Security Paper for hard copy Schedule II Controlled Substance prescriptions

JULY 12, 2013

House bill 209 was passed by the General Assembly and signed into law by Governor Deal on April 24th. The changes included in this law took effect as of July 1st, 2013.

Among these changes were to remove any requirement for hard copy prescription pads to have an identifying lot number and a sequential serial number on each separate prescription in a pad. These requirements were replaced by allowing the Board to approve and adopt the use of prescription pads or paper that meet the requirements of the Centers for Medicare and Medicaid Services (CMS).

Further, hard copy prescription security paper vendors no longer have to be approved by the board. Any such vendor that produces CMS approved security paper can market that paper for sale in Georgia.

Lastly, the board's seal of approval does not have to be affixed to any hard copy prescription security paper if that paper meets the CMS security paper requirements.

In effect, because of these changes in the law, it is unnecessary for the Board to have a policy for use of security paper for hard copy prescription drugs orders, and it no longer exists.

Chapter 480-22 REQUIREMENTS OF A PRESCRIPTION UNDER ORDER

Rule 480-22-.01 Definitions

Except as noted herein, any term contained in this chapter shall have the same meaning as set forth in O.C.G.A. §§ 16-13-21, 26-3-2, 26-4-5, and Title 43, Chapter 34.

Rule 480-22-.02 Purpose for Issuance of a Controlled Substance Prescription Drug Order

(1) For a controlled substance prescription drug order to be legal, it must be issued for a legitimate medical purpose by an authorized individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of controlled substances is upon the prescribing practitioner, but the pharmacist is responsible for the proper filling of the prescription drug order. Any person knowingly filling a purported prescription drug order, as well as the person issuing it, shall be subject to disciplinary action.

(2) A controlled substance prescription drug order issued by an individual practitioner, in his or her name or written "For Office Use" to obtain a controlled substance for the purpose of general dispensing or administration to patients in his/her office shall not be filled by a pharmacist.

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.

(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.

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 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, 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 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.

Rule 480-22-.05 Refilling of a Schedule II (C-II) Controlled Substance Prescription Drug Order

The refilling of a prescription for a schedule II (C-II) controlled substance is prohibited.

Rule 480-22-.06 Partial Filling of a Schedule II (C-II) Controlled Substance Prescription Drug Order

(1) The partial filling of a schedule II (C-II) prescription drug order is permissible, if the pharmacist is unable to supply the full quantity prescribed in a written or emergency oral prescription drug order, and the pharmacist makes a notation on the face of the written prescription drug order of the quantity supplied (dispensed).

(a) Except as provided for in paragraph (b), the remaining portion of the prescription drug order may be filled within 72 hours of the first partial filling.

(b) After this 72 hour period, the remaining quantity shall not be dispensed, thereby causing the remaining quantity to be void. No additional quantity may be dispensed without receipt of a new prescription drug order.

(2) A prescription drug order for a schedule II (C-II) controlled substance written for a patient in a Long Term Care Facility (LTCF), a hospice patient, or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities.

(a) If there is any question whether a patient may be classified as having a terminal illness (TI), the pharmacist must contact the prescribing practitioner prior to partially filling the prescription drug order. The pharmacist must record on the prescription drug order whether the patient is "terminally ill", a "hospice patient", or a "LTCF patient".

(b) A prescription drug order may not be partially filled unless it contains the notation "terminally ill", "hospice patient", or "LTCF patient", or it shall be deemed an unlawful prescription drug

order.

(c) For each partial filling, the dispensing pharmacist shall record on the back of the prescription drug order (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

(d) The total quantity of a schedule II (C-II) controlled substance dispensed in all partial fillings may not exceed the total quantity prescribed. Such C-II prescription drug orders may be partially filled for a period not to exceed 60 days from the dispensing date or sooner if the medication is discontinued.

