

GEORGIA STATE BOARD OF PHARMACY
Board Meeting Minutes
Professional Licensing Boards
237 Coliseum Drive, Macon, GA
October 10, 2012
9:30 a.m.

The Georgia State Board of Pharmacy met on **October 10, 2012** for the purpose of conducting business.

Board Members Present:

Bill Prather, Chairperson
Mike Faulk
Fred Barber
Ronnie Wallace
Al McConnell
Laird Miller

Staff Present:

Rick Allen, GDNA
Janet Wray, Board Attorney
Tanja D. Battle, Executive Director
Tamara Elliott, Board Support Specialist

Visitors Present:

Scott Biddulph, Target
Jimmie England, Walgreens
Melissa Hutchinson, CVS
Helen Sloat

Open Session

Bill Prather established that a quorum was present and called the meeting to order at 9:35a.m.

Emergency Rule 480-34-0.12-.08 Additional Synthetic Cannabinoids

Ronnie Wallace made a motion, Fred Barber seconded, and the Board voted unanimously to adopt the Emergence Rule.

Laird Miller made a motion, Ronnie Wallace seconded, and the Board voted unanimously to adopt the enforcement language as follows:

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 480-34-0.12-.08, 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 480-34-0.12-.08 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 480-34-0.12-.08 to detain or embargo such drugs. Any law enforcement agencies operating on behalf in the Board in enforcing Emergency Rule 480-34-0.12-.08 shall provide GDNA with notification of any seizure, detention or embargo. Finally, GDNA is authorized to utilize in enforcing Emergency Rule 480-34-0.12-.08 any state agency identified in O.C.G.A. Section 26-3-18.

Permanent Rule 480-34-04 Discussion

Janet Wray offered suggested language to the permanent rule for posting as clarification. Ronnie Wallace made a motion to post Rule 480-34-.04 as follows. Fred Barber seconded, and the Board voted unanimously to post Rule 480-34-.04 with the included impact statements:

480-34-.04 Synthetic Cannabinoids.

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places newly identified compounds, including any material, compound, mixture, or preparation which contains these substances or their isomers, halogens, 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-3-yl]-(2,2,3,3-tetramethylcyclopropyl) methanone (XLR11)

(O) [1,1'-biphenyl]-3-yl-carbamic acid, cyclohexyl ester (URB602)

(P) [1-(2-morpholin-4-ylethyl)-1H-indol-3-yl]-(2,2,3,3-tetramethylcyclopropyl) methanone (A-796,260)

(Q) [3-(3-carbamoylphenyl)phenyl] N-cyclohexylcarbamate (URB597).

(R) 6-methyl-2-[(4-methylphenyl)amino]-1-benzoxazin-4-one (URB754)

(S)1-pentyl-N-tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indazole-3-carboxamide (AKB48)

(T)1-pentyl-3-(1-adamantylamido)indole (2NE1)

(U)1-(5-fluoropentyl)-N-tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3-carboxamide (STS-135)

(V)1-naphthalenyl[4-(pentyl)-1-naphthalenyl]-methanone (CB-13)

(W)(1-(5-chloropentyl)indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (5-Chloro-UR-144)

(X)(1-(5-bromopentyl)indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (5-Bromo-UR-144)

(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.

The Board voted that the formulation and adoption of these amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22. Also, the Board voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Ronnie Wallace made the motion, Fred Barber seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. §43-1-19(h)(2), 43-11-47(h) 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 Bill Prather, Mike Faulk, Ronnie Wallace, Fred Barber, Al McConnell, and Laird Miller. The Board entered into Executive Session.

Executive Session

The Board held the following:

Appointments

J.D.M

M.B.B

B.M.T.

Bill Prather declared the meeting in Open Session at 11:24am

Open Session

Consideration of minutes from the September 19, 2012 Board Meeting

Laird Miller made a motion to approve the minutes as amended, Ronnie Wallace seconded and the Board voted unanimously in favor of the motion.

Ratification of Licenses Issued

Ronnie Wallace made a motion to approve the report of licenses issued September 1, 2012- September 30, 2012. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Ther-Rx

For information purposes only

Discussion on Non-Georgia Bar Attorneys

Attorney Janet Wray explained that there are attorneys not licensed in Georgia that are representing applicants and licensees in Georgia. Currently, there is no PLB rule that addresses Non-Georgia Bar attorneys representing individuals coming before the Board of Pharmacy. Bill Prather directed Tanja Battle to follow-up and report back to Board at next meeting.

Rules Discussion

Ronnie Wallace made a motion, Mike Faulk seconded, and the Board voted unanimously to post the following rules after consideration of the impact statements for each:

RULE 480-11-.02 COMPOUNDED DRUG PREPARATIONS

(1) Compounded drug preparations -Pharmacist.

(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 commercially or not commercially available in the marketplace.

