

**GEORGIA BOARD OF PHARMACY**  
**Conference Call**  
**December 19, 2013**  
**2 Peachtree St., N.W., 36<sup>th</sup> Floor**  
**Atlanta, GA 30303**  
**3:00 p.m.**

**The following Board members were present:**

Mike Faulk  
Chris Jones  
Laird Miller  
Bill Prather  
Bob Warnock

**Staff present:**

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

**Open Session**

Mr. Miller established that a quorum was present and called the meeting to order at 3:00 p.m.

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

Mike Faulk made a motion to adopt 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 derivatives, salts, isomers, or salts of 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<sup>3,7</sup>]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<sup>3,7</sup>]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 derivatives, salts, isomers, or salts of isomers, halogen analogues, 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.

#### **480-1-.02 Executive Director**

(1) The Board may appoint by a majority vote a person to serve as Executive Director of the Board who shall serve at the pleasure of the Board. Such appointment must be approved by the Board of Community Health.

(2) The Executive Director shall be vested with the following powers:

- (a) To hire such personnel as the Board approve and deems necessary to carry out its function, and with Board approval, to appoint professional qualified persons to serve as members of peer review committees;
- (b) To issue subpoenas to compel access to documents or other materials related to the fitness of any licensee, registrant, or applicant to practice or where reasonable grounds exist for the belief that a violation of the laws relating to the practice of pharmacy has taken place;
- (c) To issue subpoenas for witnesses and documentary evidence, upon approval of the President of the Board, or in his absence, the Vice President.
- (d) To issue notices of hearing with the approval of the Board;
- (e) With the approval of the Board, enter into contracts as are deemed necessary to carry out this chapter to provide for all services required of the Board;
- (f) To act as the custodian of records for the Board; and
- (g) To accept service of civil actions and administrative appeals on behalf of the Board.

(3) In the absence of the Executive Director, the Director of the Georgia Drugs and Narcotic Agency shall serve as the Assistant Executive Director and shall have all the powers of the Executive Director.

#### **480-10-.20. Required Notifications to the Board**

(1) For purposes of this rule, the following terms shall mean as follow:

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

(b) "Immediate notification" shall mean written notification sent within twenty-four hours of the event;

(c) "Significant adverse drug reaction" shall mean any reaction which requires any medical treatment beyond a consultation between Pharmacist/patient, Pharmacist/Prescriber, patient/prescriber or Pharmacist/patient/Prescriber; and

(d) "Written notification" shall mean in writing and sent by statutory overnight delivery or by email.

(2) The following occurrences require immediate notification to the Board at its address of record, unless otherwise provided:

(a) Permanent closing of a licensed pharmacy. Notification shall include the name and contact information for the person responsible for maintaining the pharmacy records after the pharmacy has closed and location of the records.

(b) Change of ownership or location of a licensed pharmacy. Since a pharmacy license cannot be transferable, unless such change has been previously approved by the Board following the submission of the appropriate applications, the existing pharmacy license is void and there is no continuing authority to operate as a pharmacy.

(c) Change in management of a licensed pharmacy.

(d) Change of the pharmacist in charge of a licensed pharmacy. When the Board receives notice that a pharmacy no longer has a pharmacist in charge and no replacement pharmacist in charge is named, the pharmacy's license is suspended pending further action by the Board.

(e) Any theft or loss of drugs or devices of a licensed pharmacy. This notification must also be made to the Georgia Drugs and Narcotics Agency, and if involving controlled substances, the pharmacy must comply with Rule 480-16-.06.

(f) Any known conviction of any employee of a licensed pharmacy of any state or federal drug laws, not previously reported.

(g) Disasters or accidents involving the licensed pharmacy.

(h) Thefts or break-ins at the licensed pharmacy.

(i) Theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law.

(j) Occurrence at a licensed pharmacy of a significant adverse drug reaction by a customer or person receiving medication dispensed or compounded by the licensed pharmacy.

#### **480-11-.02 Compounded Drug Preparations**

(1) Compounded drug preparations –Pharmacist/Patient/Prescriber Relationship.

(a) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order or in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug preparations that are ~~eommmercially~~ or not commercially available in the marketplace. Dispensing of pharmaceutical products shall be consistent with the provisions of O.C.G.A. T. 16, Ch. 13 and T. 26, Ch. 4 relating to the issuance of prescriptions and the dispensing of drugs.