(3) Information pertaining to current schedule II (C-II) prescription drug orders for patients in a LTCF, a hospice, or for terminally ill patients may also be maintained in a computerized system if this system has the capability to permit the following:

(a) Output (display or printout) of the original prescription drug order serial number, date of dispensing, identification by name of the prescribing practitioner, identification by name of the patient, address of the LTCF, hospice, the hospital, or residence of the patient, identification of the medication dispensed to include, dosage, form, strength, and quantity, listing of the partial fillings that have been dispensed under each prescription drug order, and the information required in this rule.

(b) Immediate updating of the prescription drug record each time a partial filling is conducted.

(c) Retrieval of partially filled C-II prescription drug order information is the same as required by Rule 480-22-.09 for Schedule III and IV prescription refill information.

Rule 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders

(1) A pharmacist or pharmacy intern/extern may dispense Schedule III, IV and V Controlled Substances (C-III, IV, V), as defined by O.C.G.A. §§ 16-13-27, 16-13-28, and 16-13-29, pursuant to:

(a) A written prescription drug order bearing the signature of a practitioner as permitted by this rule;

(b) A facsimile of a written, signed prescription drug order transmitted directly to the pharmacy with the requirements contained in O.C.G.A. § 26-4-80, by the practitioner of the practitioner's agent;

(c) An oral prescription drug order made by an individual practitioner and promptly reduced to writing by the pharmacist or pharmacy intern/extern to a hard copy; and

(d) A written prescription drug order transmitted via electronic means other than a facsimile, if it meets the requirements and limitations for electronically transmitted prescription drug orders set forth in O.C.G.A. § 26-4-80, and Rules as set forth by the Board. Such electronically received prescription drug orders must be promptly reduced to hard copy, except as follows:

(2) Permanent records of electronic prescriptions do not

have to be reduced to hard copy provided the following requirements are met:

A). Electronic prescription data must be maintained in the original format received for a minimum of two years; and

B). Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1hr UL approved) container, stored in a secured offsite location or backed up to a documented offsite secure storage device within 48 hours following each work day.

(3) A pharmacy must either file the original prescription drug order or generate a hard copy prescription drug order to be filled, both of which are required to contain all of the information required by this chapt

(4) Upon dispensing a C-III, IV, or V controlled substance, the dispensing pharmacist shall ensure that his or her initials, the dispensing date, and the prescription serial number appear on the face of or the rear of each such prescription. Nothing shall prohibit the use of a computer-generated label to fulfill the requirements of this paragraph and/or the requirements of this Rule.

(a) All such information shall be placed on the prescription drug order in such a manner that it does not cover or veil any information required by this chapter or any other rule or law to appear on such prescription.

(5) Prescription drug orders for schedule C-III, IV, or V controlled substances shall be maintained either in a separate prescription drug order file for such C-III, IV, or V drug orders only or in such a form that they are readily retrievable from the other prescription drug orders of the pharmacy.

(a) A prescription drug order will be deemed readily

retrievable if, at the time it is initially filled, the face of the prescription drug order is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed in the usual consecutively numbered prescription drug order file for dangerous drugs; or

(b) A pharmacy which utilizes a computerized record keeping system for prescription drug orders which permits identification of prescription drug orders by serial number and retrieval of documents by prescriber's name, patient's name, drug dispensed, and date filled, then there is no requirement to mark hard copy prescriptions with a red "C".

Rule 480-22-.08 Refilling of Schedule III, IV, and V (C-III, IV, V) Controlled Substance Prescription Drug Orders

(1) No prescription drug order for a C-III, IV, or V controlled substance shall be filled or refilled more than six (6) months after the date on which such prescription drug order was issued by the prescribing practitioner and no such prescription drug order may be authorized to be refilled for the quantity prescribed more than five (5) times.

(a) Nothing shall prohibit the refilling of such a prescription drug order in amounts less than the quantity prescribed as long as the total number of dosage units authorized for dispensing both the original quantity plus the refill quantities does not exceed six (6) months.