(b) Pharmacists shall receive, store, or use drugs that have been made in a FDA-approved facility. Pharmacists shall also receive, store, or use drugs 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 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. 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 inordinate amounts of compounded preparations without a prescriber/patient/pharmacist relationship is considered manufacturing.

(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.

(f) Pharmacists shall not offer compounded drugs to other state-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a prescriber to administer to an individual patient.

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

(2) If low, medium, and/or high risk sterile preparations are being compounded, they must be in accordance with USP 797 and/or Georgia regulations.

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

(4) 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) 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.

480-13-.01 Definitions.

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

(a) Hospital. As defined by the Department of Human Resources;

(b) Hospital pharmacy. Hospital pharmacy is defined as that portion of a hospital facility which is engaged in the manufacture, production, sale and distribution of drugs, medications, devices, and other materials used in the prevention, diagnosis and treatment of injury, illness and disease (hereinafter referred to as "drugs"); and which is registered with the State Board of Pharmacy pursuant to O.C.G.A. § 26-4-110;

(c) Hospital pharmacy license. Hospital pharmacy license shall mean a pharmacy license issued by the Georgia State Board of Pharmacy to said hospital pharmacies, pursuant to the provisions of O.C.G.A. Sections 26-4-27, 26-4-28 and 26-4-110 whereas the licensee shall be subject to special hospital pharmacy regulations as set forth herein, but exempt from other certain regulations and requirements. To obtain the hospital pharmacy license, there must be employed a Director of Pharmacy.

1. The Board authorizes the holder of a hospital pharmacy license to service patients of Nursing Homes, Long Term Care Facilities or Hospices as long as these entities are under the same ownership as the hospital pharmacy; however, such entities can only be serviced by the hospital pharmacy subject to the requirements as set forth by Georgia State Board of Pharmacy Rules 480-24, the rule for providing services to nursing homes, long term care facilities, and hospices. The hospital pharmacy is prohibited from maintaining standard ward (Floor Stock) inventories in such entities, but, it would allow the hospital pharmacy to supply emergency kits.

(d) In-patient. In-patient shall mean a patient who is confined to the hospital;

(e) Out-patient. Out-patient shall mean a patient who is not an in-patient, including patients on leave of absence;

(f) Remote Location. Remote location shall mean a location away from the hospital or hospital pharmacy located within the State of Georgia where a pharmacist reviews and enters patient specific prescription drug orders for a hospital's patients.

(g) Remote Order Entry. Remote order entry shall mean the entry a pharmacist located within the State of Georgia makes from a remote location indicating that the pharmacist has reviewed the patient specific drug order for a hospital patient, has approved or disapproved the administration of the drug for said patient, and has entered the information on the hospital's patient record system.

(h) Remote Order Entry Pharmacist. A remote order entry pharmacist shall mean a pharmacist who is licensed to practice pharmacy in the State of Georgia, who is at a remote location located within the State of Georgia, and who is under contract with or employed by the hospital to review and enter patient specific prescription drug orders for hospital patients when the hospital pharmacy is closed.

(i) Standard ward inventory. The Director of Pharmacy or his/her pharmacist designee may, in the best interest of the patients served, establish one or more lists of the kind and quantity of legend drugs to be kept at one or more locations at all times within said hospital and such stocks of legend drugs shall be known as standard ward inventory. The use of standard ward inventory shall be minimized. A copy of the list of items on standard ward inventory must be kept by the Director of Pharmacy or his/her pharmacist designee. A standard ward inventory may be placed on an emergency vehicle licensed with the State Department of Human Resources. A contract or agreement must be signed between the hospital and the ambulance service and filed with the Department of Human Resources Licensure Division and the Georgia Drugs and Narcotics Agency (GDNA) before any legend drugs may be placed on said licensed vehicle. An agreement can be made with only one hospital.

480-13-.04 Absence of Pharmacist. Amended

(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) The Director of Pharmacy shall insure that any remote order entry pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the pharmacy is open. The remote order entry pharmacist must be able to contact the prescribing practitioner to discuss any concerns identified during the pharmacist's review of the patient information. Each remote entry record must comply with all recordkeeping requirements and shall 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.

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

(i) 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 hours; or

(ii) 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.

(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) quality assurance and safety,
- (ii) mechanisms to clarify medication orders,
- (iii) processes for reporting medication errors,
- (iv) documentation and record keeping,
- (v) 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) access to hospital policies and procedures, confidentiality and security, and
- (vii) 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, 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.

(47) 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.

(58) 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.

(69) 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.
- (710) 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.
- (811) 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.

480-13-.06 Drug Distribution and Control. Amended.

