NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES, RULE 480-27-.03 RECORDS OF DISPENSING., 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-.03 RECORDS OF DISPENSING. (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 11:00 AM on January 14, 2016 at the South University School of Pharmacy, 709 Mall Boulevard, Savannah, Georgia 31406 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 January 4, 2016. 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 totalle@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 11:05 AM on 1/14/2016 at the South University School of Pharmacy, 709 Mall Boulevard, Savannah, Georgia 31406. 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, 26-4-27, 26-4-28, 26-4-80, 26-4-81, 26-4-83, 43-34-24.

At its meeting on November 18, 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 11/18/2015, 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 30th day of November, 2015.

Jacque D. Buttle
Tanja D. Butle
Executive Director

Georgia Board of Pharmacy

Posted: November 30, 2015

SYNOPSIS OF PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-27-.03 RECORDS OF DISPENSING.

Purpose of Amendments: The purpose of these amendments is to require all pharmacies licensed by the Board to maintain a perpetual inventory of all controlled substances received, stored, distributed, and dispensed by the pharmacy for two years, effective May 1, 2016.

Main Features: The main feature of these amendments is to require perpetual inventories and reconciliation logs to be maintained for two years.

DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE GEORGIA STATE BOARD OF PHARMACY RULE 480-27-.03 RECORDS OF DISPENSING.

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

480-27-.03 Records of Dispensing.

- (1) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for two years and shall include, but not be limited to:
- (a) Quantities dispensed;
- (b) Date of dispensing;
- (c) Serial number (or equivalent if an institution);
- (d) The identification of the pharmacist responsible for dispensing;
- (e) Documentation of satisfaction of state requirements for drug product selection;
- (f) Records of refills to date to include date(s) of refills, and identification of pharmacist(s) dispensing refills.
- (2) Effective May 1, 2016, all pharmacies licensed by the Board must maintain a perpetual inventory of all controlled substances received, stored, distributed and dispensed by the pharmacy for a period of two years.
- (3) A physical inventory count must be made of all controlled substances on hand and maintained in a printed form. The inventory must conform to all DEA inventory requirements and must be signed and dated by the pharmacist conducting the inventory. The date on which the inventory was made becomes the new biennial inventory date for that licensee and the controlled substances must be inventoried biennially thereafter.
- (4) All biennial inventories must be maintained for two (2) years and must be made available to the Board or its representative, upon request.
- (5) If a perpetual inventory is maintained by electronic means instead of manually, a pharmacist must perform a personal reconciliation at least every seven (7) days to verify the accuracy of the electronic inventory. Only a pharmacist can reconcile or correct a perpetual inventory. A reconciliation log must be created which contains the printed name, license number, and signature of both the person doing the reconciliation or correction along with the person verifying the reconciliation or correction. Each entry on the log must be dated and accompanied by an explanation for the reconciliation or correction.
- (6) All perpetual inventories and reconciliation logs must be maintained for a minimum of two (2) years and be immediately available to the GDNA for inspection and copying.

Authority: O.C.G.A. §§16-13-39, 26-4-27, 26-4-28, 26-4-80, 26-4-81, 26-4-83, 43-34-24.