NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-27-.05 RECORD-KEEPING WHEN UTILIZING AN AUTOMATED ELECTRONIC DATA PROCESSING SYSTEM, 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-.05 RECORD-KEEPING WHEN UTILIZING AN AUTOMATED ELECTRONIC DATA PROCESSING SYSTEM (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 12:00 PM on September 17, 2014 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 September 10, 2014. 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: 678-717-6435. 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 12:05 PM on September 17, 2014 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. §§ 16-13-39, 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-80, 26-4-83, and 26-4-111.

At its meeting on July 16, 2014, 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 July 16, 2014, 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 14th day of August, 2014.

Tanja D. Battle

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: August 14, 2014

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-27-.05 RECORD-KEEPING WHEN UTILIZING AN AUTOMATED ELECTRONIC DATA PROCESSING SYSTEM

Purpose of Rule: The purpose of this rule is to set forth the conditions under which an automated electronic data processing system can be used for record-keeping.

Main Features: The main feature of this rule is to require separate copies of sight-readable hard-copy printouts or electronic readable files of daily prescription records.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-27-.05 RECORD-KEEPING WHEN UTILIZING AN AUTOMATED ELECTRONIC DATA PROCESSING SYSTEM

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

480-27-.05 Record-Keeping When Utilizing an Automated Electronic Data Processing System.

In order to comply with the record keeping requirements of this Chapter, an automated electronic data processing system may be utilized for the record keeping system if the following conditions have been met:

(a) Except as otherwise provided herein, all original prescriptions, those hard copies written by a practitioner, telephoned to the pharmacist by a practitioner and reduced to writing, or sent via facsimile machine or other electronic means must be retained as a permanent record for two years in the usual consecutively serial numbered prescription file. Any refill information subsequently authorized by a practitioner must be maintained in the manner required by O.C.G.A. § 26-4-80(e).

(b) The system shall at a minimum produce sight-readable ~~printouts~~ records for all dangerous drug and controlled substance prescriptions filled or refilled during ~~for~~ each 24 hour period. The term "sight-readable" means that a representative of the Board or GDNA shall be able to ~~readily~~immediately retrieve and examine the record and read the information during any on-site visit to the pharmacy. For purposes of off-site audits and review, a separate copy of any sight-readable hard-copy printout or electronic readable file (such as a PDF file) of each daily record shall be made available to a representative of the Board of GDNA upon verbal request by that representative. These daily prescription records can:

1. Be generated as hard-copy print-outs at least once weekly, separated into each 24 hour period, by the pharmacy and maintained for at least two years after the last date on which the prescription was filled or refilled. If a hard-copy printout of each day's filled and refilled prescription is generated, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (*e.g.*, J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date; or

2. Be maintained electronically. The computers on which the records are maintained may be located at another location, but the records must be immediately retrievable as hard-copy print-outs or viewing on a computer monitor set aside for such viewing at each individually registered pharmacy upon a verbal request by a representative from the Board or GDNA. The computer software must be capable of printing out or transferring the prescription records in a format that is readily understandable to the representative for the Board or GDNA at the registered location. Prescription records must also be sortable and retrievable by prescriber name, patient name, drug dispensed, and date filled. When utilizing electronic daily prescription fill and refill records, each pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the prescription information entered by him or her into the computer that day has been reviewed by him or her and is correct as shown. Such a book or file must be maintained at the pharmacy employing such software for a period of two years after the date of dispensing the appropriately authorized refill. ~~These print-outs must be generated at least once weekly by the pharmacy and maintained for at least two years after the last date on which the prescription was filled or refilled. If not readily retrievable, any such printouts shall be generated as soon as possible upon the verbal request from the Board or GDNA representative.~~

(c) The information maintained by the automated electronic data processing system shall include, but not be limited to the following:

1. Date of dispensing;
2. Prescription number;
3. Patient's name;
4. Patient's address;
5. Drug name, strength and dosage form;
6. Quantity prescribed, and if the quantity dispensed is different from the quantity prescribed, the quantity dispensed;
7. Prescriber's name;
8. Identification of dispensing pharmacist;
9. Indication whether drugs are being dispensed pursuant to a new prescription or for a refill order;
10. In case of a controlled substance as allowed by federal law, the name, address and DEA registration of the practitioner and the schedule of the drug;
11. Directions for administration of the prescription to the patient;
12. Total number of refills authorized; and
13. NPI of the prescriber as assigned under federal law.

(d) Permanent records of electronic prescriptions for dangerous drugs and controlled substances do not have to be reduced to hard copy provided the following requirements are met:

1. Electronic prescription data must be maintained in the original format received for a minimum of two years; and
2. Reliable backup copies of the information are readily retrievable and stored in a secure and fireproof (minimum 1 hr 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.

(e) The individual pharmacist responsible for completeness and accuracy of the entries to the system must provide documentation that prescription information entered into the computer is correct, by dating and signing the print-out in the same manner as signing a check or legal document (e.g., Mary A. Smith or M. A. Smith).

(f) An auxiliary record-keeping system shall be established for the documentation of filling new prescriptions, refills, and transfers if the automated electronic data processing system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When this automated electronic data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated electronic data processing system as soon as possible. However, nothing in this section shall preclude the pharmacist from using his/her professional judgment for the benefit of a patient's health and safety.

(g) Any pharmacy using an automated electronic data processing system must comply with all applicable State and Federal laws and regulations.

(h) A pharmacy shall make arrangements with the supplier of data processing services or materials to insure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall insure continuity in the maintenance of records.

Authority: O.C.G.A. §§16-13-39, 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-80, 26-4-83, and 26-4-111