~ loading, or inventorying the RAMS shall be responsible for their individual actions. The responsibility of stocking or filling a RAMS by a certified registered pharmacy technician under O.C.G.A. § 26-4-28(a)(12.1)(B) shall be that of the certified registered pharmacy technician and the Georgia-licensed pharmacist supervising such stocking or filling.
- (q) A prescription drug dispensed by the RAM pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.
- (r) A licensed pharmacist may remove discontinued and/or out-dated medications from the RAMS and return such medications to the licensed pharmacy for proper disposition. A registered or licensed practical nurse may remove discontinued and/or out-dated medications and place them in the designated secured return bin in a RAMS.

480-37-.05 Inspections.

- (1) The Pharmacist in Charge, personally or by licensed pharmacist designee, shall inspect all RAMS within his/her jurisdiction and responsibility and make appropriate written records of such inspections. Such inspections, at a minimum, shall verify that:
- (a) All drugs maintained in a RAMS must inventoried and reconciled no less than once every 30 days. All controlled substances drugs in a RAMS must inventoried and reconciled not less than once every 7 days. The pharmacist-in-charge must develop a written procedure to maintain a perpetual accountability for all drugs contained in a RAMS. A system of accountability must exist for all drugs contained in a RAMS. A pharmacist with an active Georgia license must perform all actions required by this subparagraph.
- (b) Drugs requiring special storage conditions are properly stored to insure their stability;
- (c) ~~No outdated drugs are stocked in a RAMS;~~ All drugs maintained in a RAMS must be inventoried and reconciled not less than once every 30 days and all controlled drugs shall be inventoried and reconciled not less than once every 7 days. Written documentation must be maintained of all accountability inventories, including documentation of the removal of any discontinued/out-of-date medications. A pharmacist with an active Georgia license must sign and date each accountability

inventory immediately upon completion of said required inventory. The actions required by (c) must be done by a pharmacist with an active Georgia license. Inventories cannot be taken or completed by a certified or non-certified registered pharmacy technician.

(d) ~~Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;~~ The name and license number of any licensed pharmacist or pharmacy intern under the direct supervision of a Georgia-licensed pharmacist involved in the process of stocking, entering information into RAMS or inventorying the RAMS must be identified in any written inventory record. The name of all certified registered pharmacy technicians filling the RAMS must be identified in any written inventory record. No person is permitted to perform a function related the RAMS which is not authorized by law or rule to perform in a pharmacy. Such supervision must occur in the duties related to the RAMS, except that a certified pharmacy technician registered in this state may fill the RAMS if the system utilizes RFID, bar coding or direct camera observation by a Georgia licensed pharmacist in the filling process. Certified registered pharmacy technicians may fill the RAMS in accordance with O.C.G.A. §26-4-28 (a)(12.1)(B).

(e) Only medications may be stored in a RAMS and all medications stored in the RAMS must be on the RAMS inventory list.

(f) All necessary and required security and storage standards are met;

(g) A licensed pharmacist will empty the return bin at least every 30 days. Discontinued/outdated return transactions shall be documented by the RAMS.

(2) Board of Pharmacy shall be conducted by representatives of the GDNA. Such inspections shall include all aspects of the management and operation of all RAMS in this State to verify compliance with the Pharmacy Laws, the Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety, and welfare of patients of the skilled nursing facility and/or hospice are protected. A written report shall be filed with the GDNA, the licensed pharmacy, and skilled nursing facility or hospice. Any discrepancies or deficiencies noted shall be corrected and written notice filed with GDNA within 30 days after receipt of the inspection notice.

A motion was made by Jim Bracewell, 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§ 50-13-9 16 5 9 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.

Tony Moye made a motion to adopt emergency Rule 480-34-.23-.07 Hallucinogens. Chris Jones seconded and the Board voted unanimously in favor of the motion.

