

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-16-.06 THEFT, LOSS, OR UNACCOUNTED FOR CONTROLLED
SUBSTANCES OR DANGEROUS DRUGS., 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 480-16-.06 THEFT, LOSS, OR UNACCOUNTED FOR CONTROLLED SUBSTANCES OR DANGEROUS DRUGS. (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, 26-4-27, 26-4-28, 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.

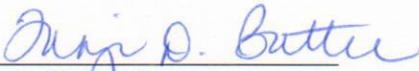
At its meeting on 9/14/2016, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A. §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these

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
480-16-.06 THEFT, LOSS, OR UNACCOUNTED FOR CONTROLLED SUBSTANCES OR
DANGEROUS DRUGS.**

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
480-16-.06 THEFT, LOSS, OR UNACCOUNTED FOR CONTROLLED SUBSTANCES OR
DANGEROUS DRUGS.**

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

480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances or Dangerous Drugs.

(1) Definitions.

(a) An "immediate notification" means 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.

(b) A "significant amount" means 20% of a manufacturer's stocking unit within a six month period.

~~(1)(2)~~ The theft, loss, or unaccounted inability to account for a significant amount of controlled substances or dangerous drugs identified by the Board as having the potential for abuse or theft stolen suffered by a pharmacy licensed by the Board to keep controlled substances must; be reported to the Georgia Drugs and Narcotics Agency (GDNA) immediately upon discovery of the occurrence as required in O.C.G.A. §26-4-112. 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. This report shall be faxed or mailed to the GDNA office address on the form or emailed to the GDNA Special Agent responsible for the area in which the facility is located within three (3) days of its discovery, must be reported to the Drug Enforcement Administration and the GDNA.

(a) All pharmacies must maintain a copy of a completed GDNA Form 215 of DEA Form 106 for two (2) years from the time of occurrence.

(3) (2) A written report must be made regarding any theft, loss or unaccounted for controlled substances by completing a DEA Form 106. 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 or dangerous drugs.

(a) Within ten (10) days of receiving such DEA Form 106, the original and one copy of the report must be sent to the Drug Enforcement Administration; and

(b) One copy must be sent to the GDNA.

(4) 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.

(3) The report shall include the following information:

- (a) Full name and address of the pharmacy;
- (b) Pharmacy DEA registration number;
- (c) Date of theft, loss, or discovery of missing controlled substance;
- (d) Type of incident, i.e. theft, loss, etc.;
- (e) List of cost codes, or identification symbols on package stolen; and
- (f) List of the controlled substances missing.

Authority: O.C.G.A. §§16-13-34, 26-4-27, 26-4-28, 26-4-112.