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 www.gbp.georgia.gov.

A public hearing is scheduled to begin at 11:00 AM on January 14, 2016 at the South University School of Pharmacy, 709 Mall Boulevard, Savannah, Georgia 31406 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 January 4, 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: 678-717-6435. 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 11:05 AM on 1/14/2016 at the South University School of Pharmacy, 709 Mall Boulevard, Savannah, Georgia 31406. 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, 26-4-38, 26-4-112.

At its meeting on November 18, 2015, 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 11/18/2015, 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 30th day of November, 2015.

Tanja D. Butle
Executive Director

Georgia Board of Pharmacy

Posted: November 30, 2015

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

Purpose of Amendments: The purpose of these amendments is to require a pharmacy licensed by the Board to keep controlled substances to immediately report the theft, loss, or unaccounted for controlled substances to GDNA upon discovery of the occurrence.

Main Features: The main feature of these amendments is to require the submission of a GDNA Form 215.

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) The theft, loss, or unaccounted for controlled substances <u>suffered by a pharmacy licensed by the Board to keep controlled substances must</u>, <u>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. This report shall be made by completing a GDNA Loss or Theft Notice of Occurrence Form (Form 215). 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 for two (2) years from the time of occurrence.</u>
- (2) <u>Additionally, aA</u> written report must be made regarding any theft, loss or unaccounted for controlled substances to the <u>Drug Enforcement Administration (DEA)</u> within three (3) days of its <u>discovery</u> by completing a DEA Form 106.
- (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 (a) A copy of the completed DEA Form 106 must be sent to the GDNA within ten (10) days of completing the form.
- (3) All pharmacies with a department which audits, investigates, or otherwise accounts for losses and thefts must include a copy of any report from such a department for any occurrence of the loss or theft of dangerous drugs or controlled substances when filing a GDNA Form 215 as provided for in Board Policy.

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, 26-4-38, 26-4-112.