NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES, RULE 480-22-.07 REQUIREMENTS OF SCHEDULE III, IV AND V (C-III, IV, V) CONTROLLED PRESCRIPTION DRUG ORDERS, 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-.07 REQUIREMENTS OF SCHEDULE III, IV AND V (C-III, IV, V) CONTROLLED PRESCRIPTION DRUG ORDERS (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 <u>www.gbp.georgia.gov</u>.

<u>A public hearing is scheduled to begin at 9:00 AM on August 18, 2021</u> at The University of Georgia College of Pharmacy, Pharmacy South Building, Room 303, 240 W. Green Street, Athens, GA 30602 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 August 11, 2021. Written comments at 2 Peachtree Street NW, 6th Floor, Atlanta, Georgia 30303. You may email your comments to elacefield@dch.ga.gov.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its <u>meeting scheduled to begin at 9:05 AM on August 18, 2021</u> at The University of Georgia College of Pharmacy, Pharmacy South Building, Room 303, 240 W. Green Street, Athens, GA 30602. 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, 26-4-27; 26-4-80, and 26-4-83.

At its meeting on April 14, 2021, 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.

Also, at its meeting on April 14, 2021, the Board 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 this chapter 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 13 day of <u>Soly</u>, 2021.

Eric R. Lacefield Executive Director Georgia Board of Pharmacy

Posted: <u>July</u> <u>13</u>, 2021

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-22-.07 REQUIREMENTS OF SCHEDULE III, IV AND V (C-III, IV, V) CONTROLLED PRESCRIPTION DRUG ORDERS

Purpose of Rule: The purpose of this amendment is to make minor clean up edits and allow for the maintenance of controlled substance III, IV, and V prescriptions in hardcopy or electronic format.

Main Feature: The main features of this amendment are to make minor grammatical changes, remove unnecessary language, and clarify that C_III, IV, and V prescription drugs orders can be maintained in hard copy or electronic format.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-22-.07 REQUIREMENTS OF SCHEDULE III, IV AND V (C-III, IV, V) CONTROLLED PRESCRIPTION DRUG ORDERS

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

480-22-.07 Requirements of Schedule III, IV, V (C-III, IV, V) Controlled 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).(a) Electronic prescription data must be maintained in the original format received for a minimum of two years; and
 - B).(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 or maintain the original prescription drug order, hard copy or electronically transmitted 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 chapter.

- (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".

Authority: O.C.G.A. Secs. 16-13-34, 16-13-39, 16-13-41, 26-4-27, 26-4-80, 26-4-83.