

**NOTICE OF INTENT TO ADOPT 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 adoption of new 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 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. 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 December 13, 2023 at Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334 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 6, 2023. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. 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 9:00 AM on December 13, 2023 at Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334. 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, and 26-4-110.

At its meeting on August 16, 2023, 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 August 16, 2023, 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 13 day of November, 2023.



Eric R. Lacefield
Executive Director
Georgia Board of Pharmacy

Posted: November 13, 2023.

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

Purpose: To amend the rule language to eliminate automatic nullification and voiding of a license in the event of a change of ownership of the licensee pharmacy. To provide a process by which a licensee may request to retain a license number in the event of a change of ownership of the licensee pharmacy. To identify events which constitute a change of ownership. To clarify that change of ownership events must be reported to the Board.

Main Features: Elimination of automatic nullification and voiding of a license in the event of a change of ownership. Provision of a process by which a license number may be retained, at the Board's discretion, upon request of the licensee. Identification of events which constitute a change of ownership. Clarification of a licensee's obligation to report changes of ownership to the Board.

**TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-7-.04 RESEARCHER'S PERMIT**

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

Text of the proposed rule is attached hereto.

Rule 480-7-.04. Researcher's Permit

- (1) Applications for registration must be filed with the Office of the Georgia State Board of Pharmacy ("Board") 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) No license issued under this Rule shall be transferred or assigned by a licensee. However, the Board may reassign a license to a licensee or successor entity by request upon application to the Board.
- (5) Prior to any change in name, ownership, mode of operation or location of a pharmacy, licensees shall apply for approval of such change by submitting a Board-approved application to the Board and paying a fee. To comply with the requirements of this Rule, applications must be made and approved prior to the change.
 - (a) A change of ownership is deemed to have occurred upon the closure of any transaction which results in a change to any of the ownership information submitted to the Board as part of the licensee's initial application for licensure or renewal of licensure.
- ~~(4)(6)~~ Licensees shall notify the Board in writing of the occurrence of any change to any of the information submitted to the Board as part of the licensee's initial application for licensure or application for renewal of licensure. This shall not apply to any event the occurrence of which these rules require immediate notification to the Board, in which event such immediate notification shall be made. Permits shall not be transferable. Permits become null and void upon the change of mode, operation and/or location of the permit holder.
- ~~(5)(7)~~ 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)(8)~~ 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)~~(9) 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)~~(10) 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)~~(11) 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. §§ 26-4-27, 26-4-28, 26-4-49, 26-4-60, 26-4-120.2.