480-34-0.23-.07 Hallucinogens

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers (whether optical, position, or geometrics), and salts of isomers under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(3) as follows:

(BBBB) Methoxyphencyclidine (MeO-PCP)

(CCCC) 4-hydroxy-N-methyl-N-isopropyltryptamine (4-OH-MiPT)

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

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

A motion was made by Jim Bracewell, seconded by Chris Jones, and the Board voted that pursuant to O.C.G.A. Section 26-4-28(a)(9), the Board has the right to seize any drugs and devices found by the Board to constitute an imminent danger to the public health and welfare. Pursuant to O.C.G.A. Section 26-3-4(a), any duly authorized agent of the Board who finds or has probable cause to believe any drug is adulterated or misbranded as to be dangerous or fraudulent may tag the article to detain or embargo the article. If the article is unsound or unsafe, O.C.G.A. Section 26-3-4(d) authorizes the Board or its authorized agents to condemn or destroy the article. The agents of the Georgia Drugs and Narcotics Agency (“GDNA”) are authorized agents of the Board. O.C.G.A. Section 26-4-29(b)(5) authorizes agents of GDNA to seize and take possession of all articles of contraband. O.C.G.A. Section 26-4-29(b)(7) provides that the GDNA shall perform such other duties as the Board may direct.

In consideration of these Code sections and the danger to the public health, safety and welfare, the Board is directing GDNA to take the lead in enforcement of Emergency Rule 480-34-0.23-.07, and is directing that GDNA designate, on behalf of the Board, POST certified officers who are members of state and local law enforcement agencies to act as Board agents to: (1) seize drugs, compounds and/or articles identified in Emergency Rule 480-34-0.23-.07 on behalf of the Board and to maintain such seized drugs, compounds and/or articles within their evidence rooms, or (2) tag adulterated or misbranded drugs identified in Emergency Rule 480-34-0.23-.07 to detain or embargo such drugs. Any law enforcement agencies operating on behalf in the Board in enforcing Emergency Rule 480-34-0.23-.07 shall provide GDNA with notification of any seizure, detention or embargo. Finally, GDNA is authorized to utilize in enforcing Emergency Rule 480-34-0.23-.07 any state agency identified in O.C.G.A. Section 26-3-18.

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

480-34-.07 Hallucinogens.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places additional newly identified compounds, including any material, compound, mixture, or preparation which contains any quantity of the following substances, their salts, isomers (whether optical, position, or geometrics), and salts of isomers under Schedule I of the Georgia Controlled Substances Act, Section 16-13-25(3) as follows:

(BBBB) Methoxyphenylcyclidine (MeO-PCP)

(CCCC) 4-hydroxy-N-methyl-N-isopropyltryptamine (4-OH-MiPT)

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

(a) that hallucinogens 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; and

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

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

In the same motion, the Board voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-9 16 5 9 4(a)(3)(A), (B), (C) and (D). The formulation and adoption of 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.

Approval of Minutes

Bill Prather made a motion to approve the Public and Executive Session minutes for the April 15, 2015 meeting. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Ratifications

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

Georgia Drugs and Narcotics Agency – Rick Allen

Director Allen gave an update on the following legislative matters:

- House Bill 1 Medical Cannabis Oil: Effective 04/16/2015
- House Bill 211 Annual Drug Update: Effective 05/06/2015
- House Bill 416 Pharmacists and all practitioners designated Doctor to wear name badges and when using any identifier to include their educational degree: Effective 07/01/2015
- House Bill 470 Pharmacy Audit Bill of Rights-MAC Pricing: Effective 07/01/2015
- House Bill 504 Vaccines-Immunization: Effective 07/01/2015
- House Bill 511 Allows pharmacy technicians to load RAMS machines: Effective 07/01/2015.
- Senate Bill 51 Biosimilars: Effective 07/01/2015
- Senate Bill 126 Department of Public Health to regulate Auto-Injection Epinephrine in Emergency Public Access Stations; allows prescribing of Albuterol for schools: Effective 07/01/2015
- Senate Bill 194 Pharmacy rules/laws shall not apply to dialysis drugs shipped to patients; allows early refills of ophthalmic products under certain conditions: Effective 07/01/2015