(b) Pharmacists shall receive, store, or use ~~drugs~~ pharmaceuticals that have been made in a FDA-approved facility. Pharmacists shall also receive, store, or use ~~drugs~~ pharmaceuticals in compounding prescriptions that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment to procure alternatives.

(c) Pharmacists may compound ~~drugs~~ pharmaceuticals prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders within an established

pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such preparations compounded at the pharmacy. Pharmaceuticals compounded in anticipation of a valid prescription drug order shall be properly labeled to include the name of the compounded pharmaceutical, date of compounding, and beyond-use date. The distribution of compounded products, for office use by a practitioner, shall not exceed 5% of production of compounded product in a calendar year by that pharmacy. Amounts produced greater than 5% shall be considered manufacturing and will require separate licensure as a manufacturer. Pharmacists must maintain a separate compounding log for each product that includes the quantity and amount of each product that is compounded. The compounding of inordinate amounts of drugs, relative to the practice site, in anticipation of receiving prescriptions without any historical basis is considered manufacturing which requires a manufacturer's license.

~~(d) The distribution of compounded preparations without a prescriber/patient/pharmacist relationship is considered manufacturing.~~ Pharmacists shall label all compounded pharmaceutical products that are dispensed pursuant to a prescription in accordance with the provisions of O.C.G.A. T. 16, Ch. 13 and O.C.G.A. T. 26, Chs. 3 and 4, and Board rules and regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

~~(e) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription drug order, pharmacists may compound, in reasonable quantities, drug products that are commercially or not commercially available in the marketplace. All pharmaceutical products compounded and labeled in accordance with Board rules and regulations regarding pharmaceutical compounding shall be deemed to meet the labeling requirements of O.C.G.A. T. 16, Ch. 13, and T. 26, Chs. 3 and 4.~~

~~(f) Pharmacists shall not offer compounded drugs to other state-licensed persons or commercial entities for subsequent resale.~~

~~(g) Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable state laws and rules regulating the practice of pharmacy.~~

(2) Compounded drug preparations – Pharmacist for Distribution to Practitioner

(a) Only a pharmacy licensed or registered by the Board may distribute compounded products to practitioners licensed in this state for administration to their patients in the course of their professional practice, either personally or by an authorized person under their direct and immediate supervision.

(b) A practitioner shall make a request to the pharmacy for a compounded pharmaceutical in the same manner as ordering pharmaceuticals from a wholesale pharmaceutical distributor or manufacturer and not by using a prescription drug order.

(c) A pharmacy receiving an order from a practitioner for a compounded pharmaceutical shall maintain such order with its compounding rules as required in Rule 480-11-.08 and other rules and regulations of the Board.

(d) Pharmacists shall label all compounded pharmaceutical products distributed to practitioners for administration to their patients with the following:

1. "By purchase order, Not by prescription"

2. "For Office Use Administration Only – Not for resale"

3. The name of the active ingredients and strengths contained in the compounded pharmaceutical,

4. The lot number or identification of the compounded pharmaceutical,

5. The pharmacy's name, address and telephone number,

6. The initials of the pharmacist verifying the finished product and the date verified,

7. The quantity, amount, size, or weight of the compounded pharmaceutical in the container,

8. An appropriate beyond-use (expiration) date of the compounded pharmaceutical as determined by the pharmacist in compliance with Board rule and USP-NF standards for pharmacy compounding, and

9. Appropriate ancillary instructions such as storage instructions or cautionary statements, and where appropriate, hazardous drug warning labels.

(e) Pharmacists shall enter into a written agreement with a practitioner for the practitioner's use of the compounded pharmaceutical before providing any compounded pharmaceutical to the practitioner. The written agreement shall provide the following information:

1. The name and address of the practitioner, license number and contact information.
2. An agreement by the practitioner that the compounded pharmaceutical may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity.
3. An agreement by the practitioner to include on the patient's chart, or medication administration record the lot number and beyond-use date of the compounded pharmaceutical administered to the patient.
4. The procedures for a patient to report an adverse reaction or to submit a complaint about a compounded pharmaceutical.
5. The procedure to be used when the pharmacy has to recall a batch of compounded pharmaceuticals.

(f) When pharmacists are compounding sterile pharmaceuticals to be provided to practitioners for use in patient care or when pharmacists are altering or repackaging such pharmaceuticals for practitioners to use in patient care in the practitioner's office, the sterile compounding shall be conducted as allowed by applicable federal law and Board rules and shall be in compliance with USP-NF standards for sterile compounding.

