NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES, CHAPTER 480-13, RULE 480-13-.04 ABSENCE OF PHARMACIST AND NOTICE OF PUBLIC HEARING

TO ALL INTERESTED PERSONS AND PARTIES:
Notice is hereby given that pursuant to the authority set forth below, the Georgia State Board of Pharmacy (hereinafter "Board") proposes amendments to the Georgia Board of Pharmacy Rules, Rule 480-13-.04 ABSENCE OF PHARMACIST (hereinafter "proposed amendments").

This notice, together with an exact copy of the proposed amendments and a synopsis of the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m. Monday through Friday, except official State holidays, at the Department of Community Health at 2 Peachtree Street, NW, Atlanta, Georgia, 30303. These documents will also be available for review on the Georgia State Board of Pharmacy's web page at www.gbp.georgia.gov.

A public hearing is scheduled to begin at 9:00 AM on December 11, 2013 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303 to provide the public an opportunity to comment upon and provide input into the proposed amendments. At the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to 5 minutes per person. Additional comments should be presented in writing. Written comments are welcome. To ensure their consideration, written comments may be received prior to December 4, 2013. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, Atlanta, Georgia 30303 FAX: 678-717-6694. You may email your comments to tbattle@dch.ga.gov.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on December 11, 2013 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed amendments pursuant to authority contained in O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-80, 26-4-83, 26-4-84, and 26-4-110.

At its meeting on October 16, 2013, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments 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, at its meeting on October 16, 2013, 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 amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

This 30 day of October, 2013

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: October 30, 2013

SYNOPSIS OF PROPOSED AMENDMENTS OF THE GEORGIA STATE BOARD OF PHARMACY RULES CHAPTER 480-13, RULE 480-13-.04 ABSENCE OF PHARMACIST

Purpose of Rule: The purpose of this rule is to permit a Director of Pharmacy at a hospital pharmacy to create protocol for the provision of drugs to medical staff and other authorized personnel in the absence of a pharmacist.

Main Features: The main feature of this rule is to require approval by the Board of Pharmacy of any procedures designed by a facility to provide drugs in the absence of a pharmacist, including limitations on the use of remote order entry pharmacists.

DIFFERENCES OF THE PROPOSED AMENDMENTS FOR THE GEORGIA STATE BOARD OF PHARMACY RULES CHAPTER 480-13, RULE 480-13-.04 ABSENCE OF PHARMACIST

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

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.

Authority: O.C.G.A. §§26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-80, 26-4-83, 26-4-84, and 26-4-110.