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

RULE 480-22-.12 REQUIREMENTS OF PRESCRIPTION DRUG ORDERS AS ISSUED BY A PHYSICIAN'S ASSISTANT (PA) OR AN ADVANCED PRACTICE REGISTERED NURSE (APRN) LICENSED TO PRACTICE IN THE STATE OF GEORGIA., 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-.12 REQUIREMENTS OF PRESCRIPTION DRUG ORDERS AS ISSUED BY A PHYSICIAN'S ASSISTANT (PA) OR AN ADVANCED PRACTICE REGISTERED NURSE (APRN) LICENSED TO PRACTICE IN THE STATE OF GEORGIA. (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. §§ 16-13-21, 16-13-41, 16-13-70.1, 16-13-72, 26-4-5, 26-4-27, 26-4-28, 26-4-80, 43-34-25, 43-34-103, 21 C.F.R. 1301.22, and 45 C.F.R. Part 162.

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

480-22-.12 REQUIREMENTS OF PRESCRIPTION DRUG ORDERS AS ISSUED BY A PHYSICIAN'S ASSISTANT (PA) OR AN ADVANCED PRACTICE REGISTERED NURSE (APRN) LICENSED TO PRACTICE IN THE STATE OF GEORGIA.

Purpose of Rule: The purpose of these rule amendments is to require the use of security paper when the prescription is a hard-copy of an electronic visual image prescription drug order given directly to the patient or his/her agent.

Main Features: The main feature of these rule amendments is to no longer require the use of security paper for all prescriptions.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-22-.12 REQUIREMENTS OF PRESCRIPTION DRUG ORDERS AS ISSUED BY A PHYSICIAN'S ASSISTANT (PA) OR AN ADVANCED PRACTICE REGISTERED NURSE (APRN) LICENSED TO PRACTICE IN THE STATE OF GEORGIA.

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

RULE 480-22-.12 Requirements of Prescription Drug Orders as Issued by a Physician's Assistant (PA) or an Advanced Practice Registered Nurse (APRN) Licensed to Practice in the State of Georgia.

- (1) Under O.C.G.A. § 43-34-103(e.1), a physician's assistant (PA) licensed by the Georgia Composite Medical Board is permitted to issue a prescription drug order or orders for any dangerous drugs, as defined in O.C.G.A. § 16-13-71, or for any Schedule III, IV, or V controlled substance without the co-signature of a supervising physician under the following conditions:
- (a) The supervising physician has delegated the authority to prescribe dangerous drugs and/or controlled substances in the PA's job description on file with the Georgia Composite Medical Board.
- (b) If the prescription is for controlled substances, the PA has a DEA number.
- (c) If the prescription is a hard-copy of an electronic visual image prescription drug order given 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.
- (e)(d) The prescription drug order must be on security paper and include the following:
- (i) The name, address, and telephone number of the supervising physician and the PA;
- (ii) The patient's name and address;
- (iii) The drug name, strength and quantity prescribed;
- (iv) The directions to the patient with regard to taking the drug;
- (v) The number of authorized refills, if any;
- (vi) A NPI number; and
- (vii) If applicable, the DEA permit number of the PA.
- (d) If the prescription is transmitted by facsimile or computer, the prescription shall include:
- (i) The complete name and address of the supervising physician and the PA;
- (ii) In the case of a prescription drug order for a controlled substance, the DEA registration number
- (iii) The telephone number of the PA for verbal confirmation;
- (iv) The name and address of the patient;

- (v) The time and date of the transmission;
- (vi) The full name of the person transmitting the order; and
- (vii) The drug name, strength and quantity prescribed;
- (viii) The directions to the patient with regard to taking the drug;
- (ix) The number of authorized refills, if any;
- (x) A NPI number; and
- (xi) The signature of the PA as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.
- (e) No prescription drug order issued by a PA can be used to authorized refills more than twelve (12) months past the date of the original drug order.
- (2) Under O.C.G.A. § 43-34-25, an advanced practice registered nurse (APRN) who is recognized by the Georgia Board of Nursing as having met the requirements to engage in advanced nursing practice, and whose registered nurse license and advanced practice registered nurse license are in good standing with the Georgia Board of Nursing, is permitted to issue a prescription drug order or orders for any dangerous drugs, O.C.G.A. § 16-13-71 except for drugs intended to cause an abortion to occur pharmacologically, or for any Schedule III, IV, or V controlled substance without the cosignature of a delegating physician under the following conditions:
- (a) The APRN has been delegated the authority to issue prescription for the dangerous drugs and controlled substances by a physician licensed by the Georgia Composite Medical Board in a nurse protocol agreement and that agreement has been filed with the Georgia Composite Medical Board.
- (b) If the prescription is for controlled substances, the APRN has a DEA number.
- (c) If the prescription is a hard-copy of an electronic visual image prescription drug order given 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.
- (e)(d) The prescription drug order must be on security paper and include the following:
- (i) The name, address, and telephone number of the delegating physician and the APRN;
- (ii) The patient's name and address;
- (iii) The drug name, strength and quantity prescribed;
- (iv) The directions to the patient with regard to taking the drug;
- (v) The number of authorized refills, if any;
- (vi) A NPI number: and
- (vii) If applicable, the DEA permit number of the APRN.
- (d) If the prescription is transmitted by facsimile or computer, the prescription shall include:
- (i) The complete name and address of the delegating physician and the APRN;
- (ii) In the case of a prescription drug order for a controlled substance, the DEA registration number of the APRN;
- (iii) The telephone number of the APRN for verbal confirmation;
- (iv) The name and address of the patient;
- (v) The time and date of the transmission;
- (vi) The full name of the person transmitting the order; and
- (vii) The drug name, strength and quantity prescribed;
- (viii) The directions to the patient with regard to taking the drug;
- (ix) The number of authorized refills, if any;
- (x) A NPI number: and
- (xi) The signature of the APRN as provided in Rule 480-27-.02(2) or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22.
- (e) No prescription drug order issued by an APRN can be used to authorize refills more than twelve
- (12) months past the date of the original drug order unless the prescription drug order is for oral contraceptives, hormone replacement, or prenatal vitamins. Oral contraceptives, hormone

replacement and prenatal vitamins may be refilled up to twenty-four (24) months from the date of the original drug order.

- (3) Nothing in this Rule, Title 16, Chapter 13 or Title 43, Chapter 34, shall be construed to create a presumption of liability, either civil or criminal, on the part of a pharmacist who in good faith fills a prescription drug order presented by a patient that had been issued by a PA or an APRN consistent with this Rule.
- (a) A pharmacist shall presume that a prescription drug order issued by a PA or APRN was issued by a PA or APRN duly licensed and qualified under Title 43, Chapter 34 to prescribe pharmaceutical agents.
- (b) A pharmacist shall presume that the drug prescribed by the PA is a drug approved by the supervising physician in the PA's job description and that the drug prescribed by an APRN is a drug authorized by the delegating physician in the APRN's nurse protocol agreement, unless the pharmacist has actual or constructive knowledge to the contrary.
- (4) Any prescription drug order form containing less information than that described in this Rule shall not be offered to or accepted by any pharmacist.

Authority: O.C.G.A. §§16-13-21, 16-13-41, 16-13-70.1, 16-13-72, 26-4-5, 26-4-27, 26-4-28, 26-4-80, 43-34-25, 43-34-103, 21 C.F.R. 1301.22, and 45 C.F.R. Part 162.