NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,

RULE 480-22-.03 MANNER OF ISSUANCE OF A CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER., 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 480-22-.03 MANNER OF ISSUANCE OF A CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER. (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 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 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. §§ 16-13-34, 16-13-41, 26-4-27, 26-4-80, 26-4-80.1.

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. Buttle
Executive Director

Georgia Board of Pharmacy

Posted: June 8, 2015

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-22-.03 MANNER OF ISSUANCE OF A CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER.

Purpose of Rule: The purpose of these rule amendments is to require the use of security paper for some hard copy prescription drug orders.

Main Features: The main feature of these rule amendments is to permit the electronic transmission of prescription drug orders that meet the requirements of state and federal law and regulation.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-22-.03 MANNER OF ISSUANCE OF A CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER.

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

RULE 480-22-.03 MANNER OF ISSUANCE OF A CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER.

- (1) All controlled substance prescription drug orders issued by the authorized practitioner shall bear the prescribing practitioner's name, address, telephone number and the Drug Enforcement Administration (DEA) permit number assigned to the practitioner for that corresponding address, and each shall be signed and dated on the same day when issued. At the time of dispensing, at a minimum, each shall bear the name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and indications for any refills or zero for none.

 (a) A practitioner shall sign a prescription in the same manner as he or she would sign a check or legal document, except as the rules allow regarding the issuance of electronic or facsimile prescriptions. Such controlled substance prescription drug orders shall be written with ink or indelible pencil, pen, typewriter, or printer and shall either be done manually or electronically via computer, as defined by the Board, and signed by the practitioner. Such prescription drug orders may be prepared for the practitioner's signature by the practitioner's authorized agent, but the practitioner is responsible for ensuring that the prescription conforms to all essential respects to the laws and regulations.
- (b) A hard copy prescription drug order for any Schedule II controlled substance must be on security paper.
- 1. 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 order must be on security paper.

 (2) If a practitioner gives a hard copy of an electronic visual image prescription drug order directly to the patient or his/her agent, the hard copy must be printed on security paper with the wording that indicates the signature was electronically generated.
- (3) Practitioners may electronically transmit prescription drug orders directly to the pharmacy of the patient's choice where the prescription meets the requirements of O.C.G.A. §§16-13-41, 26-4-80, 26-4-80.1, 21 C.F.R. 1306, 21 C.F.R. 1311 and any other applicable state or federal law or regulation for dispensing of a controlled substance prescription drug order transmitted via electronic means.

- (2)(4) Practitioners not registered with the DEA, but affiliated with hospitals or other institutions, shall include the registration number of the hospital or other institutions as well as the special internal code assigned to the authorized practitioner by the hospital or other institution, as provided for in federal regulations 21 CFR 1301.22(c), in lieu of a DEA registration when prescribing or issuing a controlled substance drug order.
- (a) Each such hand written prescription drug order shall meet the requirements of Rule 480-22-.04(a) and shall have the name of the practitioner stamped, typed or hand printed on it, as well as the signature of the practitioner, along with the telephone number where the practitioner can be contacted for verification.
- (b) Such prescription drug orders can only be issued by such practitioner for patients treated as a part of his/her duties at such hospital or other institution.

Authority: O.C.G.A. §§16-13-34, 16-13-41, 26-4-27, 26-4-80, 26-4-80.1.