- (1) General. A drug distribution system is the entirety of that mechanism by which a prescription drug order is executed, from the time the practitioner transmits the order either orally or in writing to an authorized health professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration.
- (2) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution, control, and accountability for drugs, including IV solutions and irrigation solutions. The other professional staff of the hospital shall cooperate with the Director of Pharmacy in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials to achieve this purpose. The Director of Pharmacy shall establish written procedures for the distribution of parenteral medications to achieve this goal. Accordingly, the Director of Pharmacy shall be responsible for, at a minimum, the following:
 - (a) The compounding, admixture, and quality control of large volume parenterals is the responsibility of a pharmacist and shall be prepared under a Laminar Flow Hood or utilizing such other equipment to protect the integrity of the product, within the pharmacy department. Individuals who prepare or administer large volume parenterals must have special training to do so. These functions of IV admixture compounding shall be done primarily by the pharmacy department with exceptions allowed for specialty-care areas such as Intensive Care Units, Cardiac Catheterization Laboratories Intensive Care Units, etc., during emergency situations, or during unattended hours of the pharmacy department. When any part of the above functions (preparing, sterilizing, and labeling parenteral medications and solutions) is performed within the hospital but not under direct pharmacist supervision, the Director of Pharmacy shall be responsible for providing written guidelines and for approving the procedures to assure that all pharmaceutical requirements are met;
 - (b) All drugs must be identified up to the point of administration;

(c) The pharmacy must receive a direct copy, electronic or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by hospital stat order policy;

(d) Utilization of a pharmacy-generated patient profile. The patient profile shall be the official record of medications dispensed to the patient. The patient profile or the ability to generate such profile electronically shall be under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:

1. Given and last name of the patient;
2. Age;
3. Sex;
4. Provisional diagnosis;
5. Room number;
6. Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;
7. Identification or differentiation of controlled substances;
8. Intravenous therapy;
9. Selected medical data;
10. Drug history interview (when possible); and
11. Sensitivities and allergies to drugs and foods;

(e) No more than a 72-hour supply of a patient's medication shall be available at the patient-care area at any time except for those drugs in bulk packages which cannot be repackaged in unit-dose containers;

(f) Manufacture of drugs, if applicable;

(g) Establishment of specifications or use of compendia specifications for procurement of drugs, chemicals, devices and biologicals, subject to approval of the appropriate committee of the hospital;

(h) Participation in the development of a drug formulary for the hospital;

(i) filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;

(j) Maintaining and making available a sufficient inventory of antidotes and other emergency drugs. Current antidote information, telephone numbers of regional poison control center(s) and other emergency assistance organizations, and other material and information as may be deemed necessary shall be maintained;

(k) Records of all transactions of the hospital pharmacy as may be required by law, and as may be necessary to maintain accurate control over the accountability for all pharmaceutical drugs, devices and materials.

Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;

(l) Participation in those aspects of the hospital patient care evaluation program which relate to pharmaceutical drug, device and material utilization and effectiveness; and

(m) Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.

(3) Labeling.

(a) For use inside the hospital, all drugs dispensed by a hospital pharmacy, including those for standard ward inventory, shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum, brand name or generic name, strength, lot number, and expiration date.

(b) For use outside the hospital, all drugs dispensed by a hospital pharmacy to patients about to be discharged or on leave of absence shall be labeled with the following information:

1. Name, address, and telephone number of the hospital pharmacy;
2. Date and identifying serial number;
3. Patient's given and last name;
4. Name of drug, (brand or generic) and strength;
5. Directions for use by patient;
6. Name of prescribing practitioner;
7. Required precautionary information regarding controlled substances; and
8. Such other and further accessory cautionary information as may be required or desirable for proper use by and safety of the patient.

(c) Drugs added to parenteral solutions. Wherever any drugs are added to parenteral solutions, whether within or outside the direct and personal supervision of a licensed pharmacist, such admixture shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date and time if applicable, and the identity of the person so adding.

(4) Discontinued drugs. The Director of Pharmacy shall develop and implement policies and procedures to insure that outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(a) Full doses of controlled substances prepared for administration and not given must be destroyed by a licensed pharmacist or a licensed nurse and one witness. Any portions of controlled substances discontinued and taken from a medication delivery device shall be destroyed by a licensed pharmacist or a licensed nurse and one witness. The two persons witnessing the destruction must sign the destruction record at the time of destruction. The destruction record shall be returned to the pharmacy and must be signed by the pharmacist who is ultimately responsible for the accuracy of the information contained therein.

