

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-10-.01 CONTROLLED SUBSTANCES AND DANGEROUS DRUGS:
INSPECTION, RETENTION OF RECORDS AND SECURITY., 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 480-10-.01 CONTROLLED SUBSTANCES AND DANGEROUS DRUGS: INSPECTION, RETENTION OF RECORDS AND SECURITY. (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 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 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. §§ 16-13-34, 16-13-39, 16-13-45, 16-13-46, 26-3-17, 26-4-4, 26-4-27 to 26-4-29, 26-4-37, 26-4-50, 26-4-53, 26-4-106, 26-4-115.

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.

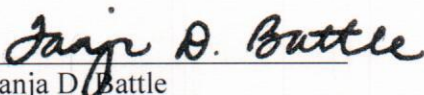
At its meeting on 11/18/2015, the Board also voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of

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.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: November 30, 2015

**SYNOPSIS OF PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-10-.01 CONTROLLED SUBSTANCES AND DANGEROUS DRUGS: INSPECTION,
RETENTION OF RECORDS AND SECURITY.**

Purpose of Amendments: The purpose of these amendments is to authorize GDNA personnel to conduct inspections, examine records, and provide inspection reports.

Main Features: The main feature of these amendments is to authorize GDNA personnel to examine drugs and records.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
480-10-.01 CONTROLLED SUBSTANCES AND DANGEROUS DRUGS: INSPECTION,
RETENTION OF RECORDS AND SECURITY.**

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

**480-10-.01 Controlled Substances and Dangerous Drugs: Inspection,
Retention of Records and Security.**

- (1) Every retail pharmacy, possessing or having possessed any controlled substances and/or dangerous drugs, within a period of two years, and/or possessing any record related to the same, which is required to be kept by O.C.G.A. T. Ch. 16-13, shall exercise diligent care in protecting such controlled substances and/or dangerous drugs and/or records related to the same from loss or theft.
- (a) Every licensed retail pharmacy shall ensure that all controlled substances and/or dangerous drugs are purchased from and/or returned to firms holding a current permit issued by the Georgia State Board of Pharmacy (Board). This requirement can be met by a pharmacy maintaining a copy of such firms' current Georgia Board permit.
- (2) All controlled substances and/or dangerous drugs shall be kept in a secure place accessible only to an authorized person.
- (3) ~~Special Agents or Deputy Directors of the~~ The Georgia Drugs and Narcotics Agency (GDNA) shall have the authority to conduct inspections of any place or premises used by any such licensed retail pharmacy in relation to such controlled substances and/or dangerous drugs and/or any records pertaining to their acquisition, dispensing, disposal, or loss.
- (4) ~~The GDNA Special Agents or Deputy Directors~~ shall have the authority to examine, copy, or remove all such records, and to examine, copy, remove, or inventory all such controlled substances and/or dangerous drugs.
 - (a) It shall be the responsibility to such person possessing such controlled substances and/or dangerous drugs and/or records to make the same available for such inspection, copying, examination, or inventorying by said GDNA, ~~Special Agents or Deputy Directors~~.
 - (b) At the conclusion of an inspection, the GDNA ~~Special Agents or Deputy Director~~ personnel examining said drugs and/or records shall have the responsibility of providing to such retail pharmacy a copy of a written inspection report on which any deficiencies or violations are made along with any recommendations, if any, concerning the satisfactory storage, keeping, handling and security of controlled substances and/or dangerous drugs.

(5) Any person possessing controlled substances and/or dangerous drugs and/or records may request that such an inspection be made, and upon receipt of such written request, the GDNA Director shall make, or cause to be made, without reasonable delay, an inspection in compliance with said request.

Authority O.C.G.A. §§16-13-34, 16-13-39, 16-13-45, 16-13-46, 26-3-17, 26-4-4, 26-4-27 to 26-4-29, 26-4-37, 26-4-50, 26-4-53, 26-4-106, 26-4-115.