NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES, RULE 480-27-.01 DEFINITIONS, 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 480-27-.01 DEFINITIONS (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 9:00 AM on August 18, 2021 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 should be addressed to the Executive Director of the Georgia State Board of Pharmacy 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 meeting scheduled to begin at 9:05 AM on August 18, 2021 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. §§ 26-4-27 and 26-4-28.

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 13th day of **Suly**, 2021.

Eric R. Lacefield
Executive Director

Georgia Board of Pharmacy

Posted: Zuly 13,2

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-27-.01 DEFINITIONS

Purpose of Rule: The purpose of this amendment is to make minor clean up edits and delete the term "practitioner drug order" which is not found in the statutes or other rules.

Main Feature: The main feature of this amendment deletes subsection (q) for "practitioner drug order."

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-27-.01 DEFINITIONS

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

480-27-.01 Definitions

For purposes of these Rules and Regulations, the following definitions apply:

- (a) Authentication. Any process by which the identities of the parties sending and receiving electronic prescription data are verified.
- (b) Automated Electronic Data Processing System. A system utilizing computer software and hardware for the purpose of record-keeping and/or receiving prescription drug orders. Any and all such systems that are compatible and capable of interacting with, and electronically transferring prescription drug data with any other system must be in compliance with the rules of the Board for use in electronic prescription monitoring.
- (c) Board. The Georgia State Board of Pharmacy.
- (d) Computer. Programmable electronic device capable of multifunctions including but not limited to storage, retrieval, and processing of information.
- (e) Controlled Substances. Those drug items regulated by federal law and/or the Georgia Controlled Substances Act.
- (f) Dangerous Drugs. Those drug items and devices regulated by the Georgia Dangerous Drug Act.
- (g) Digital ID. An authenticated identifiable signature than can be attached to an electronic email and is tamper proof.
- (h) Downtime. That period of time when a computer is not operable.
- (i) Electronic Means. An electronic device used to send, receive, and/or store prescription drug order information, including computers, facsimile machines, etc.
- (j) Electronic Signature. An electronically reproduced visual image signature or an electronic data signature of a practitioner, which appears on, is attached to or is logically associated with an electronic prescription drug order.
- (k) Facsimile. A hard copy prescription drug order sent via a facsimile machine.
- (l) Hard Copy. A fileable prescription drug order which is written or printed via electronic means.
- (m) Hardware. The fixed component parts of a computer.
- (n) HIPPA. The Health Insurance and Portability and Accountability Act and the associated security standards for the protection of electronic protected health information.
- (o) Intervening Electronic Formatter. An entity that is not prohibited under O.C.G.A. Section 26-4-80(c)(1) and (5), and that provides the infrastructure that connects a computer or automated

electronic data processing system or other electronic device used by a prescribing practitioner with a computer or automated electronic data processing system or another electronic device used by the pharmacy to facilitate the secure transmission of:

- 1. An electronic prescription drug order;
- 2. A refill authorization request;
- 3. A communication; and
- 4. Other patient care information between a practitioner and pharmacy.
- (p) NPI. National Provider Standard Identifier.
- (q) Practitioner Drug Order. A drug order written in an institutional practice/setting in a patient's chart for a specific patient. It is not necessary to reduce to writing as required for a prescription drug order.
- (r)(q) Prescriber. A practitioner authorized to prescribe and acting within the scope of this authorization.
- (s)(r) Prescription Drug Order. A lawful order from a practitioner, acting within the scope of his or her license to practice, for a drug or device for a specific patient. Such order includes a written order from the practitioner, a telephone order reduced to writing by the pharmacist, and electronic image prescription drug order and an electronic data prescription drug order.
- (t)(s) Print-out. A hard copy document generated by computer or other electronic means that is readable without the aid of any special device.
- (u)(t) Regulatory Agency. Any federal or state agency charged with enforcement of pharmacy or drug laws and regulations, i.e., the Georgia Drugs and Narcotics Agency (GDNA), the Drug Enforcement Administration (DEA), or the Georgia Department of Medical Assistance (Medicaid).
- (v)(u) Security Paper. Paper with security features on which the electronic visual image prescription drug order of a practitioner is printed and presented to a patient so as to ensure that a prescription drug order is not subject to any form of copying, reproduction, or alteration, and may include a watermark produced by the electronic digital process when a prescription is printed that clearly shows if a prescription has been reproduced or copied in an unauthorized manner. Such security paper shall include, at a minimum, but not limited to, the following security features:
 - 1. A latent, repetitive pattern shall be visible across the entire front of the prescription blank if the prescription is scanned or photocopied; and
 - 2. A chemical void protection that prevents alteration by chemical washing.
- (w)(v) Software. Programs, procedures, and systems for receipt and/or storage of required information data.
- (x)(w) Stop Date. In institutional settings, the practitioner normally indicates on his/her drug order, the length of time to administer the medication. In absence of such a notation, a committee will have determined by policy, the length of time to administer the medication by category.

Authority: O.C.G.A. Secs. 26-4-5, 26-4-27 to 26-4-29, 26-4-37, 26-4-80, 26-4-83.