(b) In accordance with the policies and procedures developed by the Director of Pharmacy, discontinued non-controlled substances dispensed to hospital patients shall be returned to the pharmacy and evaluated by the licensed pharmacist to assure the integrity of the medication. If the integrity can be assured, the medication may be returned to the hospital's drug distribution system for re-issue. When the integrity cannot be assured, the medication must be separated immediately from the regular drug inventory and destroyed or transferred to a reverse distributor with a current license issued by the Board. The following method of destruction of non-controlled substances is approved by the Board for medications dispensed to hospital patients or patients residing in nursing homes or long term care units which are part of a hospital facility;

1. Placed in a secure storage area at the facility separated from other medications. The drugs may be destroyed at the facility by the pharmacist and another licensed healthcare practitioner designated by the facility. However, before the destruction can take place, it must be verified that an inventory has been taken and recorded. The facility must maintain a written record of the destruction and the inventory for a two year period. This record shall include at a minimum the date, time, and personnel involved with the destruction and the method of destruction; or

2. If the drugs are to be transferred to a reverse distributor with a current license issued by the Board, a record of the following must be maintained by the hospital pharmacy for a minimum of two years:

(i) An inventory of the drugs to be transferred including the names of the drugs; the dosage form(s) of the drugs and the quantity of the drugs; the inventory shall be verified by a pharmacy representative and a representative of the reverse distributor;

(ii) The date and time the drugs were taken from the pharmacy;

(iii) The name, Board permit number, address and telephone number of the destruction firm removing the drugs;

(iv) The name and signature of the responsible person representing the reverse distributor who is physically removing the drug(s);

(v) The name and signature of the pharmacist representing the pharmacy transferring the drug(s) to the reverse distributor.

(c) The following methods of destruction of controlled substances are approved by the Board of Pharmacy:

1. A securely attached wooden or metal cabinet within a locked limited-access area shall be used to store the drugs until the drugs are destroyed. When controlled drugs are discontinued or the patient expires, the medication shall be pulled from the active stock immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional. The inventory must be recorded into a permanent record and the drugs shall then be placed in the aforementioned cabinet. This medication shall remain within the locked cabinet until such time as it is removed for destruction.

2. The pharmacist shall establish a form, which shall include the following data:

(i) Date of discontinuance or inventory date;

(ii) Name of patient;

(iii) Name of pharmacy;

(iv) Identifying serial numbers;

(v) Name and strength of the drug; and

(vi) Quantity of the drugs in container(s) at the time of inventory.

3. A licensed pharmacist or licensed nurse and one witness must destroy the drugs.

4. Inventory of the drugs included in the final destruction must be taken with one copy retained by the facility. The inventory shall be certified by the two witnesses present at the destruction in the following format:

"We, whose signatures appear below, certify that these controlled substances have been reconciled, accounted for, and destroyed at _____ (location) on _____ (date) at _____ o'clock. "

Name of drug
Strength of drug
Dosage form
Quantity of drug

(Signature and Title)

(Signature and Title)

(Signature and Title)

5. The Board and/or the GDNA may prohibit any pharmacist or hospital pharmacy from utilizing this method.

(d) A method of off-site destruction allowable by the Board is as follows:

1. The drugs to be destroyed shall be immediately removed from the active stock and stored in a separate and secure location in the pharmacy until the drugs are transferred. When the drugs are transferred to a reverse distributor licensed by the Board, an inventory must be recorded and include the following information: the names of the drugs, the dosage forms of the drugs and the quantities of the drugs taken and witnessed by an authorized representative of the hospital pharmacy and the responsible person representing the reverse distributor.

2. A receipt including the date and time the drugs were taken from the pharmacy; the name, Board permit number, address and telephone number of the reverse distributor removing the drugs; the inventory of the drugs; the name, signature and title of the responsible person representing the reverse distributor; and the name, signature and title of the pharmacy representative transferring the drugs. This receipt/record must be maintained by the hospital pharmacy for a minimum of two years.

(5) Prescription drug orders. Drugs may be dispensed from the hospital pharmacy only upon written orders, direct or mechanical copies thereof, of authorized practitioners.

(a) Authorization. The appropriate committee of the hospital shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.

(b) Abbreviations. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the hospital.

(c) Requirements — Prescription drug orders for drugs, devices or materials for use by in-patients.

Prescription drugs orders for use by in-patients shall, at a minimum, contain:

1. Patient name and room number;
2. Drug name, strength, directions for use; and
3. Date and practitioner's signature.

(d) Requirements — Prescription drug orders for drugs, devices or materials for use by out-patients.

Prescription drug orders for drugs, devices or materials for use by outpatients shall, at a minimum, contain all of the information required by Rule 480-13-

.06(5)(c), and in addition include:

1. Quantity to be dispensed;
2. Practitioner's address and Drug Enforcement Administration identification code, if applicable, and
3. Patient's address, if applicable.

(6) Accountability of controlled drugs.

(a) Proof of use of controlled drugs on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the hospital, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:

1. Name of drug, strength, and dosage form;
2. Dose administered;
3. Name of authorized practitioner. This shall include, at a minimum, the initial and last name;
4. Given and last name of the patient;
5. Date and time of administration to the patient;
6. Signature of the individual administering, which shall include at a minimum, the initial, last name, and title;
7. Documentation of the destruction of any and all unused portions by two signature verifications;
8. Proof of receipt of the medications that bears identifying serial numbers; and
9. Date the medication was issued and the date that the proof of use form was returned to the pharmacy.

