**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,**
**RULE 480-22-.04 REQUIREMENTS OF A SCHEDULE II (C-II) 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-.04 REQUIREMENTS OF A SCHEDULE II (C-II) 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, 16-13-39, 16-13-41, 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-60, 26-4-80.1, 26-4-82, and 26- 4-111.

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-.04 REQUIREMENTS OF A SCHEDULE II (C-II) CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER.

Purpose of Rule: The purpose of these rule amendments is to permit the electronic transmission of C-II prescription drug orders that meet the requirements of state and federal law and regulation.

Main Features: The main feature of these rule amendments is to require the use of security paper except as provided for within the rule and applicable law.

## DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-22-.04 REQUIREMENTS OF A SCHEDULE II (C-II) CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER.

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

## RULE 480-22-.04 REQUIREMENTS OF A SCHEDULE II (C-II) CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDER.

(1) A pharmacist or pharmacy intern/extern shall dispense a schedule II Controlled Substance (C-II), as defined by O.C.G.A. § 16- 13-26, only pursuant to a ~~written~~ prescription drug order on security paper, except as provided in subparagraphs (1)(a) and (1)(b) and paragraph (3) of this Rule.
(a) A C-II prescription drug order, meeting the requirements of Rule 480-22-.03(1)(a), may be transmitted by the practitioner or the practitioner's agent, to a pharmacy via facsimile machine or equipment. Prior to the practitioner's agent transmitting such schedule II (C-II) prescription via facsimile machine, the C-II prescription drug order, meeting the requirements of Rule 480-22-.03(1)(a), may be transmitted by the practitioner or the practitioner's agent, but not the patient or patient's agent, to a pharmacy via facsimile machine or equipment. The original written, signed prescription drug order must be presented to the pharmacist prior to the actual dispensing of the schedule II (C-II) drug, except as provided in paragraphs (4), (5) or (6) of this section.
(b) A pharmacist may dispense a C-II pursuant to an electronic data prescription drug order where the prescription is transmitted by the practitioner directly to the pharmacy and the prescription otherwise 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 or any other applicable state or federal law or regulation for dispensing of a C-II prescription drug order transmitted via electronic means.
(2) Upon dispensing a schedule II (C-II) drug, the pharmacist shall physically sign his or her name on either the face or rear of the schedule II (C-II) prescription drug order in such a manner that the signature does not cover any information required by this chapter. In addition, the pharmacist will ensure that the dispensing date and the serial number for the prescription drug order are indicated on either the face or the back of the C-II prescription drug order.
(3) In the case of an emergency situation, a pharmacist may dispense a schedule II (C-II) controlled substance only upon receiving oral authorization of the prescribing practitioner. For purposes of this paragraph, an emergency situation means a situation in which the prescribing practitioner determines that immediate administration of a schedule II (C-II) controlled drug is necessary, there is no appropriate alternative treatment or drug in a schedule less than CII, and it is not reasonably possible for the practitioner to provide a written prescription drug order for the pharmacist dispensing the drug prior to issuance. Such emergency prescription drug order is permissible provided that:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period must be pursuant to an additional written prescription drug order signed by the prescribing practitioner;
(b) The prescription drug order shall be immediately reduced to writing by the pharmacist or pharmacy intern/extern working under the direct supervision of a licensed pharmacist and shall contain all information required in Rule 480-22-.03, except for the signature of the prescribing practitioner;
(c) If the prescribing practitioner is not known to the pharmacist, the pharmacist must make reasonable effort to determine that the oral authorization came from a licensed practitioner, such effort may include a callback to the prescribing individual using his or her telephone number and/or other good faith efforts to insure the practitioner's identity; and
(d) Within 7 days after authorizing an emergency oral prescription drug order, the prescribing practitioner shall cause a written prescription drug order to be delivered to the dispensing pharmacist for the emergency quantity prescribed. In addition to conforming to the requirements of Rule 480-22-.03, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order.
1. The written prescription drug order shall be delivered to the pharmacist in person or by other means, but if delivered by mail or common carrier it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription drug order to the emergency oral prescription drug order, which had earlier been reduced to writing. The pharmacist shall notify the Georgia Drugs and Narcotics Agency, if the prescribing practitioner fails to deliver a written prescription drug order to the dispensing pharmacist.
(4) A prescription drug order for a terminally ill patient, prepared in accordance with Rule 480- 22-.03 written for a Schedule II Controlled Substance as defined by O.C.G.A. §16-13-26, may be transmitted directly by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile machine.
(a) Prior to the prescribing practitioner's agent transmitting such Schedule II Controlled Substance prescription via facsimile machine, the name of the agent and a telephone number for the prescribing practitioner must be included in the face of prescription. The information may be used for verification of the prescription.
(b) The facsimile serves as the original, written prescription drug order for purposes of this paragraph, and it shall be maintained in accordance with Rule 480-22-.04(7) and this chapter. After transmission of the original prescription, the pharmacist should suggest that the practitioner mark "VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical record chart.
(5) A prescription drug order prepared in accordance with Rule 480-22-.04 written for any C-II substance for a resident of Long Term Care Facility (LTCF) may be transmitted directly by the prescribing practitioner or the practitioner's agent, but not the patient or the patient's agent, to the dispensing pharmacy by facsimile machine or equipment.
(a) The practitioner, ~~or~~ practitioner's agent, or pharmacist will note on the prescription drug order that the patient is a LTCF patient by writing "LTCF" on the face of the prescription.
(b) In addition to the term LTCF being noted on the face of the prescription, whenever a practitioner's agent transmits or a pharmacist receives such a prescription, the name of the agent and the practitioner's telephone number or the name and license number of the pharmacist must be included on the face of the prescription. This information may be used for verification of the prescription drug order.
(c) The facsimile serves as the original, written prescription drug order for purposes of this paragraph (c), and it shall be maintained in accordance with Rule 480-22-.04(a) and this chapter. After transmission of the original prescription, the pharmacist should suggest that the practitioner mark

"VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical record chart.
(6) A prescription drug order prepared in accordance with Rule 480-22-.03 written for any Schedule II Controlled Substance as defined by O.C.G.A. § 16-13-26, for a patient of a hospice program licensed by the State of Georgia Department of ~~Human Resources~~ Community Health may be directly transmitted by the practitioner or the practitioner's agent, but not the patient or the patient's agent, to the dispensing pharmacy by facsimile machine or equipment.
(a) The practitioner or practitioner's agent will note on the prescription drug order that the patient is a hospice patient by writing "HOSPICE" on the face of the prescription.
(b) In addition to the term "HOSPICE" being noted on the face of the prescription, whenever a practitioner's agent transmits such prescription, the name of the agent and the practitioner's telephone number must be included on the face of the prescription. This information may be used for verification of the prescription drug order.
(c) The facsimile serves as the original, written prescription drug order for purposes of this paragraph, and it shall be maintained in accordance with Rule 480-22-.04(a) and this chapter. After transmission of the original prescription drug order, the pharmacist should suggest that the practitioner mark "VOID" across the face of the prescription, and that it be maintained by the practitioner in the patient's medical chart.
(7) Record keeping for Schedule II Controlled Substances shall be as follows:
(a) Original and all other hard copy schedule II (C-II) prescription drug orders shall be maintained in a separate file from all other prescription drug orders.
(b) Whenever a pharmacy utilizes a computerized record keeping system in addition to hard copies to record the dispensing of prescription drug orders for C-II drugs, such records shall be immediately retrievable without delay in a printout form by the prescribing practitioner's name, patient's name, drug name or date of dispensing upon a verbal request from a representative of the Georgia Drugs and Narcotics Agency (GDNA), and/or one of its agents.
(8) Whenever a pharmacist receives a prescription for a C-II controlled substance, and either the quantity of the drug to be dispensed or the strength of the drug to be dispensed has not been included by the prescribing practitioner, or when the strength of the prescribed drug is not immediately available, in order to dispense this drug, the pharmacist must perform the following:
(a) Contact and speak directly with the practitioner, not with an agent for the practitioner, and inform the practitioner of the missing information on the face of the prescription, or the problem with the prescription in question by:
1. Determining the quantity of the drug the practitioner intended to be dispensed; or
2. Determining the strength of the drug the practitioner intended to be dispensed; or
3. Informing the practitioner the drug in the strength prescribed is not immediately available, but another strength of the prescribed drug is available.
(b) Regarding the information provided by the practitioner, the pharmacist must write the missing quantity, the missing strength, or the changed quantity and strength of the prescribed drug on the face of the prescription along with the initials of the pharmacist.
(c) On the back of the prescription, the pharmacist must write the date and time the pharmacist spoke with the practitioner, along with a brief explanation of the situation and how it was resolved.
(d) Nothing in this rule is intended to require a pharmacist in a hospice or LTCF setting to obtain a new prescription drug order when changes are made to a patient's dosing requirements. This action may be taken as long as the pharmacist verifies the change(s) with the practitioner and makes a notation of the change(s) along with the date of the change(s) on the original hardcopy prescription drug order.
(9) A Schedule II narcotic controlled substance prescription prepared in accordance with Rule 480-22-.03 and as defined by O.C.G.A. § 16-13-26, to be compounded for the direct administration to a

patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this rule and it shall be maintained in accordance with this rule and state and federal law.

Authority: O.C.G.A. §§16-13-34, 16-13-39, 16-13-41, 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-60, 26-4-80.1, 26-4-82, and 26- 4-111.