Petition for Rule Waiver from Doris J. Farr

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 Waiver from Peggy Davis

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 Waiver from Athens Regional Oncology Pharmacy-Monroe

Chris Jones made a motion to grant the rule waiver petition. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Athens Regional Oncology Pharmacy-Winder

Chris Jones made a motion to grant the rule waiver petition. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Correspondence from Charles Stephenson, AthentaScripts, Inc.

The Board considered this correspondence regarding AuthentAScripts.com. The Board directed staff to respond to Mr. Stephenson by stating that it suggests he submit the information provided to the Georgia Composite Medical Board and the Office of the Insurance and Safety Fire Commissioner for further guidance regarding this product.

Correspondence from Marjorie S. Phillips, GA Regional Medical Center

The Board considered this correspondence regarding incoming pharmacy residents. The Board directed staff to respond to Ms. Phillips by stating that the Board expects all grading from the June exam to be completed by the middle of July. Additionally, refer Ms. Phillips to O.C.G. A. § 26-4-46 and let her know that an option to allow for work during the time an applicant is waiting to test or receive results for the exam, is to apply for pharmacy technician registration.

Correspondence from John Guy, Richmar

The Board considered this correspondence regarding LidoFLEX 4% lidocaine patch. The Board recommended tabling this matter until later in the day for consideration.

Correspondence from Connie M. VanOrman, Habersham Medical Center

The Board considered this correspondence regarding the use of certified pharmacy technicians for medical reconciliation. The Board directed staff to respond to Ms. VanOrman by stating that based on the information provided in her letter, the Board states an employee of the hospital or the pharmacy technician may collect the information from a patient and compile it for a physician's verification as this is not a licensed function. As such, it would not require the pharmacy technician to be under the direct supervision of a pharmacist.

Correspondence from Rejani Rajan

The Board considered this correspondence requesting to know if the Board would exempt State Public Health from paying an application fee for a wholesale permit. Mike Faulk made a motion to grant the request since they are a governmental agency. Jim Bracewell seconded and the Board voted, with the exception of Bill Prather who opposed, in favor of the motion.

Attorney General's Report – Janet Wray

No report.

Executive Director's Report – Tanja Battle

Ambrosia Treatment Center: Ms. Battle explained that this facility is requesting to be approved as a treatment provider for the Board. At the Board's March 2015 meeting, the Board requested additional information. Ms. Battle passed out additional information received for the Board members to consider. The Board directed staff to request additional information regarding monitoring, random drug screens, and initial assessment.

Georgia NAPLEX MPJE Memorandum of Understanding: Jim Bracewell made a motion to accept the Memorandum of Understanding. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Miscellaneous: Ms. Battle stated that the Board has a situation of where the alternate for the Board will not be able to participate in the 3rd meeting at NABP. Bill Prather made a motion for Jim Bracewell to be the alternate. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Renewals: Ms. Battle reported that the Board has 27,000 licenses in renewal. She stated that almost 5,385 pharmacy technicians with a 2017 expiration date and 769 retail pharmacies with a 2017 expiration date have renewed. There are currently 553 pharmacy technicians and 294 retail pharmacies in “active-renewal pending” status.

Ms. Battle explained that because of renewals, the phone call volume has increased greatly. The Board office is currently averaging 230 calls per day and staff are returning those calls within 24 hours.

Lastly, Ms. Battle stated that the Board office did send out 7,800 paper renewal reminders for those licensees that did not have a valid email address on file. The cost of that task was \$4600.

Bob Warnock 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 Vicki Arnold, Jim Bracewell, Mike Faulk, Chris Jones, Laird Miller, Tony Moye, Bill Prather, and Bob Warnock.