- (b) Anesthesia departments that obtain controlled drugs from the hospital pharmacy must show accountability of the controlled drugs by proof of use as defined above.
- (c) Use of computer generated hard copy is permitted where such copy meets all other requirements of the law.
- (d) Any hospital pharmacy licensed by the Georgia State Board of Pharmacy and in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for parenteral and oral administration provided:
1. The controlled substance is either a whole dose or a partial dose of a single-dosage unit; and
 2. The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.
- (e) Perpetual inventory of Schedule II substances shall be required and accountability of said drugs shall be by a proof of use form.
- (7) Recall. The Director of Pharmacy shall develop and implement a policy and procedure to assure that all drugs within the hospital included on a recall are returned to the pharmacy for proper disposition.
- (8) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering authorized practitioner, the pharmacy, and to the appropriate committee of the hospital. An appropriate entry on the patient's medical record shall also be made.
- (9) Records and reports. The Director of Pharmacy shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety and welfare. Such records shall be readily available and subject to inspections by the Board of Pharmacy, the GDNA or its employees. These shall include, at a minimum, the following:
- (a) Patient profile;
 - (b) Proof of use;
 - (c) Reports of suspected adverse drug reactions;
 - (d) Inventories of night cabinets and emergency kits/crash carts;
 - (e) Inventories of the pharmacy;
 - (f) Biennial controlled substances inventories;
 - (g) Alcohol and flammables reports; and
 - (h) Such other records and reports as may be required by state Law and the Rules and Regulations of the Board of Pharmacy.
- (10) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a hospital for the purpose of establishing and/or maintaining a standard ward inventory. Such drugs may be distributed only upon a signed requisition from a nurse or other authorized representative of said hospital or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order. This practitioner's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A record of administration of drugs administered to patients in ancillary areas such as but not limited to the operating room, emergency room, anesthesiology, and x-ray shall be forwarded to the pharmacy and these medications shall be recorded on the patient profile. A survey of usage trends of each standard ward inventory shall be prepared monthly. Such records shall be retained for a period of two years.
- (11) Emergency room dispensing. An authorized practitioner may, when drugs or controlled substances are not otherwise available from a licensed pharmacy, dispense an emergency amount of medication, but only sufficient quantities until such time as medication can be obtained from a pharmacy licensed as a retail pharmacy. Nurses or other unauthorized personnel may not dispense medication from the emergency room. The total act of dispensing shall be performed by an authorized practitioner in accordance with Pharmacy Laws, Rules and Regulations. Such medications shall be labeled as required in Section 480-13-.06(3)(b).

480-16-.02 Receipt of Prescription Drug Order by a Non-Pharmacy.

- (1) No person or entity other than an establishment licensed under O.C.G.A. 26-4 shall engage in the practice of accepting and receiving prescriptions and forwarding same to a drug store or pharmacy to be filled and returned to the forwarding agency, which, in turn, delivers the filled prescriptions to the patient or agent of the patient and collects the charge therefor.
- (a) Once a pharmacy receives a patient's prescription drug order, that pharmacy cannot forward such prescription drug order to a second pharmacy in order for the second pharmacy to fill the prescription drug order and return the filled drug container to the original pharmacy for dispensing or delivery to the patient.

(2) It shall be illegal for any person or entity to attempt to or to eliminate the patient/pharmacist contact, and for any such person or entity to prevent a pharmacist from properly supervising and controlling the dispensing of prescription drugs. Such pharmacist-patient contact is essential to the proper practice of pharmacy care.

(a) It shall be deemed detrimental to the health, safety, and welfare of the people of the State of Georgia for any firm, partnership, corporation, or business, other than a Pharmacy licensed by the Board under O.C.G.A. 26-4, to accept or receive any prescription drug order;

(b) Such practice is prohibited, and any such practice taking place shall be discontinued immediately upon verbal or written notice of the Board or the Georgia Drugs and Narcotics Agency.

(3) In order for a patient to authorize a licensed medical practitioner to hold, administer, or deliver the patient's prescription drug at his or her office location, and the drug was previously dispensed and delivered to the practitioner's office by a pharmacy, the patient must first provide the pharmacy with written authority to conduct such a delivery.

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, except as provided in 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.

(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 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 such a 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 (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 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 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. When such computerized record keeping system is centralized and cannot produce on-site printouts, such printouts shall be provided within 48 hours of the original request.

(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 hard-copy 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-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders.