(2) The date of each refilling of a prescription drug order shall be entered on the back of the prescription drug order or in a computerized record system, with which all documents must be uniformly maintained and readily retrievable.

(3) If the pharmacist initials and dates the back of the prescription drug order, it shall be deemed that the full face amount of the prescription has been dispensed. If an amount other than the full face amount is dispensed, the quantity shall be noted next to the initials of the pharmacist.

(4) The prescribing practitioner may authorize additional refills of the original C-III, IV or V controlled substance prescription drug order through an oral refill authorization transmitted directly to the pharmacist or pharmacy intern/extern working under the direct supervision of a licensed pharmacist provided the following conditions are met:

(a) The total quantity of refills authorized, including the quantity of refills indicated on the original prescription drug order does not exceed five (5) refills and does not extend beyond six (6) months from the date of issue of the original prescription drug order.

(b) The pharmacist or pharmacy intern/extern that receives the oral authorization shall record on the reverse side of the original prescription drug order the date, quantity of refill, number of additional refills authorized (for the quantity prescribed), and the initials showing who received the authorization from the prescribing practitioner that issued the original prescription drug order.

(c) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription drug order.

(d) The prescribing practitioner must execute or authorize a completely new and separate prescription drug order for any additional

quantities beyond the five (5) refills and/or six (6) month limitation.

(e) If the authorization comes from a practitioner that is not the original prescriber, the authorization shall be treated as a new prescription drug order authorized by the new prescribing practitioner.

(5) An automated data processing (ADP) or computerized system may be used for the storage and retrieval of refill information for prescription drug orders for C-III, IV or V substances, subject to the requirements as set forth in Rule 480-27-.04.

Rule 480-22-.09 Partial Filling of Schedule III, IV, and V (C-III, IV, V) Controlled Substance Prescription Drug Ord

The partial filling of a C-III, IV, or V prescription drug order is permissible, subject to the following requirements:

(a) Each partial filling is recorded in the same manner as a refill;

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

(c) No dispensing occurs six (6) months after the date on which the prescription drug order was issued.

Rule 480-22-.10 Labeling of Controlled Substance Prescription Drug Orders

(1) A pharmacist filling a prescription drug order for a C-II, III, IV or V substance shall affix to the package a label showing the following:

(a) The name, address and telephone number of the pharmacy;

(b) The prescription drug order serial number;

(c) The date the prescription was initially filled or refilled;

(d) The name of the patient;

(e) The name of the prescribing practitioner;

(f) The directions for use;

(g) The expiration date of the dispensed drug; and

(h) Cautionary statements, if any, as required.

(2) All prescription drug orders for C-II, III, IV or V controlled substances shall be kept in accordance with this chapter.

Rule 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes

(1) The transfer of original prescription drug order information for a C-III, IV, or V substance for the purpose of refill dispensing is permissible between pharmacies one time only.

(a) However, pharmacies electronically sharing a real-time, online computerized database may transfer the prescription drug order information as many times as there are authorized refills, up to the maximum of five (5) times, if it is within six (6) months from the date of issuance.

(2) A transfer is considered a communication between two licensed pharmacists and/or pharmacy interns/externs. Transfers are subject to the following requirements:

(a) The transferring pharmacist or pharmacy intern/extern shall record the following

information in either real time or at the first opportunity after the transfer:

1. The word "VOID" must be written on the face of the original, hard copy, invalidated prescription drug order;

2. The following must be written on the back of the original, invalidated prescription drug order: the name, address, telephone number, and DEA number of the pharmacy to which it is transferred, and the name of the pharmacist receiving the prescription information; and

3. The date of the transfer and the name of the pharmacist transferring the information must be recorded on the back of the prescription drug order.

(b) The pharmacist or pharmacy intern/extern receiving the transferred prescription drug order information shall reduce it to writing and record the following information:

1. The word "TRANSFER" shall be written on the face of the transferred prescription drug order hard-copy;

2. All information required to be recorded on a prescript ion drug order pursuant to this chapter, which shall include:

   (i) Date the prescription drug order was originally issued by the prescribing practitioner;

   (ii) The number of refills authorized on the original prescription drug order.

