NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-33-.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 480-33-.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, 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-82, 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 5th day of October, 2016.

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: October 5, 2016

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-33-.06 DRUG DISTRIBUTION AND CONTROL.

Purpose of Rule: The purpose of these amendments is to require notification of GDNA upon the theft or loss of controlled substances and dangerous drugs.

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

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-33-.06 DRUG DISTRIBUTION AND CONTROL.

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

480-33-.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, in writing, or electronically 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 pharmacist-in-charge 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 clinic shall cooperate with the pharmacist-in-charge in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials so as to achieve this purpose. The pharmacist-in-charge shall establish written procedures for the distribution of medications including standard ward inventory, emergency kits, etc. to achieve this goal.
(a) The drugs must be identified up to the point of administration;
(b) The pharmacy must receive a direct, electronic (only for drugs to be administered on site) or mechanical copy of a practitioner's order before the first dose of medication is dispensed except as defined by the clinic stat order policy;
(c) Records of all transactions of the clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials within the scope of the clinic practice. Nothing in this section shall prohibit the use of computerized records, where such records meet all other requirements of the law. If an outpatient clinic pharmacy elects to dispense prescription medications other than outpatient prescriptions as defined herein, the pharmacy must meet all applicable State and Federal Laws and regulations and must also obtain a retail pharmacy permit; and
(d) Participation in those aspects of the clinic patient care evaluation program which relate to pharmaceutical material utilization and effectiveness.
(3) Labeling.
(a) For use inside the clinic, all drugs dispensed by a clinic 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) Drugs added to parenteral admixtures. Wherever any drugs are added to parenteral admixtures, 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 identity of person preparing the admixture.
(4) Discontinued drugs. The pharmacist-in-charge shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.
(5) Accountability of controlled drugs.
(a) Proof of use of controlled drugs on standard ward inventory and/or those issued for a specific patient. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the clinic, shall be submitted to the pharmacy, on forms provided by the pharmacy. Proof of use forms shall specify at a minimum:
1. Drug name, strength, and dosage form;
2. Dose;
3. Name of prescriber. This shall include, at a minimum, the given and last name;
4. Given and last name of patient;
5. Date and time of administration to patient;
6. Signature of individual administering, which shall include at a minimum, the initial, last name and title;
7. Documentation by two signature verifications of destruction of all unused portions;
8. Proof of receipt of medications that bears identifying serial numbers; and
9. Date medication was issued and the date that the proof of use form was returned.
(b) Anesthesia, surgical, diagnostic and treatment departments that obtain controlled drugs from the clinic pharmacy must show accountability of the controlled drugs by proof of use as defined above.
(c) Use of computer hard copy is permitted where such copy meets all other requirements of the law.
(d) Any outpatient clinic pharmacy licensed by the Georgia State Board of Pharmacy 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 the remainder of a single-dose 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.
(f) Recall. The pharmacist-in-charge shall develop and implement a recall policy and procedure to assure that all drugs within the clinic included on the recall are returned to the pharmacy for proper disposition.
(g) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering practitioner, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's record shall also be made.
(h) Records and reports. The pharmacist-in-charge shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board or its agents. These shall include, at a minimum, the following:
1. Patient profile, chart or other appropriate record;

2. Proof of use forms for controlled substances;
3. Reports of suspected adverse drug reactions;
4. Inventories of night cabinets, cabinets or enclosures; emergency drug kits; and standard ward inventories;
5. Inventories of the pharmacy;
6. Biennial controlled substances inventories;
7. Alcohol and flammables reports; and
8. Such other records and reports as may be required by law and the rules and regulations of the Georgia State Board of Pharmacy.
(i) Standard Ward Inventory. The outpatient clinic pharmacy may distribute drugs within a clinic for the purpose of establishing and/ or maintaining a standard ward inventory.
Such drugs may be supplied only upon a signed requisition from an authorized licensed health care professional of said clinic or by an inventory replacement system. These drugs may be administered only pursuant to a practitioner's order and shall be documented in the patient's record. A record of drugs administered to patients in ancillary areas such as surgical suite, treatment rooms, anesthesiology and diagnostic areas will become a part of the patient's record and shall be retrievable by the pharmacy. A survey of usage trends of each standard ward inventory shall be made monthly. Such records shall be maintained for a period of two years.
(j) Security of controlled substances. Controlled drugs that are maintained as authorized standard ward inventory in patient care/ treatment areas outside the pharmacy shall be stored in secured cabinets or areas that provide a double lock system.
(6) 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. §§16-13-39, 26-3-8, 26-3-16, 26-4-27, 26-4-28, 26-4-82, 26-4-110, 26-4-112.