(1) A pharmacist or pharmacy intern/extern may dispense Schedule III, IV and V Controlled Substances (C-III, IV, V), as defined by O.C.G.A. §§ 16-13-27, 16-13-28, and 16-13-29, pursuant to:

(a) A written prescription drug order bearing the signature of a practitioner as permitted by this rule;

(b) A facsimile of a written, signed prescription drug order transmitted directly to the pharmacy with the requirements contained in O.C.G.A. § 26-4-80, by the practitioner of the practitioner's agent;

(c) An oral prescription drug order made by an individual practitioner and promptly reduced to writing by the pharmacist or pharmacy intern/extern to a hard copy; and

(d) A written prescription drug order transmitted via electronic means other than a facsimile, if it meets the requirements and limitations for electronically transmitted prescription drug orders set forth in O.C.G.A. § 26-4-80, and Rules as set forth by the Board. Such electronically received prescription drug orders must be promptly reduced to hard copy, except as follows:

(1) Permanent records of electronic prescriptions do not have to be reduced to hard copy provided the following requirements are met:

- A). Electronic prescription data must be maintained in the original format received for a minimum of two years; and
- B). Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1hr UL approved) container, stored in a secured offsite location or backed up to a documented offsite secure storage device within 48 hours following each work day.
- (2) A pharmacy must either file the original prescription drug order or generate a hard copy prescription drug order to be filled, both of which are required to contain all of the information required by this chapter.
- (3) Upon dispensing a C-III, IV, or V controlled substance, the dispensing pharmacist shall ensure that his or her initials, the dispensing date, and the prescription serial number appear on the face of or the rear of each such prescription. Nothing shall prohibit the use of a computer-generated label to fulfill the requirements of this paragraph and/or the requirements of this Rule.
- (a) All such information shall be placed on the prescription drug order in such a manner that it does not cover or veil any information required by this chapter or any other rule or law to appear on such prescription.
- (4) Prescription drug orders for schedule C-III, IV, or V controlled substances shall be maintained either in a separate prescription drug order file for such C-III, IV, or V drug orders only or in such a form that they are readily retrievable from the other prescription drug orders of the pharmacy.
- (a) A prescription drug order will be deemed readily retrievable if, at the time it is initially filled, the face of the prescription drug order is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed in the usual consecutively numbered prescription drug order file for dangerous drugs; or
- (b) A pharmacy which utilizes a computerized record keeping system for prescription drug orders which permits identification of prescription drug orders by serial number and retrieval of documents by prescriber's name, patient's name, drug dispensed, and date filled, then there is no requirement to mark hard copy prescriptions with a red "C".

Rule 480-27-.05

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

In order to comply with the record keeping requirements of this Chapter, an automated electronic data processing system may be utilized for the record keeping system if the following conditions have been met:

- (a) Except as otherwise provided herein, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the usual consecutively serial numbered prescription file. Any refill information subsequently authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(e).
- (b) The system shall at a minimum produce sight-readable printouts for all dangerous drug and controlled substance prescriptions for each 24 hour period. The term sightreadable means that a representative of the Board or GDNA shall be able to readily retrieve and examine the record and read the information during any on-site visit to the pharmacy. These print-outs must be generated at least once weekly by the pharmacy and maintained for at least two years after the last date on which the prescription was filled or refilled. If not readily retrievable, any such printouts shall be generated as soon as possible upon the verbal request from the Board or GDNA representative.
- (c) The information maintained by the automated electronic data processing system shall include, but not be limited to the following:
1. Date of dispensing;
 2. Prescription number;
 3. Patient's name;
 4. Patient's address;
 5. Drug name, strength and dosage form;
 6. Quantity prescribed, and if the quantity dispensed is different from the quantity prescribed, the quantity dispensed;
 7. Prescriber's name;
 8. Identification of dispensing pharmacist;
 9. Indication whether drugs are being dispensed pursuant to a new prescription or for a refill order;

10. In case of a controlled substance as allowed by federal law, the name, address and

DEA registration of the practitioner and the schedule of the drug;

11. Directions for administration of the prescription to the patient;

12. Total number of refills authorized; and

13. NPI of the prescriber as assigned under federal law.

(d) Permanent records of electronic prescriptions for dangerous drugs and controlled substances do not have to be reduced to hard copy provided the following requirements are met:

1. Electronic prescription data must be maintained in the original format received for a minimum of two years; and

2. Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1 hr UL approved) container, stored in a secured offsite location or backed up to a documented offsite secure storage device within 48 hours following each work day.

(e) The individual pharmacist responsible for completeness and accuracy of the entries to the system must provide documentation that prescription information entered into the computer is correct, by dating and signing the print-out in the same manner as signing a check or legal document (e.g., Mary A. Smith or M. A. Smith).

(f) An auxiliary record-keeping system shall be established for the documentation of filling new prescriptions, refills, and transfers if the automated electronic data processing system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When this automated electronic data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated electronic data processing system as soon as possible. However, nothing in this section shall preclude the pharmacist from using his/her professional judgment for the benefit of a patient's health and safety.

(g) Any pharmacy using an automated electronic data processing system must comply with all applicable State and Federal laws and regulations.

(h) A pharmacy shall make arrangements with the supplier of data processing services or materials to insure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall insure continuity in the maintenance of records.