(c) Date the prescription drug order was originally dispensed by the transferring pharmacy;

(d) Number of valid refills remaining, and date(s) and pharmacy location(s) where any previous refills were dispensed;

(e) The pharmacy's name, address, telephone number, DEA number, and prescription serial number from which the prescription information was transferred; and

(f) The name of the pharmacist who transferred the prescription drug order.

(3) The original and transferred prescription(s) must be maintained for a period of two yearsfrom the date of the last refill.

(4) Pharmacies electronically transferring a prescription drug order for the purpose of refills must maintain the same information and record keeping requirements as do pharmacies with manual, non-electronic record keeping systems.

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 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.

(d) The prescription drug order must 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 of the PA;

(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 authorize 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 co-signature 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.

(d) The prescription drug order must 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.

Rule 480-22-.13 Requirements of a Prescription Drug Order for Drugs that are Scheduled Under the Georgia Controlled Substances Act, but not Scheduled Under the Federal Controlled Substances Act

(1) Any drug scheduled under the Georgia Controlled Substances Act (GCSA), but not scheduled under the Federal Controlled Substances Act (FCSA), must be purchased, stored, inventoried, recorded, distributed, or dispensed in the same manner as any other controlled substance, except:

(a) The manufacturer of the product is not required to indicate the schedule of the drug on the label of its commercial container; and

(b) The manufacturer of the product is not required to print the symbol designating the schedule of the drug on the label of its commercial container.

(2) A prescription drug order for any drug scheduled under the GCSA, but not scheduled under the Federal CSA, must be maintained in the same manner for the corresponding controlled substance prescription drug order as previously set forth in this chapter (480-22).

Rule 480-22-.14 Ordering and Receipt of Samples

(1) For purposes of this rule, a practitioner means:

(a) A physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, with respect to, or to administer a controlled substance or dangerous drug in the course of professional practice in this state;

(b) An advanced practice registered nurse (APRN) acting pursuant to the authority of Code Section 43-34-26.3. For purposes of this chapter and Code Section 43-34-26.3, an advanced practice registered nurse (APRN) who is registered with the Federal Drug Enforcement Administration (DEA) and appropriate state authorities; or

(c) A physician's assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103. For purposes of this chapter and subsection (e.1) of Code Section 43-34-103, a physician's assistant (PA) who is registered with the federal Drug Enforcement Administration (DEA) and appropriate state authorities.

(2) Only a practitioner which has been issued an individual permit number by the DEA and is licensed by its respective state licensing board is authorized to or any other type of container.

(3) Any practitioner receiving, maintaining, and dispensing professional drug samples shall maintain records of all drug samples requested and received, along with a complete list of the specific number and dosage of each professional drug sample and medication dispensed by the practitioner and the person to whom the drug samples were dispensed; Such records must be maintained for a minimum of two years by the practitioner at each facility or office location where professional drug samples are received, maintained, and dispensed.

(4) In addition to the requirements of this rule, practitioners shall maintain all professional drug samples as required by all applicable state and federal laws and regulations.

Rule 480-22-.15 Refilling of Ophthalmic Topical Products

Ophthalmic topical products may be refilled without authorization from a practitioner to prevent unintended interruptions in drug therapy provided that:

(1) The original prescription order contains valid refills;

(2) Refills occur at 70 percent or greater of the predicted days of use; and

(3) Refills are purchased through retail and/or mail order pharmacies.

Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes

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

Rule 480-22-.13 Requirements of a Prescription Drug Order for Drugs that are Scheduled Under the Georgia Controlled Substances Act, but not Scheduled Under the Federal Controlled Substances Act

Rule 480-22-.14 Ordering and Receipt of Samples

Rule 480-22-.15

Refilling of Ophthalmic Topical Products