NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-8-.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 480-8-.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 480-8-.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 480-8-.06 DRUG DISTRIBUTION AND CONTROL.

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

480-8-.06 Drug Distribution and Control.

Drug Distribution and Control shall be as follows:
(a) General. A drug distribution system is the entirety of that mechanism by which a practitioner's prescription drug order is executed, from the time the prescriber transmits the order either orally or in writing to an authorized health professional through the time the ordered drug is administered to the patient or delivered to the patient for self-administration.
(b) Responsibility. The Director of Pharmacy shall be responsible for the safe and efficient distribution control, and accountability for drugs. The other professional staff of the prison clinic shall cooperate with the Director in meeting this responsibility and in ordering, administering, and accounting for the pharmaceutical materials so as to achieve this purpose. Accordingly the Director shall be responsible for, at a minimum, the following:
1. The drugs must be identified up to the point of administration;
2. The pharmacy must receive a direct copy or mechanical copy of a physician's order before the first dose of medication is dispensed except as defined by prison clinic stat order policy;
3. Utilization of a pharmacy-generated patient profile. This shall be the official record of medications dispensed to the patient. The patient profile shall be maintained under the control of the Director of Pharmacy for a period of two (2) years. The patient profile shall contain at a minimum:
(i) Given and last name;
(ii) DOC I.D. Number or any other assigned I.D. Number;
(iii) Date of birth;
(iv) Sex;
(v) Dorm or permanent housing assignment;
(vi) Drug product dispensed, date dispensed, strength, dosage form, quantity and directions, and identification of dispensing pharmacist;
(vii) Identification or differentiation of controlled substances;
(viii) Selected medical data; and
(ix) Sensitivities and allergies to drugs and foods.
4. Maintaining no more than a 7day's supply of unit dose medication with prison clinic labeling or no more than a 30-day supply of maintenance medication with retail labeling.

5. Establishment of specifications or use of compendial specifications for procurement of drugs, chemicals, and biologicals, subject to approval of the appropriate committee of the prison clinic;
6. Participation in development of a drug formulary for the prison clinic;
7. Filling and labeling all containers from which drugs are to be administered, after visual screening to determine that same are neither adulterated nor misbranded;
8. 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 such other materials and information as may be deemed necessary shall also be maintained;
9. Records of all transactions of the prison clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials. Nothing in this section shall prohibit the use of computer hard copy, where such copy meets all other requirements of the law;
10. Participation in those aspects of the prison clinic patient care evaluation program which relate to pharmaceutical material utilization and effectiveness, and,
11. Efficient messenger and delivery service to connect the pharmacy with appropriate parts of the facility throughout the normal workday.
(c) Labeling. Labeling shall include:
1. For use inside the prison clinic, all drugs dispensed by a prison 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.
2. For use outside the prison clinic or institution, all drugs dispensed by a prison clinic pharmacy to inmates housed outside the prison clinic or those about to be released or on leave shall be labeled with the following information:
(i) Name, address and telephone number of the prison clinic pharmacy;
(ii) Date and identifying serial number;
(iii) Full name of patient;
(iv) Name of drug, (brand or generic) and strength;
(v) Directions for use to the patient;
(vi) Name of practitioner prescribing;
(vii) Require precautionary information regarding controlled substances; and,
(viii) Such other and further accessory cautionary information as may be required or desirable for proper use and safety to the patient.
(d) Discontinued drugs. The Director of Pharmacy 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 prison clinic pharmacy for proper disposition according to the following:
1. The following method of destruction of non-controlled substances is approved by the Board for medications dispensed to patients residing in a prison facility. When noncontrolled drugs are expired, discontinued from use or the patient for whom they are ordered expires, the drugs shall be immediately removed from the active stock and inventoried by a pharmacist, along with another licensed healthcare professional or a corrections officer. The completed inventory shall be signed and dated by those two individuals. The original inventory shall be maintained by the facility for two years, and a copy shall be kept with the drugs until their final disposition. Once inventoried, these drugs can either be:

a. Placed in a secure storage area at the facility separated from medications with active orders. The drugs can 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 along with the inventory for two years. This record shall include at a minimum the date, time, personnel involved with the destruction and the method of destruction; or

b. The drugs for destruction are removed from the pharmacy by transfer to a reverse distributor with a current permit issued by the Board and a record of the following is maintained by the Prison Clinic for at least two years:

(1) 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;

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

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

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

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

2. The following methods of destruction of controlled substances are approved by the Board of Pharmacy:

(a) A securely attached wooden or metal cabinet will be made available within a locked limited-access area. When controlled drugs are discontinued or the patient expires, the medication shall be pulled ~~form~~from the active stock immediately and inventoried and verified by a pharmacist along with another licensed healthcare professional or a correction officer. The inventory must be recorded into a permanent record and the drugs shall then be placed in the aforementioned cabinet. This medication would remain within the locked cabinet until such time that it is removed for destruction.

