

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-48-.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 amendments to the Georgia Board of Pharmacy Rules, Rule 480-48-.02 CONDITIONS FOR USE OF DELIVERY BY MAIL. (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. §§ 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, 26-4-114.1.

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.

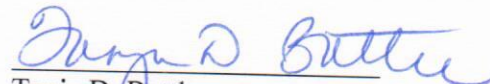
At its meeting on 9/14/2016, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these

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 5th day of October, 2016.



Tanja D. Battle

Executive Director

Georgia Board of Pharmacy

Posted: October 5, 2016

**SYNOPSIS OF PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-48-.02 CONDITIONS FOR USE OF DELIVERY BY MAIL.**

Purpose of Rule: The purpose of these amendments is to update the rule since the passage of HB886.

Main Features: The main feature of these amendments is to permit the use of temperature tags, time temperature strips, or a combination of those, consistent with HB886.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-48-.02 CONDITIONS FOR USE OF DELIVERY BY MAIL.**

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

480-48-.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 deliver by mail his/her filled prescription drugs. Any pharmacy providing delivery by mail to its patients is required to follow applicable Georgia laws and rules.
- (2) A mail order pharmacy located outside this state is required to follow all applicable pharmacy and drug rules and laws of the state in which the pharmacy is physically located.
- (3) A mail order pharmacy shall ensure that all prescription drug order medications are delivered to the patient in accordance with ~~standards~~ of the drug manufacturer's temperature standards as set by the Food and Drug Administration (FDA). The Ppharmacy shall ~~insure~~ ensure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by mail order by enclosing in each medication's packaging a USP-recognized method by which the patient can easily detect improper storage or temperature variations, which may include the use of temperature tags, time temperature strips, or a combination of these.
- (4) Any pharmacy using delivery by mail to deliver dispensed prescription drugs shall comply with the following conditions:
 - (a) Any pharmacy that uses delivery by mail is accountable to the Board to arrange for the appropriate mailing/shipping process.
 - (b) A mail order pharmacy shall provide a method by which a patient or patient's caregiver can notify the mail order pharmacy as to any irregularity in the delivery of their medication to include but not be limited to:
 1. Timeliness of delivery;
 2. Condition on the prescription drug upon delivery; and
 3. Failure to receive the proper prescription drug.
 - (c) Medications designated as requiring special handling by this rule must be signed for upon delivery by the patient or patient's designee. In the event that the medication cannot be delivered, the package will not be left behind and shall be returned to the mailing or shipping service to be held for pickup until signed for by the patient or the patient's designee, or redelivered to the patient if so requested by the patient or the patient's caregiver. The Board has designated the following drugs as requiring special handling:
 1. All Schedule II, III, IV, and V controlled substances

- (d) A mail order pharmacy shall provide a process by which, if the delivery of a prescription medication is in any way compromised, the pharmacy will replace the patient's medication, to be delivered by next-day delivery or the mail order pharmacy will immediately contact the patient's prescriber to arrange for a prescription for a minimum seven (7) day supply of the medication to be dispensed to the patient by a licensed pharmacy of the patient's choice.
- (e) A pharmacy that employs delivery by mail must provide written information, set forth in Board Rule 480-31-.01, for each drug that is delivered, and a method of electronic or telephonic communications for a pharmacist or a Georgia-licensed pharmacy intern under direct supervision of the pharmacist to provide consultation or counseling in accordance with the obligations of O.C.G.A. § 26-4-85. All such counseling will be documented in the pharmacy's patient records. It is sufficient proof to show counseling was refused if a patient or patient's caregiver does not contact the pharmacy.
- (f) The pharmacy shall provide information to the patient on the procedure that 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.
- (g) A pharmacy using delivery by mail shall document in its records when the prescription drug was sent to the patient.
- (h) A pharmacy using delivery by mail shall document the 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. In addition, the mail order pharmacy shall maintain reports of patient complaints and internal/external audits about timeliness of deliveries, condition of the medication when received by patient including medication that was compromised in delivery, misfills of prescriptions, and the failure of a patient to receive medication. Such records shall be provided to the Board, upon request.
- (i) 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.
- (j) A mail order pharmacy shall make available to the patient or the patient's caregiver contact information of the Board of Pharmacy.

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, 26-4-114.1