Robotic Rule 480-10-.19 Discussion

Mike Faulk made a motion, Ronnie Wallace seconded, and the Board voted unanimously post the rule after consideration of the impact statements.

480-10-.19. Use of Automated and or Robotic Pharmacy Systems

(a) As used in this rule, the following terms shall mean:

(1) "Automated pharmacy systems" (APS) means a mechanical system that perform operations or activities, other than compounding or administration, relative to storage, packaging, and labeling of medication for the purpose of dispensing of medication to a patient or patient's agent.

(2) "Robotic pharmacy systems" (RPS) means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, and labeling of medication for the purpose of distribution (dispensing) of medication to a patient or a patient's agent.

(3) "Board" shall mean the Georgia State Board of Pharmacy.

(b) A Georgia licensed retail pharmacy may use automated pharmacy systems or robotic pharmacy systems in the preparation of medication for dispensing provided such systems meet the following requirements:

(1) The system collects, controls, and maintains all transaction information;

(2) The system is located within the licensed pharmacy, or if in a general merchandising store, within the pharmacy department;

(3) Medication loaded into the system can be visually identified as well as identified by bar code or other such secondary identification system to ensure the proper medication is being placed into and recognized as the correct medication by the system;

(4) The system has adequate security systems and procedures to prevent unauthorized access to the system;

(5) The system complies with federal laws and state regulations;

(6) The system maintains patient confidentiality;

(7) The system provides a visual image and a description of the medication along with a visual image of the prescription or drug order hard copy at final verification for each new prescription as well as subsequent refills; and

(8) The system can only be accessed by personal code.

(c) Each retail pharmacy utilizing an APS or RPS must maintain documentation, as to type of equipment, serial numbers, content, policies and procedures, on-site in the pharmacy for review by an agent of the Board.

(d) The filling/stocking of all medications in the APS or RPS shall be performed by licensed pharmacist, licensed pharmacy intern or a registered pharmacy technician under the direct, on-site supervision of a licensed pharmacist. An electronic or hard copy record of medications produced by the system shall be maintained for two years, and shall include identification of the person stocking/filling the system, and if a pharmacy intern or registered pharmacy technician, the name of the pharmacist providing the supervision.

(e) Access to and limits on access to the APS or RPS must comply with state and federal laws and regulations. Proper identification and access control, including electronic passwords, biometric identification, unique credentials or other coded identification, must be authorized by the pharmacist on duty. These identifications, credentials or passwords shall be valid for no more than 24 hours. After 24 hours, they must be renewed in order to gain access to the system. A record of who was assigned the identifications, credentials or passwords must be maintained for two years in order to ascertain who accessed the APS or RPS.

(f) The pharmacist in charge ("PIC") of the retail pharmacy is responsible for maintaining all records pertaining to the access, usage, audits and maintenance of the systems. These records must be readily accessible and available for inspection upon request by an agent of the Board. In addition, the PIC is responsible for developing and maintaining policies and procedures to assign, discontinue, or change access to the system, insure that access to the medications comply with state and federal regulations, and insure that the system is filled/stocked.

(g) The pharmacist in charge is responsible to assure that the APS or RPS is in good working order.

(h) Any pharmacist utilizing the APS or RPS must assure that the system is accurately producing the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.

(i) Any retail pharmacy utilizing an APS or RPS in violation of this rule is subject to disciplinary action which may include, but is not limited to, a restriction on the authority to utilize an APS or RPS.

(j) Nothing herein shall relieve a pharmacist of the professional responsibility to verify the accuracy of the medication being dispensed prior to its being delivered to the patient or the patient's agent.

Georgia Drugs and Narcotics Agency - Rick Allen

Rick Allen discussed the NECC ongoing investigation. GDNA is working with DHR and FDA to notify physicians and pharmacies that NECC was not a licensed wholesaler in Georgia. NECC has taken down its website and telephone number. It is anticipated that this will be an ongoing investigation for quite some time.

Executive Director's Open Session - Ms. Tanja D. Battle

Tanja Battle states that only 13% of the Pharmacist Population have renewed their licenses.

Ms. Battle presented proposed meeting dates for 2013 and was instructed to email the proposed dates to Board members for consideration and a vote at the November Board meeting.

Peachford Behavioral Health Systems Rule Waiver 480-13-.05 was discussed from the previous meeting. Al McConnell made a motion, and Ronnie Wallace seconded and the Board voted unanimously to affirm the previous decision made.

Ronnie Wallace made the motion, Mike Faulk seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. §43-1-19(h)(2), 43-11-47(h) 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 Ronnie Wallace, Mike Faulk, Bill Prather, Fred Barber, Al McConnell, and Laird Miller. The Board entered into Executive Session.

