

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-10-.20 REQUIRED NOTIFICATIONS TO THE BOARD., 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 480-10-.20 REQUIRED NOTIFICATIONS TO THE BOARD. (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, 26-4-27, 26-4-28, and 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.

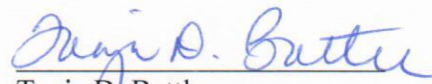
At its meeting on 9/14/2016, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A. §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these

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
480-10-.20 REQUIRED NOTIFICATIONS TO THE BOARD.**

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
480-10-.20 REQUIRED NOTIFICATIONS TO THE BOARD.**

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

480-10-.20 Required Notifications to the Board.

(1) For purposes of this rule, the following terms shall mean as follow:

- (a) "Board" shall mean the Georgia Board of Pharmacy;
- (b) "Immediate notification" shall mean written notification sent within twenty-four hours of the event;
- (c) "Significant adverse drug reaction" shall mean any reaction which requires any medical treatment beyond a consultation between Pharmacist/patient, Pharmacist/Prescriber, patient/prescriber or Pharmacist/patient/Prescriber; and
- (d) "Written notification" shall mean in writing and sent by statutory overnight delivery or sent electronically via email.

(2) The following occurrences require immediate notification to the Board at its address of record, unless otherwise provided:

- (a) Permanent closing of a licensed pharmacy. Notification shall include the name and contact information for the person responsible for maintaining the pharmacy records after the pharmacy has closed and location of the records.
- (b) Change of ownership or location of a licensed pharmacy. Since a pharmacy license cannot be transferable, unless such change has been previously approved by the Board following the submission of the appropriate applications, the existing pharmacy license is void and there is no continuing authority to operate as a pharmacy.
- (c) Change in management of a licensed pharmacy.
- (d) Change of the pharmacist in charge of a licensed pharmacy. When the Board receives notice that a pharmacy no longer has a pharmacist in charge and no replacement pharmacist in charge is named, the pharmacy's license is suspended pending further action by the Board.
- (e) Any theft or loss of drugs or devices of a licensed pharmacy. This notification must ~~also~~ be made to the Georgia Drugs and Narcotics Agency (GDNA), and if involving controlled substances, the pharmacy must comply with Rule 480-16-.06.
- (f) Any known conviction of any employee of a licensed pharmacy of any state or federal drug laws, not previously reported.
- (g) Disasters or accidents involving the licensed pharmacy.

(h) Thefts or break-ins at the licensed pharmacy. Notifications of thefts or break-ins at a licensed pharmacy must also be made to the GDNA.

(i) Theft, destruction, or loss of records of a licensed pharmacy required to be maintained by state or federal law. Notification of theft, destruction, or loss of records required to be maintained by state or federal law must be made to the GDNA.

(j) Occurrence at a licensed pharmacy of a significant adverse drug reaction by a customer or person receiving medication dispensed or compounded by the licensed pharmacy.

(3) 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, 26-4-27, 26-4-28, and 26-4-112.