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., 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 (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 <u>www.gbp.georgia.gov</u>.

<u>A public hearing is scheduled to begin at 11:30 AM on July 12, 2017</u> at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th 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 July 5, 2017. 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 <u>tbattle@dch.ga.gov</u>.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its <u>meeting scheduled to begin at 11:35 AM on 7/12/2017</u> at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th 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 April 12, 2017, 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 4/12/2017, 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 <u>8th</u> day of <u>May</u>, 2017.

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Tanja D. Battle Executive Director Georgia Board of Pharmacy

Posted: May 8, 2017

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-16-.06 THEFT, LOSS, OR UNACCOUNTED FOR CONTROLLED SUBSTANCES.

Purpose of Rule: The purpose of this rule is to require immediate notification for the suspected theft, loss, or inability to account for controlled substances.

Main Features: The main feature of this rule is to permit up to seventy-two (72) hours for written notification.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-16-.06 THEFT, LOSS, OR UNACCOUNTED FOR CONTROLLED SUBSTANCES.

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.

(1) Definitions.

(a) "Immediately notify" means "report within seventy-two (72) hours." Immediate notification does not mean reporting after the completion of an investigation, audit, or reconciliation.
(b) A "significant amount" shall mean an amount consistent with what is considered to be a significant loss as explained in the Pharmacist's Manual of the U.S. Drug Enforcement Administration (DEA).

(1) The theft, loss, or unaccounted for controlled substances must, within three (3) days of its discovery, must be reported to the Drug Enforcement Administration and the GDNA. (2) A pharmacy licensed by the Board to keep controlled substances must immediately notify the Georgia Drugs and Narcotics Agency (GDNA) upon discovery of the suspected theft, loss, or inability to account for a significant amount of any controlled substance, pursuant to O.C.G.A. §26-4-112. A DEA Form 106 shall be used to report the suspected theft, loss, or inability to account for a significant amount of any controlled substance. The pharmacy shall send a completed copy of the appropriate form to GDNA. This report shall be faxed or mailed to the GDNA office or emailed to the GDNA Special Agent responsible for the area in which the facility is located.

(a) All pharmacies must maintain a copy of a completed DEA Form 106 for two (2) years from the time of the discovery of the theft, loss, or inability to account.

(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 DEA Form 106 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.

(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, theft, or inability to account for controlled substances 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;(e) List of cost codes, or identification symbols on package stolen; and

(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.