NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES, RULE 480-27-.02 PRESCRIPTION DRUG ORDER REQUIREMENTS., 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 480-27-.02 PRESCRIPTION DRUG ORDER REQUIREMENTS. (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 July 15, 2015 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 July 8, 2015. 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 thattle@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 7/15/2015 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. §§ 16-13-41, 16-13-73, 16-13-74, 26-4-5, 26-4-27, 26-4-28, 26-4-37, 26-4-80, 26-4-80.1, 26-4-83, 42 C.F.R. Part 423.

At its meeting on May 13, 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 5/13/2015, 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 8th day of June, 2015.

Tanja D. Battle
Executive Director

Georgia Board of Pharmacy

Posted: June 8, 2015

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-27-.02 PRESCRIPTION DRUG ORDER REQUIREMENTS.

Purpose of Rule: The purpose of these rule amendments is to require the use of security paper in some circumstances.

Main Features: The main feature of these rule amendments is to require the use of security paper for a hard copy prescription drug order for a Schedule II controlled substance and when the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-27-.02 PRESCRIPTION DRUG ORDER REQUIREMENTS.

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

RULE 480-27-.02 Prescription Drug Order Requirements.

- (1) Prescription drug orders shall include, but not be limited to, the following information:
- (a) Date of issue:
- (b) Name and address of patient (or patient location if in an institution):
- (c) Name and address of prescriber, telephone number, and NPI as assigned under federal law;
- (d) DEA registration number of the prescriber in the case of controlled substances;
- (e) Name, strength, dosage form and quantity of drug prescribed;
- (f) Number of authorized refills;
- (g) Directions for use by patient;
- (h) If a written prescription drug order, the signature of the prescribing practitioner; and
- (i) Any cautionary statements as may be required or necessary.
- (2) Electronically transmitted prescription drug orders shall contain all information required for written prescriptions above and required by state and federal law including the prescriber's name, address, and phone number, except the signature may be an electronic signature as provided below and the electronically transmitted prescription must include the time and date of transmission. Such electronically transmitted prescription may not be for controlled substances except as may be allowed by federal law.
- (a) Electronically transmitted prescription drug orders transmitted from the practitioner and received by a pharmacy via facsimile must contain either an electronically reproduced visual image signature or original signature of the practitioner.
- (b) Electronically generated prescription drug orders transmitted from the practitioner and received by a pharmacy as e-mails must contain an electronic data signature of the practitioner.
- (c) All electronic prescription drug orders generated by a practitioner containing an electronically reproduced visual image signature or an electronic data signature must bear wording that appears on the face of the prescription which indicates the signature was electronically generated.
- (3) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists isare entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from an intervening electronic formatter that comply with this rule.

- (4) An electronic visual image prescription drug order that bears an electronic reproduction of the visual image of the practitioner's signature and is given directly to the patient must be printed on security paper Electronically generated drug orders presented to a patient by a practitioner must be printed on security paper, and must contain either an electronically reproduced visual image signature of the practitioner with the wording that indicates the signature was electronically generated or the original signature of the practitioner.
- (a) Every hard copy prescription drug order for any Schedule II controlled substance written in this state by a practitioner shall be written on security paper. If a hard copy of an electronic data prescription drug order for any Schedule II controlled substance is given directly to the patient, the manually signed hard copy prescription drug order must be on security paper.
- (5) Pharmacies are prohibited from receiving electronic data from intervening electronic formatters that do not meet all of the following requirements:
- (a) Utilize recognized encrypted technology and secure servers.
- (b) Maintain HIPAA compliance.
- (c) Maintain a combination of technical and administrative security measures, such as, but not limited to those listed in Security Standards for the Protection of Electronic Protected hHealth Information (HIPAA), to ensure a reasonable and appropriate level of:
- 1. Practitioner and dispenser authentication;
- 2. Content integrity; and
- 3. Confidentiality.
- (d) Refrain from collecting and disseminating patient and/or prescriber data to sources other than the originating prescriber and the receiving pharmacy.

Authority: O.C.G.A. §§16-13-41, 16-13-73, 16-13-74, 26-4-5, 26-4-27, 26-4-28, 26-4-37, 26-4-80, 26-4-80.1, 26-4-83, 42 C.F.R. Part 423.