NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-13-.06 DRUG DISTRIBUTION AND CONTROL., 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-.06 DRUG DISTRIBUTION AND CONTROL. (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 11:30 AM on November 9, 2016 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, Georgia 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 must be received prior to November 2, 2016. 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 11:35 AM on 11/9/2016 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, Georgia 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. §§ 16-13-39, 16-13-41, 16-13-72, 16-13-73, 16-13-74, 26-3-4, 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-29, 26-4-37, 26-4-80, 26-4-83, 26-4-110, 26-4-112.

At its meeting on September 14, 2016, 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.

At its meeting on 9/14/2016, the Board also 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 4th day of October, 2016.

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: October 4, 2016

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-13-.06 DRUG DISTRIBUTION AND CONTROL.

Purpose of Rule: The purpose of this rule is to require notification of GDNA upon the theft, loss, or lack of account for controlled substances and dangerous drugs.

Main Features: The main feature of this rule is to specify the time period and forms for notification.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-13-.06 DRUG DISTRIBUTION AND CONTROL.

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

480-13-.06 Drug Distribution and Control.

(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 give n 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 s 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 noncontrolled 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 inpatients.

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 outpatients. 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).

(12) Reports of Loss or Theft.

(a) Definitions.

1. An "immediate notification" is within seventy-two (72) hours of loss or theft being discovered. Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.

2. A "significant amount" is 20% of a manufacturer's stock unit within a six-month period.

(b) The Georgia Drugs and Narcotics Agency (GDNA) shall immediately be notified of the occurrence of the following: the theft of a significant amount of any controlled substance or any dangerous drug identified by the Board as having the potential for abuse or theft; the theft or any loss of a significant amount of any controlled substance where theft is suspected; or the theft or any loss of any dangerous drug identified by the Board as having the potential for abuse or theft where theft is suspected. The registrant shall send a completed copy of the appropriate form to GDNA. A GDNA Form 215 shall be used to report theft or loss of dangerous drugs, and a DEA Form 106 shall be used to report theft or loss of controlled substances.

(c) A GDNA Form 215 or DEA Form 106 shall be maintained at the facility for two (2) years. Such form shall be made immediately available upon verbal request by the GDNA.

(d) The submission of a GDNA Form 215 to GDNA does not relieve any DEA registrant from the responsibility of complying with DEA rules and regulations regarding the reporting of the losses of controlled substances.

(e) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must submit a copy of any final report to GDNA from such a department for any occurrence of the loss or theft of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft within seventy-two (72) hours of the conclusion of the audit, investigation or accounting.

(f) The Board may impose a fine and/or sanctions on the license, permit or registration based on each day a licensee, permit-holder, or registrant fails to file a completed GDNA Form 215 or DEA Form 106 where required under this rule.

(g) Copies of a GDNA Form 215 can be found at http://gdna.georgia.gov/ or http://gbp.georgia.gov/ or by contacting GDNA at (404) 656-5100 or (800) 656-6568.

Authority: O.C.G.A. §§26-4-27, 26-4-28, 26-4-37, 26-4-110, 26-4-112.