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

i. Date of discontinuance or inventory date;

ii. Name of patient;

iii. Name of issuing pharmacy;

iv. Identifying serial numbers;

v. Name and strength of drug; and

vi. Quantities of drugs in containers when inventoried.

2. A licensed pharmacist must destroy the drugs in the presence of at least two witnesses.

3. 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 all three witnesses present at the destruction in the following format:

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

Name of drug

Strength of drug

_____

(Signature and Title)

_____

(Signature and Title)

_____

(Signature and Title)

4. The Board and/or the GDNA may prohibit any pharmacist or prison clinic facility from utilizing this method.

(b) 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 they are transferred. When the drugs are transferred to a reverse distributor licensed by the Georgia Board, an inventory including the names of the drugs, the dosage forms of the drugs and the quantities of drugs is taken and witnessed by an authorized representative of the prison clinic pharmacy and the responsible person representing the reverse distributor.

2. The prison clinic pharmacy must maintain a receipt/record with the following information: 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 ~~pharamcy~~ pharmacy representative transferring the drugs. This receipt/record must be maintained by the prison clinic pharmacy for a minimum of two years.

(e) Prescription Drug orders. Drugs may be dispensed from the prison clinic pharmacy only upon written orders, direct or copies thereof, of authorized practitioners.

1. Authorization. The appropriate committee of the prison clinic shall, from time to time as appropriate, designate those practitioners who are authorized to issue prescription drug orders to the pharmacy.

2. 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 prison clinic.

3. Requirements--orders for drugs for use by inpatients. Orders for drugs for use by inpatients shall, at a minimum, contain:

(i) Patient name and dorm or permanent housing assignment;

(ii) Drug name, strength, directions for use; and

(iii) Date and physician's signature.

4. Requirements--orders for drugs for use by outpatients. Orders for drugs for use by outpatients shall at a minimum, contain all of the items required by Rule 480-8-.06(e)3., and in addition:

(i) Dispensing quantity; and

(ii) Practitioner's address and Drug Enforcement Administration permit number, if applicable.

(f) Accountability of Controlled Drugs--Proof of Use of controlled substances on standard ward inventory. Proof of use of controlled substances and such other drugs as may be specified by the appropriate committee of the prison clinic, shall be submitted to the pharmacy, on forms provided by the pharmacy.

1. Proof of use forms shall specify at a minimum:

(i) Name of drug, strength, and dosage form;

(ii) Dose;
(iii) Name of ordering physician. This shall include, at a minimum, the initial and last name;
(iv) Given and last name of inmate, DOC I.D. Number, or any other assigned I.D. Number;
(v) Date and time of administration to patient;
(vi) Signature of individual administering the drug, which shall include at a minimum, the initial, last name and title;
(vii) Documentation of destruction of all unused portions by two signature verifications of two licensed staff members;
(viii) Proof of receipt of medications that bears identifying serial numbers; and
(ix) Date the medication was issued and the date that the proof of use form was returned.
2. Use of computer hard copy is permitted where such copy meets all other requirements of the law.
3. Any prison clinic pharmacy licensed by the Board and in which controlled substances are administered to patients, may make on-premises destruction of small quantities of controlled substances prepared for oral administration provided:
(i) The controlled substance is the remainder of a single-dosage unit; and
(ii) The single-dosage unit from which the ordered dose prepared is the nearest possible size to the dose ordered.
4. Perpetual inventory of Schedule II controlled substances shall be required and accountability of said drugs shall be by proof of use form.
(g) Recall. The Director of Pharmacy shall develop and implement a recall procedure to assure that all drugs within the prison included on the recall are returned to the prison clinic pharmacy for proper disposition.
(h) 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 prison clinic. An appropriate entry on the patient's record shall also be made.
(i) Records and reports. The Director of Pharmacy 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 employees. These shall include, at a minimum, the following:
1. Patient profile;
2. Proof of use documents;
3. Reports of suspected adverse drug reactions;
4. Inventories of night cabinets and emergency kits/crash carts;
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 Rules and Regulations of the Board of Pharmacy.
(j) Standard ward inventory (floor stock). The pharmacy department may distribute drugs within a prison clinic 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 prison clinic or by an inventory replacement system. These drugs may be administered only pursuant to a physician's order. This physician's order will be forwarded to the pharmacy and these medications will be recorded on the pharmacy patient profile. A survey of

usage trends of each standard ward inventory shall be made monthly. Such records shall be maintained for a period of two (2) years.

(k) Reports of Loss or Theft.

1. Definitions.

(i) 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.

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

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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, 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.