NOTICE OF INTENT TO ADOPT PROPOSED RULE TO THE GEORGIA STATE BOARD OF PHARMACY RULES RULE 480-38-.02 CONDITIONS FOR USE OF DELIVERY BY MAIL 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 a new Rule to the Georgia Board of Pharmacy Rules, Rule 480-38-.02 CONDITIONS FOR USE OF DELIVERY BY MAIL (hereinafter "proposed rule").

This notice, together with an exact copy of the proposed rule and a synopsis of the proposed rule, 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 proposed rule, and a synopsis of the proposed rule 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 January 22, 2014 at the Mercer University of College of Pharmacy, 3001 Mercer University Drive, Atlanta, Georgia 30341 to provide the public an opportunity to comment upon and provide input into the proposed rule. 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 may be received prior to January 15, 2014. 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 teatheadth: beattle@dch.ga.gov.

The proposed rule will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on January 22, 2014 at the Mercer University of College of Pharmacy, 3001 Mercer University Drive, Atlanta, Georgia 30341. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed rule pursuant to authority contained in O.C.G.A §§ 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-85, 26-4-110, 26-4-110.1, and 26-4-114.1.

At its meeting on November 13, 2013, the Board voted that the formulation and adoption of this rule do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule 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 November 13, 2013, 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 rule 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 25th day of November, 2013

Гапја **D**. Battle

Executive Director

Georgia Board of Pharmacy

Posted: November 25, 2013

SYNOPSIS OF PROPOSED RULE OF THE GEORGIA STATE BOARD OF PHARMACY RULES RULE 480-38-.02 CONDITIONS FOR USE OF DELIVERY BY MAIL

Purpose of Rule: The purpose of this rule is to describe the conditions under which a pharmacy may ship prescription drugs by mail or common commercial carrier.

Main Features: The main feature of this rule is to establish record-keeping requirements for pharmacies that ship prescription drugs by mail or common commercial carrier.

PROPOSED RULE FOR THE GEORGIA STATE BOARD OF PHARMACY RULES RULE 480-38-.02 CONDITIONS FOR USE OF DELIVERY BY MAIL

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

480-38-.02 Conditions for Use of Delivery by Mail

- (1) Any pharmacy can regularly employ the U.S. Postal Service or a common commercial carrier to deliver a drug which requires a prescription to a patient only after the patient has requested that a pharmacy use this method of delivery for his/her filled prescription drugs.
- (2) A pharmacy must document in writing a patient's request for delivery by mail of his/her filled prescription drugs. Such documentation must be maintained for at least two years after the last delivery by mail.
- (3) Any pharmacy regularly using delivery by mail to deliver dispensed prescription drugs shall comply with the following conditions:
- (a) The pharmacy shall provide an electronic, telephonic, or written communications mechanism which provides a proof of delivery which records when the medications delivered by mail were received by the patient or their designee.
- (b) The pharmacy shall ensure that the mail service will not leave medications unattended and will hold the medications for pickup by the patient or his/her designee.
- (c) A pharmacy that regularly employs delivery by mail must provide a method, including a local or toll-free telephone number, for the patient to call and speak with a pharmacist at the pharmacy if the patient has any questions regarding their medication and to allow the pharmacist or pharmacy intern under the supervision of the pharmacist to offer counseling on each filled prescription drug in accordance with and obligated by Code Section 26-4-85, unless the patient refuses such consultation or counseling and such refusal is documented.
- (d) The pharmacy shall utilize, in accordance with standards of the manufacturer, United States Pharmacopeia and National Formulary, Federal Drug Administration and other standards, temperature tags, time temperature strips, insulated packaging, or a combination of these which protect the integrity of and indicate when the integrity of any drug which has been delivered by mail order has been compromised.
- (e) The pharmacy shall provide information to the patient on the procedure the patient should follow if any prescription drug does not arrive in a timely manner, or if the integrity of the packaging or medication has been compromised during shipment and delivery by mail.
- (f) Any pharmacy utilizing delivery by mail shall immediately replace any prescriptions drugs that are compromised during shipment and delivery by mail or that do not arrive in a timely manner.

- (g) A pharmacy using delivery by mail shall document in its records when the prescription drug was sent to the patient and received by the patient or his/her designee, and such records shall be maintained for the same time period and in the same method as when a patient is delivered the medication in person or by courier.
- (h) A pharmacy using delivery by mail shall document instances when prescription drugs have been compromised during shipment and delivery by mail or when drugs do not arrive in a timely manner, and shall maintain such documentation for two (2) years.
- (4) The following drugs may not be delivered by mail:
- (a) Schedule II controlled substances;
- (b) Prescription drugs that require refrigeration:
- (c) Chemotherapy drugs deemed by the federal Environmental Protection Agency as dangerous; and
- (d) Medications in suppository form; and
- (e) Quantity of C3-C4 30 day supply or 180 tabs
- (6) A pharmacy or a pharmacist shall refuse to deliver by mail a prescription drug which, in the professional opinion of the pharmacy or pharmacist, may be clinically compromised by delivery by mail.

Authority: O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-85, 26-4-110, 26-4-110.1, and 26-4-114.1.