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 9:00 AM on August 18, 2021 at The University of Georgia College of Pharmacy, Pharmacy South Building, Room 303, 240 W. Green Street, Athens, GA 30602 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 August 11, 2021. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, 6th Floor, Atlanta, Georgia 30303. You may email your comments to elacefield@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 9:05 AM on August 18, 2021 at The University of Georgia College of Pharmacy, Pharmacy South Building, Room 303, 240 W. Green Street, Athens, GA 30602. 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, and 26-4-112.

At its meeting on April 14, 2021, 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.

Also, at its meeting on April 14, 2021, the Board 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 this chapter 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 13 day of **July**, 2021.

Eric R. Lacefield Executive Director

Georgia Board of Pharmacy

Posted: 3, 2021

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

Purpose of Rule: The purpose of this amendment is to address the conflict between the state and federal reporting requirements.

Main Feature: The main features of this amendment are to remove the requirement to report all theft/loss to the DEA and address duplicate language that appeared to be out of order.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 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 <u>the discovery of</u> unaccounted for controlled substances <u>must</u>, within three (3) days of its discovery, must be reported to <u>the Drug Enforcement Administration</u> and the GDNA.
- (2) A written report must be made regarding any theft<u>or significant loss</u>, <u>as defined under 21</u>
 <u>C.F.R. 1301.76</u>, <u>of loss or unaccounted for</u> controlled substances by completing a DEA Form 106 <u>and submitted to the Drug Enforcement Administration</u>, <u>with a copy to the GDNA</u>.
 - (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.
- (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. Secs. 16-13-34, 26-4-27, 26-4-28, 26-4-38, 26-4-112.

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 - (e) List of cost codes, or identification symbols on package stolen; and
 - (f) List of the controlled substances missing.

Authority: O.C.G.A. Secs. 16-13-34, 26-4-27, 26-4-28, 26-4-38, 26-4-112.