The Following applications were discussed:

01. A.N.-Pharmacist
02. API-Wholesale Pharmacy
03. A.P.B.-Pharmacy Technician
04. B.M.S.-Pharmacist
05. B.L.G.-Pharmacy Technician
06. C.C.A. III-Pharmacist
07. C.V.-Pharmacy Technician
08. C.B.-Pharmacist
09. C.L.C.-Pharmacy Technician
10. C.J.P.-Pharmacist
11. E.L.R.-Pharmacy Technician
12. H.A.D.-Pharmacy Technician
13. H.D.B.-Pharmacist
14. J.S.D. Jr.-Pharmacist
15. L.N.T.-Pharmacist
16. M.C.B.-Pharmacy Technician
17. M.B.G.-Pharmacist
18. P.A.H.-Pharmacist
19. R.L.M.-Pharmacist
20. S.S.-Pharmacy Technician
21. S.M.B.-Pharmacy Technician
22. S.C.Y. Jr.-Pharmacy Technician
23. T.P.A.-Pharmacy Technician
24. V.M.K.-Pharmacist
25. W.I.M.-Pharmacist Intern

Cognizant Report – Al McConnell

GDNA Case #A12-25
GDNA Case #A12-54
GDNA Case #A12-57
GDNA Case #A12-58
GDNA Case #B-29717
GDNA Case #B-30202
GDNA Case #B-30433
GDNA Case #A-30464
GDNA Case #B-30469
GDNA Case #B-30507

Executive Director’s Report - Ms. Tanja D. Battle

M.C.-RPH020254

Georgia Drugs and Narcotics Agency - Rick Allen

No Report

Attorney General’s Report - Janet Wray

No Report

Bill Prather concluded Executive Session, in which no votes were taken, and declared the meeting back in Open Session.

VOTE:

Applications:

Ronnie Wallace made a motion to accept the following recommendations based on discussions in Executive Session:

01. A.N.-Pharmacist-approve
02. API-Wholesale Pharmacy-approve
03. A.P.B.-Pharmacy Technician-table for additional information
04. B.M.S.-Pharmacist-approve
05. B.L.G.-Pharmacy Technician-approve
06. C.C.A. III-Pharmacist-approve
07. C.V.-Pharmacy Technician-approve
08. C.B.-Pharmacist-Deny
09. C.L.C.-Pharmacy Technician-approve
10. C.J.P.-Pharmacist-send correspondence to confirm applicant knows the rules and regulations and all exam requirements before they decide to meet with the Board
11. E.L.R.-Pharmacy Technician-approve
12. H.A.D.-Pharmacy Technician-approve
13. H.D.B.-Pharmacist-approve
14. J.S.D. Jr.-Pharmacist-approve
15. L.N.T.-Pharmacist-Deny
16. M.C.B.-Pharmacy Technician-Schedule for appearance
17. M.B.G.-Pharmacist-approve
18. P.A.H.-Pharmacist-approve
19. R.L.M.-Pharmacist-approve
20. S.S.-Pharmacy Technician-approve
21. S.M.B.-Pharmacy Technician-approve
22. S.C.Y. Jr.-Pharmacy Technician-approve
23. T.P.A.-Pharmacy Technician-Deny
24. V.M.K.-Pharmacist-Deny
25. W.I.M.-Pharmacist Intern-approve

Laird Miller seconded the motion and the Board members voted in favor of the motion.

Cognizant Report

Ronnie Wallace made a motion to accept the following recommendations based on discussions in Executive Session:

- GDNA Case #A12-25-Accept Signed Voluntary Surrender
- GDNA Case #A12-54-Revoke Pharmacy Technician Registration
- GDNA Case #A12-57-Accept Signed Voluntary Surrender
- GDNA Case #A12-58 – Not accepting Voluntary Surrender as requirements were met.
- GDNA Case #B-29717 –Close with no action
- GDNA Case #B-30202-Table for further investigation
- GDNA Case #B-30433-Approve in accordance with Board Policy #1
- GDNA Case #A-30464-Close with no action
- GDNA Case #B-30469-Close with no action
- GDNA Case #B-30507-Approve License along with a letter of concern.

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

Executive Director's Report - Ms. Tanja D. Battle

Mike Faulk made a motion to approve M.C. for an appearance at the November Board meeting. Fred Barber Seconded the motion and the Board members voted in favor of the motion.

Miscellaneous

Bill Prather discussed the processing of inactive status requests. Ronnie Wallace made a motion granting staff administrative authority to process requests for inactive statuses provided that the licenses are in good standing. Mike Faulk seconded the motion and the Board members voted in favor of the motion.

Bill Prather expressed his appreciation to Fred Barber and his service on the Pharmacy Board.

No more business was discussed and the meeting adjourned at 1:50 p.m.

The next Pharmacy Board meeting will be on Wednesday, November 14, 2012 at 9:30 a.m. at the Office of the Professional Licensing Boards, 237 Coliseum Drive, Macon, Georgia 31217.

Bill Prather, President
The Georgia State Board of Pharmacy

Date

Tanja D. Battle, Executive Director
The Georgia State Board of Pharmacy

Date