(g) Sterile compounded pharmaceuticals may be dispensed to practitioners in quantities no more than 100 individual dosage containers and must have a beyond-use date no less than one week.

(h) Pharmacist may not compound Schedule II, III, IV or V controlled substances, as defined in Article 2 of Chapter 13 of Title 16 without a patient specific prescription drug order.

(i) Prior to any pharmacy engaging in the practice of compounding pharmaceuticals for use in the practitioner's office, the pharmacy must notify the Georgia Drugs and Narcotic Agency ("GDNA") of its practice, and must maintain on file the written acknowledgement of receipt of the notice from GDNA.

(j) Nothing in this paragraph shall be construed to apply to pharmacies owned or operated by institutions or to pharmacists or practitioners employed by an institution or its affiliated entities; provided, however, pharmacies owned or operated by institutions and pharmacists and practitioners within or employed by institutions or affiliated entities shall remain subject to the other rules and regulations of the Board governing the compounding of pharmaceuticals.

(3) Pharmacists must maintain documentation of proof that the beyond-use date on compounded pharmaceuticals is valid.

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

(5) Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

(6) Pharmacists may use prescription bulk substances in compounding when such bulk substances:

(a) Comply with the standards of an applicable USP-NF monograph, if such monograph exists, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-91) and the Board rules on pharmaceutical compounding; or are substances that are components of pharmaceuticals approved by the FDA for use in the United States; or otherwise approved by the FDA;

(b) Are manufactured by an establishment that is registered by the FDA; and

(c) Are distributed by a wholesale distributor licensed by the Board and are distributed by a supplier approved by the FDA to distribute bulk substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

(7) Pharmacists shall maintain records of all compounded pharmaceutical products. Pharmacist shall maintain a complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail when such instructions are

necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

(8) Pharmacists engaged in the compounding of pharmaceuticals shall operate in conformance with USP 795 and applicable state laws regarding the practice of pharmacy. (2) If low or medium risk preparations are being compounded, they must be compounded in accordance with USP 795 and applicable laws and rules. If and/or high risk sterile preparations are being compounded, they must be in accordance with USP 797 and Georgia laws and regulations.

~~(3)~~(9) Radiopharmaceuticals. If radiopharmaceuticals are being compounded, conditions set forth in the Board's rules for nuclear pharmacists and pharmacies must be followed.

~~(4)~~(10) Special precaution preparations. If drug preparations with special precautions for contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

~~(5)~~(11) Cytotoxic drugs. In addition to the minimum requirements for a pharmacy established by rules of the Board, the following requirements are necessary for those pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved.

(a) All cytotoxic drugs should be compounded in a vertical flow, Class II, biological safety cabinet or an appropriate barrier isolator. Other preparations should not be compounded in this cabinet.

(b) Personnel compounding cytotoxic drugs shall wear protective apparel as outlined in the National Institute of Occupation Hazards (NIOSH.) in addition to appropriate compounding attire as described in USP 797.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations.

(d) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and delivered in a manner to minimize the risk of accidental rupture of the primary container.

(g) Disposal of cytotoxic and/or hazardous wastes. The pharmacist-in-charge is responsible for assuring that there is a system for the disposal of cytotoxic and/or infectious waste in a manner so as not to endanger the public health.

(12) Pharmacists shall not engage in the following:

(a) The compounding for human use of a pharmaceutical product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe.

(b) The compounding of any pharmaceutical products that are essentially copies of commercially available pharmaceutical products. However, this prohibition shall not include:

1. The compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient,

2. The compounding of a commercially available manufactured pharmaceutical during times when the product is not available from the manufacturer or wholesale distributor,

3. The compounding of a commercially manufactured pharmaceutical whose manufacturer has notified the FDA that the pharmaceutical is unavailable due to a current drug shortage,

4. The compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or

5. The mixing of two or more commercially available products of which the end product is a commercially available product.

(13) Practitioners who may lawfully compound pharmaceuticals for administering or dispensing to their own patients pursuant to O.C.G.A. Section 26-4-130 shall comply with all the provisions of this rule and other applicable Board laws, rules and regulations.

**480-5-.03 Code of Professional Conduct. Amended.**

The Board is authorized to take disciplinary action for unprofessional conduct. Consistent with the authority to assure that licensees operate in a professional manner and the Board's responsibility to protect the public health with a safe, dependable and sufficient supply of medication, the Board establishes a Code of Professional Conduct which shall apply to and be observed by all persons engaged in the practice of pharmacy in the State of Georgia.

