NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-18-.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 480-18-.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. §§ 16-13-34, 16-13-41, 26-3-8, 26-4-27, 26-4-28, 26-4-80, 26-4-86, 26-4-87, 26-4-110, 26-4-111, 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 480-18-.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 480-18-.06 DRUG DISTRIBUTION AND CONTROL.

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

480-18-.06 Drug Distribution and Control.

(1) General. A drug distribution system is the entirety of that mechanism by which a physician's drug order is executed, from the time the practitioner transmits the order either orally, in writing, or electronically to a licensed health care professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration. No drugs can be dispensed or administered without a physician's medication drug order.
(2) Responsibility. The Director shall be responsible for the safe and efficient distribution, control, and accountability for drugs. The other professional staff, including the physicians, at the OTP clinic shall cooperate with the Director in meeting this responsibility and in ordering, administering, and accounting for the drugs and devices so as to achieve this purpose.
(a) The Director shall establish written policies and procedures for the distribution of medications including emergency kits, etc. to achieve this goal.
1. The drugs must be identified up to the point of administration;
2. The pharmacy must receive a direct, electronic (only for drugs to be administered on site) or mechanical copy of a physician's order before the first dose of medication is dispensed as defined by the clinic stat order policy.
3. At a minimum, the pharmacy must maintain a patient profile for each OTP clinic patient for use in prospective and retrospective drug reviews, for comparing with the central registry as required by the DHR and to report violators to the GDNA and DHR, for discharge from another OTP, and for urine or blood tests to check for drug positive test results.
4. Records of all transactions of the OTP clinic pharmacy, such as daily drug dosing summaries, daily drug inventory sheets, patient medication profiles, and bulk drug inventory records must be maintained by the clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all drugs and devices within the scope of the clinic practice.
5. All drug invoices must be attached to their accompanying DEA form 222 order form and must be filed separately from all other drug records. A biennial inventory of all controlled substances on hand must be taken every two years from the date of the pharmacy opening for business. This inventory must be an accurate count of all such drugs, signed in indelible ink by the pharmacist taking the inventory and dated on the date it is taken.
6. Any drug compounded by the pharmacy must be accounted for by use of a compounding log form. This form, at a minimum must display the date the drug was compounded, the name of the drug, the

strength, quantity made, manufacturer's lot number, manufacturer's expiration date, and the signature of the pharmacist compounding the drug.
7. Nothing in this section shall prohibit the use of computerized records, where such records meet all other requirements of the law. An OTP clinic pharmacy may not dispense or administer prescription medications other than OTP program medications; and
8. The pharmacy must participate in those aspects of the OTP clinic patient care evaluation program which relate to drug and device utilization and effectiveness.
(b) All records must be maintained by the pharmacy for a minimum of two years and be readily retrievable upon request by an agent of the Board.
(3) Labeling:
(a) For use inside the clinic, all drugs dispensed by an OTP clinic pharmacy, including those for use in an after hours safe or emergency kit shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum:
1. Brand name or generic name of the drug;
2. Drug strength;
3. Lot number assigned by either the drug manufacturer or the clinic pharmacy; and
4. Expiration date assigned either by the drug manufacturer or the clinic pharmacy.
(b) Any drug container dispensed by the pharmacy for take-home use by an OTP clinic patient must display a label which contains at least the following:
1. Patient name;
2. Name of the prescribing physician;
3. Name, address and telephone number of the OTP clinic pharmacy;
4. Drug name (either brand or generic name);
5. Drug strength;
6. Date of dispensing;
7. Expiration date of the drug as determined by the pharmacy;
8. "Federal Caution" for controlled substances;
9. Clinic Pharmacy serial number for that specific prescription drug order;
10. Any other labeling or information as required by the DEA;
(c) All take-home medication dispensed by the pharmacy, including one-time use containers, must be in child-proof containers which meet the requirements of the U.S. Consumer Product Safety Commission.
(4) Discontinued drugs. The Director 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 substances.
(a) Nothing shall prohibit the use of controlled substance drugs issued via proof of use forms for general or emergency use for specific patients. Proof of use controlled substances forms shall be provided by the pharmacy.
(b) Each proof of use form shall display the name of the patient to or for which it has been issued and an indication that the drugs are for general or emergency use and a serial number. The form shall also show the date the form was issued and the signature of the pharmacist issuing the form and the signature of the licensed medical practitioner receiving the form for storage in the after-hour safe. A detachable receipt reflecting all the previous information must be returned and filed by the pharmacy as a safeguard to prevent drug diversion.
(c) Each proof of use sheet shall provide space to record the administration information necessary to account for each dose of medication. This information shall specify at a minimum:
1. Drug name, strength, and dosage form;
2. Dose administered;

3. Name of prescriber. This shall include, at a minimum, the first initial and complete last name of the prescriber;
4. First and last name of the patient;
5. Date and time of administration to patient;
6. Signature of individual administering the dose, which shall include at a minimum, the first and last name and title;
7. Documentation of destruction of all unused portions by two signature verifications of licensed healthcare professionals;
8. Proof of receipt of medication bearing identifying serial numbers;
9. Date the medication was issued and date the proof of use form was returned.
(6) Any OTP clinic pharmacy licensed by the Board may make on-premises destruction of small quantities of controlled substances prepared for oral administration provided:
(a) The controlled substance is the remainder of a single-dose unit; and,
(b) The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.
(7) Perpetual inventory of Schedule II controlled substances shall be required and accountability of said drugs shall be by an appropriate form indicating at a minimum the date used, name of shipper or drug recipient, corresponding serial number of a drug order, invoice or proof of use form, and quantity received or issued.
(8) Recall. The Director 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.
(9) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering physician, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's pharmacy profile shall also be made.
(10) Security. All areas occupied by an OTP clinic pharmacy shall be capable of being locked by key or combination, so as to prevent unauthorized personnel access except by force. Such areas shall meet the security requirements of all applicable Federal and State laws and rules. Only those persons so authorized shall be permitted to enter these areas.
(a) All drugs shall be stored in designated areas within the clinic pharmacy or all dispensing medications shall be stored in designated areas within the clinic which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage areas shall be locked or otherwise secured when licensed health care professionals are not present.
(b) Storage for Schedule II controlled substances shall be in an enclosed room or space with controlled limited access capable of showing forced entry is preferable. However, a safe or a lockable metal cabinet that is permanently affixed to the structure is acceptable.
(c) Whenever any area of an OTP clinic pharmacy is not under the personal and direct supervision of authorized licensed personnel, such areas shall be locked and secured.
(11) Reports and records. The Director 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, the GDNA or its designated agents. All such records shall be maintained for a minimum of two years. These shall include, at a minimum, the following:
(a) Patient profile, chart or other appropriate record;
(b) Proof of use forms for controlled substances;
(c) Reports of suspected adverse drug reactions;
(d) Inventories of after hours safe(s) and emergency drug kits,
(e) All perpetual inventories maintained by the pharmacy, and all other records pertaining to controlled substances, including a biennial controlled substances inventory;
(f) Such other records and reports as may be required by Federal or State laws and/or rules;

(12) The compounding, labeling and quality control of large volumes of opioid treatment medication is the responsibility of a pharmacist and shall be prepared within the on-site pharmacy.
(13) 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. §§16-13-34, 16-13-41, 26-3-8, 26-4-27, 26-4-28, 26-4-80, 26-4-86, 26-4-87, 26-4-110, 26-4-111, 26-4-112.