Executive Session

Cognizant’s Report – Mike Faulk

- GDNA Case #B-31360
- GDNA Case #B-31329
- GDNA Case #B-31362
- GDNA Case #B-31234
- GDNA Case #B-31221
- GDNA Case #B-31391

Applications

- M.W.J.
- A.T.E.
- D.T.
- J.M.J.
- K.A.K.
- K.P.P.
- L.J.
- L.D.
- M.A.R.
- M.M.F.
- W.H.C.
- W.B.B.
- A.M.E.
- B.P.I.

- A.P.I.
- A.P.C.
- L.G.N.L.
- L.G.N.L.
- L.G.N.L.
- A.
- A.P.C.
- H.I.T.I.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.S.C.S.
- U.C.
- U.C.
- L.G.N.A.
- A.H.G.I.
- K.C.P.
- R.A.W.

Correspondences

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

Open Session

Jim Bracewell made a motion for the Board to take the following actions:

Appearance

- T.H.A. Remote order entry policy Approved pending receipt of additional information

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- Karen Dunlap Public consent order accepted
- L.E. Public consent order to be accepted and signed with express permission upon receipt of the original

Ms. Wray discussed the following case:

- P.D.S. No action taken

Georgia Drugs and Narcotics Agency – Rick Allen

- Online changes by licensed facilities: No action taken
- Update on training session attended by GDNA: No action taken

Appearances

- S.C.L. Denied Non-Resident Pharmacy Overturn denial and approve for registration upon receipt of additional information
- W.V.P. Denied Non-Resident Pharmacy Overturn denial and approve for registration upon receipt of additional information

Executive Director's Report – Tanja Battle

- C.P. Manufacturing Pharmacy Approved request for application to be extended thru August 5, 2015

Applications

- M.A.H. Denied Pharmacy Technician No action taken
- Hayley E. Kinsey Pharmacy Technician Approved for registration
- K.N.T. Pharmacy Technician Denied registration
- C.O.S. Pharmacy Technician Denied registration
- Kirby D. Smith Pharmacy Technician Approved for registration
- Vladimir Moricette Pharmacy Technician Approved for registration
- M.L.M. Pharmacy Technician Denied registration
- B.C. Pharmacy Technician Approved pending receipt of additional information
- A.S.B. Pharmacy Technician Denied registration
- J.B.S. Pharmacy Technician Schedule for Investigative Interview
- Amanda C. Hamilton Pharmacy Technician Approved renewal
- Jessica K. Padilla Pharmacy Technician Approved for registration
- C.Y.L. Pharmacy Technician Denied renewal

Cognizant's Report – Mike Faulk

- GDNA Case #B-15-10 Accept Private Interim Consent Order
- GDNA Case #T-31469 Accept Voluntary Surrender
- GDNA Case #B-31325 Close case with no action
- GDNA Case #A-31333 Refer to the Attorney General's office for discipline
- GDNA Case #B-31360 Refer to the Attorney General's office for discipline
- GDNA Case #B-31329 Misfill policy #1
- GDNA Case #B-31362 Close case with no action
- GDNA Case #B-31234 Close case with no action
- GDNA Case #B-31221 Refer to the Attorney General's office for discipline
- GDNA Case #B-31391 Refer to the Attorney General's office for discipline