(a) Ethics. No pharmacist, intern, extern, technician, or pharmacy owner shall engage in any conduct in the practice of pharmacy or in the operation of a pharmacy which tends to reduce the public confidence in the ability and integrity of the profession of pharmacy, or endangers the public health, safety and welfare, or have been guilty of any fraud, misrepresentation, culpable negligence, concealment, dishonest dealings, fix, scheme or device, or breach of trust in the practice of pharmacy or in the conduction of business related to prescriptions, drugs or devices.

(b) Patient Self-Referral. No pharmacist, employee or agent thereof acting on his/her behalf, shall offer, agree to accept, or receive compensation in any form for the referral of professional services to or from another health care provider or entity. This prohibition includes any form of fee division or charging of fees for the referral of patients.

(c) Error or Uncertain Prescriptions. No pharmacist or pharmacy intern/extern shall compound or dispense any prescription, which, in his/her professional opinion, contains any error omission, irregularity or ambiguity. Upon receipt of such prescription, the pharmacist, pharmacy intern/extern shall contact the prescriber and confer with him/her before dispensing the prescription. No pharmacist or intern/extern shall dispense any medication by virtue of a prescription if said pharmacist or intern has any doubt existing in his mind that such prescription is not legitimate.

(d) Betrayal of Confidence. A pharmacist shall not discuss with the patient or representative such matters that should be discussed only with the prescriber.

(e) Diagnosis or Treatment. No pharmacist or employee of a pharmacy shall diagnose, treat, prescribe for, or attempt to do so, any disease, illness, or organic disorder. This limitation shall not be construed to prevent a licensed pharmacist from advising individuals on matters concerning simple ailments, first aid measures, sanitary matters, or the merits and qualities of medicines, nor shall it prevent the full practice of pharmacy as provided in O.C.G.A. Section 26-4-4.

(f) Coded Prescriptions. No pharmacist, pharmacy intern, or extern shall compound or dispense any prescription that is coded. A "coded" prescription is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength and directions for its use, other than normal letters, numbers, words, symbols or other media recognized by the profession of pharmacy as a means for conveying information by prescription. No symbol, word or any other device shall be used in lieu of the name of said preparation.

(g) False or Misleading Advertising. No pharmacist or licensed pharmacy shall disseminate through any communication media any false, misleading or fraudulent advertising.

(h) Changes in Prescriptions. No pharmacist, pharmacy intern or extern shall supply medications or devices which contain an ingredient or article different in any manner from the medication or device that is prescribed upon a prescription unless prior approval has been obtained from the prescriber thereof. Such difference shall immediately be recorded upon said prescription after being approved by said prescriber, showing the date, time and method of ascertaining the said approval.

- (i) Prescription Sub-Stations. No pharmacist, employer or employee of a licensed pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Board, from which to solicit, accept or dispense prescriptions.
- (j) Physician Agreements. No pharmacist or licensed pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with a physician or other practitioner for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement if any kind, whereby in any way a patient's free choice of a pharmacist or licensed pharmacy is or may be limited.
- (k) Independent Judgement and Practices. No pharmacist shall offer or engage in professional pharmaceutical services under any terms and conditions that shall tend to interfere with or impair the free and complete exercise of professional judgment and skill of a pharmacist or enter into any agreement that denies the public the right of free choice of pharmacists or pharmacies.
- (l) Return of Prescriptions. Except as authorized by Rule 480-10-.17, no pharmacist or employer or employee of a pharmacy may knowingly place in the stock of any pharmacy any part of any prescription dispensed to, or compounded for, any patient of any pharmacy and returned by said patient.
- (m) Evasion of Code of Professional Conduct. No pharmacist, licensed pharmacy or employee or agent thereof, shall act in any way to evade the rules and regulations of the Board and the laws applying to licensed pharmacies and pharmacists, interns, externs and technicians, but may apply methods of their own to enhance compliance with said laws, rules and regulations. Said persons shall be responsible for being acquainted with said laws, rules and regulations, and ignorance of said laws, rules, regulations shall not be a valid defense of the same.
- (n) Refusal to Fill Prescription. It shall not be considered unprofessional conduct for any pharmacist to refuse to fill any prescription based on his/her professional judgment or ethical or moral beliefs.
- (o) Valid Prescription Drug Orders. Prescription drugs shall be dispensed only pursuant to a valid prescription drug order. A pharmacist shall not dispense a prescription which the pharmacist knows or should know is not a valid prescription. A pharmacist shall have the same corresponding liability for prescriptions as an issuing practitioner as set forth in 21 C.F.R. as such regulation exists on January 1, 2013. Valid prescription drug orders shall include those issued by a physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state, or of any state or territory of the United States, to prescribe dangerous drugs or controlled substances or both.
- (p) Violations of the Code of Professional Conduct. The above set out Code of Professional Conduct is expressly adopted by the Board and shall govern the conduct of all those admitted to practice pharmacy in their capacities as pharmacists, all those issued licenses as a pharmacy in their capacities as licensees and all pharmacy interns/externs in their capacities as pharmacy interns/externs. A license to practice pharmacy or a permit to operate a licensed pharmacy confers to vested right to the holder thereof, but is a conditional privilege revocable for cause. The primary purpose of this Code of Professional Conduct is the protection of the profession of pharmacy and the public health, safety and welfare. It is the responsibility of the Board to purge the profession of those unworthy to practice pharmacy or operate pharmacies in this state. It is the obligation of every licensed pharmacy holder and every licensed pharmacist to give unlimited cooperation and assistance to the Board in the discharge of this responsibility. Violation of this code may subject the violator to suspension or revocation of any license issued to him/her by the Board and/or public reprimand, fines, probation, letters of concern or other disciplinary actions deemed appropriate by the Board.

