

**NOTICE OF INTENT TO AMEND RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-7-.04 RESEARCHER'S PERMIT, 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 480-7-.04 RESEARCHER'S PERMIT (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 December 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 December 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: 678-717-6694. 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 12/17/2014 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. §§ 26-4-27, 26-4-28, 26-4-49, 26-4-60, 26-4-120.2.

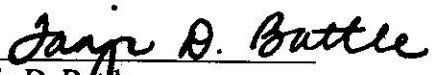
At its meeting on October 22, 2014, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

At its meeting on 10/22/2014, 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 November, 2014.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: November 14, 2014

**SYNOPSIS OF PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-7-.04 RESEARCHER'S PERMIT**

Purpose of Rule: The purpose of this rule is to require the filing of an application prior to the issuance of a researcher's permit.

Main Features: The main feature of this rule is to set forth the application procedure for issuance of a researcher's permit.

**DIFFERENCES OF THE PROPOSED AMENDMENTS TO THE
GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-7-.04 RESEARCHER'S PERMIT**

480-7-.04 Researcher's Permit.

- (1) Applications for registration must be filed with the Office of the Georgia State Board of Pharmacy ("Board"), ~~in duplicate~~ with the required fees.
- (2) Registration of a Researcher will be considered on the basis of the application filed and a report from the director of the GDNA certifying the applicant possesses the necessary qualifications for a permit.
- (3) Application fees shall NOT be refundable.
- (4) Permits shall not be transferable. Permits become null and void upon the change of mode, operation and/or location of the permit-holder.
- (5) Permits are renewable every two (2) years and expire on June 30th of the even-numbered years. Permits may be renewed upon the payment of the required renewal fee and the filing of the renewal application form. If the application is not made and the fee not paid before September 1st of the even-numbered year, the permit shall lapse and shall not be renewable except by application for a new permit.
- (6) Minimum Qualifications:
 - (a) The Board will consider the following factors in determining eligibility for persons or entities applying for permits to engage in research.
 1. Any convictions of the applicant under any Federal, State, or local laws related to dangerous drugs or controlled substances;
 2. Any felony convictions of the applicant under any Federal, State, or local laws;
 3. The applicant's past experience in research related to dangerous drugs including controlled substances;
 4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug research;
 5. Suspension or revocation by Federal, State or local government of any permit currently or previously held by the applicant for drug research;
 6. Compliance with the requirements under previously granted permits or licenses, if any;
 7. Compliance with requirements to maintain and/or make available to the State licensing or permitting authority or to Federal, State or local law enforcement officials those records required to be maintained by researchers;
 8. Any other factors or qualifications such as age, education, training, etc. the Board considers relevant to be inconsistent with the public health and safety; and
 9. Having a Peace Officer Certification suspended or revoked by the Georgia Peace Officers Standard and Training (POST) or other professional licensing authority.
 - (b) The Board reserves the right to deny a permit to any applicant if it determines that the granting of such a permit would not be in the public interest.
- (7) Storage and Security:
 - (a) All drugs including dangerous drugs and controlled substances shall be stored at appropriate temperatures and under appropriate conditions in accordance with labeled requirements or those published in the current edition of an official compendium, such as the United States Pharmacopoeia (USP) Compendiums;
 - (b) All facilities used for storage of drugs including dangerous drugs and controlled substances shall be of suitable size and construction to facilitate cleaning, maintenance and proper operations; and shall provide security from unauthorized entry as approved by the Board or GDNA.

1. All such facilities will be located in an appropriately zoned district, such as a college, school, university, law enforcement office, or commercial area. No permit will be issued to any researcher whose facility is located in a residential area, dwelling, or location. The Board may choose to grant an exception to this rule upon receipt of a written request from such applicant stating the reason for such an exemption.

(8) Record Keeping and Accountability:

(a) Researchers shall establish and maintain records of all transactions regarding receipt, distribution or other disposition of dangerous drugs or controlled substances.

(b) All records required by these regulations shall be retained for a minimum period of two (2) years following any disposition of any drugs received.

(c) Such records shall be kept at the storage site or shall be immediately retrievable by computers or other electronic means for authorized inspection during the retention period.

(9) Sanctions and Penalties:

(a) The Board under these regulations shall have the power to suspend or revoke any permit issued or to reprimand or to fine, not to exceed \$500 per violation, the holder of such permit when such holder shall have:

1. Become unfit or incompetent;

2. Been convicted of a felony or any other crime involving moral turpitude;

3. Violated any Pharmacy laws or rules or regulations promulgated by the Board, or violated any other state, federal, or local laws and rules related to drugs.

4. The Board may refuse to grant a permit or renewal to any person, firm, corporation, agency, department or other entity for any of the grounds set forth in O.C.G.A. Section 26-4-49 and/or 26-4-60 of the Georgia Pharmacy Practice Act.

Authority: O.C.G.A. Secs. 26-4-27, 26-4-28, 26-4-49, 26-4-60, 26-4-120.2.