Applications

- M.W.J. Pharmacist Cert of DTM Table pending receipt of additional information
- A.T.E. Pharmacist Exam Applicant Approved to sit for the exam
- Denesh Thiagarajah Nuclear Pharm Applicant Approved application
- J.M.J. Pharmacist Exam Applicant Approved to sit for the exam
- K.A.K. Pharmacist Exam Applicant Approved to sit for the exam
- K.P.P. Pharmacist Applicant Denied request to sit for June examination
- L.J. Pharmacist Exam Applicant Denied application
- L.D. Pharmacist Reactivation Table pending receipt of additional information
- M.A.R. Pharmacist Reinstatement Approved with letter of concern
- M.M.F. Pharmacist Reinstatement Refer to the Attorney General's office
- W.H.C. Pharmacist Reinstatement Refer to the Attorney General's office
- W.B.B. Pharmacist Reinstatement Refer to the Attorney General's office
- A.M.E. Pharmacist Exam Applicant Denied request for exemption
- Banner Pharmacaps Wholesaler Pharmacy Approved renewal
- Associated Pharmacies Inc Wholesaler Pharmacy Approved renewal
- Auburn Pharmaceutical Co Wholesaler Pharmacy Approved renewal
- Linde Gas North America Wholesaler Pharmacy Approved renewal
- Linde Gas North America Wholesaler Pharmacy Approved renewal
- Linde Gas North America Wholesaler Pharmacy Approved renewal
- APIRX Wholesaler Pharmacy Approved renewal
- Auburn Pharmaceutical Co Wholesaler Pharmacy Approved renewal
- Healix Infusion Ther Wholesaler Pharmacy Approved renewal
- UPS Supply Chain Solutions Wholesaler Pharmacy Approved renewal
- UPS Supply Chain Solutions Wholesaler Pharmacy Approved renewal
- UPS Supply Chain Solutions Wholesaler Pharmacy Approved renewal
- UPS Supply Chain Solutions Wholesaler Pharmacy Approved renewal
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- UPS Supply Chain Solutions Wholesaler Pharmacy Approved renewal
- UPS Supply Chain Solutions Wholesaler Pharmacy Approved renewal
- UPS Supply Chain Solutions Wholesaler Pharmacy Approved renewal
- U.S. Compounding Wholesaler Pharmacy Approved renewal
- U.S. Compounding Wholesaler Pharmacy Approved renewal
- Linde Gas North America Manufacturing Pharmacy Approved renewal
- A.H.G.I. Retail Pharmacy Table pending receipt of additional information
- K.C.P. Denied Non-Resident Pharm No action taken
- Rebecca A. Whitehead Pharmacist Intern Approved

Correspondences

- A.S.D. Application extension request Request denied
- T.B.G. Request for reduction of reinstatement fee Request denied
- O.T.S. Appearance request Request denied
- J.B.M. Request to terminate probation Request approved
- S.D.D. Request to terminate consent order Request approved
- S.C.P. Notice of discipline Place on file with pending application
- E.G. Request regarding CE courses Request approved
- E.S. Notice of discipline No action taken
- K.W.A. Request to lift PIC restriction Request approved
- L.H.W. Request to terminate consent order Request approved
- J.L.K. Correspondence For informational purposes only
- A.B.D. Request to lift probation Request approved
- J.R.O. Request for waiver of reinstatement fee Request denied
- B.P. Request for waiver of renewal fee Request denied
- C.O.C. Records request Request approved
- K.N. Request regarding intern hours Request approved
- J.B. Request regarding August exam Request denied

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

Mike Faulk made a motion to adopt emergency Rule 480-34-0.24-.08 Lidocaine. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

480-34-0.24-.08 Lidocaine.

(1) This rule was adopted to protect the health, safety, and welfare of the public. Lidocaine topical, 40 mg/gm. or less (4.0%) is deleted from Official Code of Georgia Annotated (O.C.G.A.) §16-13-71(b)(520).

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

(a) that lidocaine topical, 40 mg/gm. or less (4.0%) does not have a high potential for abuse;

(b) that the Board has considered the scientific evidence of its pharmacological effects, the state of current scientific knowledge regarding the drug, the history and current pattern of abuse, the scope,

duration, and significance of abuse, the potential of the drug to produce psychic or physiological dependence liability; and

(c) that the drug is no longer included as a prescription drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 301, et. seq., as amended.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, June 10, 2015 at 9:00 a.m. at the University of Georgia, College of Pharmacy, 250 W. Green Street, Athens, Georgia 30602.

The Board meeting adjourned at 5:10 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director