#### **480-13-.04 Absence of Pharmacist.**

(1) General. When a licensed pharmacist is not physically present in the hospital and the pharmacy is closed, written policies and procedures shall be prepared in advance by the Director of Pharmacy for the provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and/or by access to the pharmacy. The policies and procedures may include the use of remote order entry pharmacist to ensure that in-patient needs are met at the hospital when a licensed pharmacist is not physically present. All policies and procedures providing for the use of night cabinets and/or access to the pharmacy when a licensed pharmacist is not physically present shall be made available to the Georgia State Board of Pharmacy, its designee, or a representative of the Georgia Drugs and Narcotics Agency (GDNA), upon request.

(2) A hospital utilizing a remote order entry pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current licensure in the State of Georgia, and the address of each location where the pharmacist will maintain records of remote order entries.

(3) A hospital pharmacy shall be authorized to utilize remote order entry when:

(~~i~~a) The licensed pharmacist is not physically present in the hospital, the hospital pharmacy is closed, and a licensed pharmacist will be physically present in the hospital pharmacy within ~~16~~24 hours;~~or~~

(~~ii~~b) When at least one licensed pharmacist is physically present in the hospital pharmacy and at least one other licensed pharmacist is practicing pharmacy in the hospital but not physically present in the hospital pharmacy or;

(c) When it is a weekend and the hospital has a daily census of less than ten acute patients, and the remote licensed pharmacist is physically present in another hospital in this state which is owned or under the same management as the hospital.

(4) Before a hospital may engage in remote order entry as provided in this paragraph, the director of pharmacy of the hospital shall submit to the board written policies and procedures for the use of remote order entry. The required policies and procedures to be submitted to the board shall be in accordance with the American Society of Health-System Pharmacists and shall contain provisions addressing:

(~~i~~a) quality assurance and safety,

(~~ii~~b) mechanisms to clarify medication orders,

(~~iii~~c) processes for reporting medication errors,

(~~iv~~d) documentation and record keeping,

(~~v~~e) secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to,

(~~vi~~f) access to hospital policies and procedures, confidentiality and security, and

(~~vii~~g) mechanisms for real-time communication with prescribers, nurses, and other care givers responsible for the patient's health care.

(5) Each remote entry record must comply with all recordkeeping requirements and shall ~~entify~~ identify, by name or other unique identifier, the pharmacist involved in the preview and verification of the order. The remote entry pharmacist shall maintain records of any and all records entered for the hospital for a minimum of two (2) years, and such records shall be readily available for inspection, copying by, or production of upon request by the Board, its designee, or a representative for the Georgia Drugs and Narcotics Agency (GDNA), upon request.

(6) If the board concludes that the hospital's actual use of remote order entry does not comply with this rule or paragraph O.C.G.A. 26-4-80, it may issue a cease and desist order after notice and hearing.

(7) Night cabinets. Access to drugs, in the absence of a licensed pharmacist, shall be by locked cabinet(s) or other enclosure(s) constructed and located outside of the pharmacy area to which only specifically authorized personnel as indicated by written policies and

procedures may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The Director of Pharmacy shall, in conjunction with the appropriate committee of the hospital, develop inventory listings of those drugs to be included in such cabinet(s) and shall insure that:

(a) Such drugs are available therein, properly labeled, with drug name, strength, lot number and expiration date;

(b) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(c) Whenever access to such cabinet(s) has been gained, written practitioner's orders and proofs of use for controlled substances must be provided;

(d) All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and

(e) Written policies and procedures are established to implement the requirements of this subsection.

(8) Access to pharmacy. Whenever a drug is not available from floor supplies or night cabinets, and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the pharmacy pursuant to the practitioner's order and the requirements of this subsection. One nursing supervisor (registered professional nurse or licensed practical nurse) in any given shift may have access to the pharmacy and may remove drugs there from. Such licensed nurse shall be designated in writing by the Director of Pharmacy of the hospital and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training approved by the Director of Pharmacy, in the proper methods of access, removal of drugs, and records and procedures required. The Director of Pharmacy, or designee, shall document the nurse's competence following the education and training. In addition, such licensed nurse accessing a closed pharmacy must receive specific step-by-step instructions in a policy manual, approved by the Director of Pharmacy, before accessing the pharmacy. At any time that a nurse is accessing a closed pharmacy, the Director of Pharmacy must designate a licensed pharmacist, not a remote order entry pharmacist, who is available to the nurse by telephone, and who, in the event of an emergency, is available to come to the hospital. When a nurse accesses drugs directly from the closed pharmacy, the nurse must:

(a) provide a copy of the order,

(b) document on a suitable form the name of the drug, the strength and amount of the drug removed, the date and time it was removed, and sign the form.

(c) The container from which the drug is removed shall then be placed conspicuously to be promptly reviewed and inspected by the next pharmacist coming on duty. The Director of Pharmacy's policies and procedures must provide that the next pharmacist physically coming into the pharmacy must document that they have reviewed the drugs removed and the orders filled.

(9) Emergency kits/crash carts. Drugs may also be provided for use by authorized personnel by emergency kits/crash carts, provided such kits/carts meet the following requirements:

(a) Emergency kit/crash cart drugs defined. Emergency kit/crash cart drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients;

(b) Drugs included. The Director of Pharmacy and the medical staff of the hospital shall jointly determine the drugs, by identity and quantity, to be included in the emergency kits/crash carts;

(c) Storage. Emergency kits/crash carts shall be sealed and stored in limited access areas to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them;

(d) Labeling — exterior. The exterior of emergency kits/crash carts shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit/crash cart and is for use in emergencies only. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of the contents shall be attached. Nothing in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by an agent of the Board;

(e) Labeling — interior. All drugs contained in emergency kits/ crash carts shall be labeled in accordance with such State and Federal Laws and Regulations which pertain thereto; and shall also be labeled with such other and further information as may be required by the medical staff of the hospital to prevent misunderstanding or risk of harm to the patients;

(f) Removal of drugs. Drugs shall be removed from emergency kits/crash carts only pursuant to a valid practitioner's order, by authorized personnel, or by a pharmacist of the institutional facility;

(g) Notification. Whenever an emergency kit/crash cart is opened, the pharmacy shall be notified; and pharmacy personnel shall restock and re-seal the kit/cart within a reasonable time so as to prevent risk of harm to patients. In the event the kit/cart is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

(h) Inspections. Each emergency kit/crash cart shall be opened and its contents inspected by a pharmacist at least once every ninety (90) days. Upon completion of inspection, the emergency kit/crash cart shall be re-sealed;

(i) Procedures. The Director of Pharmacy shall, in conjunction with the medical staff of the hospital, develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

(10) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be readily available in areas outside the pharmacy where these drugs are stored.

(11) Nothing in this rule shall be construed to relieve the hospital pharmacy of the requirement of having an on-site pharmacist to provide routine pharmacy services within the hospital in order to qualify as a licensed pharmacy.

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

**All pharmacies are required to purchase or receive dangerous drugs and/or controlled substances from a firm licensed by this state as a drug wholesaler, distributor or manufacturer.**

Bill Prather seconded and the Board voted unanimously in favor of the motion.

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

The Board meeting adjourned at 3:05 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director