

**NOTICE OF INTENT TO ADOPT PROPOSED RULE TO THE GEORGIA STATE BOARD
OF PHARMACY RULES
RULE 480-6-.02 NONRESIDENT PHARMACY 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 a new Rule to the Georgia Board of Pharmacy Rules, Rule 480-6-.02 NONRESIDENT PHARMACY PERMIT (hereinafter "proposed rule").

This notice, together with an exact copy of the proposed rule and a synopsis of the proposed rule, 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 proposed rule, and a synopsis of the proposed rule 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 9:00 AM on December 11, 2013 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303 to provide the public an opportunity to comment upon and provide input into the proposed rule. 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 may be received prior to December 4, 2013. 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 rule will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on December 11, 2013 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, GA 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed rule pursuant to authority contained in O.C.G.A. §§ 26-3-8, 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-83, 26-4-85, 26-4-110, 26-4-110.1, 26-4-114.1.

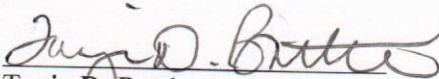
At its meeting on October 16, 2013, the Board voted that the formulation and adoption of this rule do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A. §§ 26-4-27, 26-4-28, 16-13-22.

Also, at its meeting on October 16, 2013, 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 rule 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 11th day of November, 2013


Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: November 12th, 2013

**SYNOPSIS OF PROPOSED RULE OF THE
GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-6, RULE 480-6-.02 NONRESIDENT PHARMACY PERMIT**

Purpose of Rule: The purpose of this rule is to set forth the conditions under non-resident pharmacies may lawfully ship, mail, or deliver prescription drugs into the state of Georgia.

Main Features: The main feature of this rule is to establish the information required on an application for a non-resident pharmacy permit.

**PROPOSED RULE FOR THE GEORGIA STATE BOARD OF PHARMACY RULES
RULE 480-6-.02 NONRESIDENT PHARMACY PERMIT**

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

480-6-.02 Nonresident Pharmacy Permit.

(1) Effective 05/01/2014, every pharmacy located out of the State of Georgia that ships, mails or delivers dispensed drugs into the State of Georgia must hold a permit issued by the Georgia State Board of Pharmacy in accordance with the laws and regulations of this State before shipping, mailing or delivering prescription drugs or offering to ship, mail or deliver prescription drugs into this State.

(2) Nonresident pharmacies that intend to ship, mail or deliver prescription drugs into this state must file an application for a Nonresident Pharmacy permit as follows:

(a) Applications must be filed in duplicate with the Georgia State Board of Pharmacy located at 2 Peachtree Street, SW, 36th Floor, Atlanta, Georgia 30303.

(b) The Board requires the following information from each applicant for a nonresident pharmacy permit as part of the initial licensing procedure and as part of any renewal of such permit.

1. The name, full business address, and telephone number of the applicant;

2. All trade or business names used by the applicant;

3. Address, telephone numbers, and the names of contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;

4. Address, telephone number and name of agent of service for the applicant;

5. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship);

6. The name(s) of the owner and/or operator of the pharmacy, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the incorporation; and the name of the parent company, if any; or

(iv) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.

7. Where operations are conducted at more than one location by a single pharmacy, each such location shall be permitted by the Board;

8. Proof of a valid, unexpired license, permit, or registration to operate a pharmacy in the compliance with the laws and rules of each state in which the applicant received and dispenses prescription drug orders;

9. The names and license numbers of each pharmacist and pharmacy technician involved in dispensing drugs to residents of this state and evidence that the pharmacist(s) and pharmacy technicians are licensed and in good standing in the state where they are located;
 10. Information necessary to demonstrate compliance with O.C.G.A. T. 50, Ch. 36;
 11. Evidence satisfactory to the Board that the applicant is in compliance with all laws and investigations from each regulatory or licensing agency in which the applicant holds a license; and
 12. If dispensing sterile or nonsterile compounding for practitioners to use in patient care in the practitioner's office, a copy of the most recent inspection report which is no older than six months before the date of application was submitted and which is from an inspection conducted by the regulatory or licensing agencies of the jurisdiction in which the applicant is located that indicates compliance with the Board's rules and regulations and compliance with USP-NF standards for pharmacies performing sterile and nonsterile compounding, or another inspection approved by or conducted by the Board.
- (3) Registration of a nonresident pharmacy permit will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the GDNA certifying the applicant possesses the necessary qualifications for a permit.
- (4) Application fees and renewal fees shall be set by the Board in a fee schedule, and shall not be refundable.
- (5) Permits may be denied for failure to comply with rules of the Board, for failure to meet the minimum qualifications for a permit, for the conviction by a owner or pharmacist of a felony involving the practice of practice or the distribution of drugs, for false representations on an application, and for any other good cause related to evidence of misfeasance or malfeasance by the applicant.
- (6) Permits become null and void upon the sale, transfer or change of mode of operation or location of the business. Prior to the sale, transfer or change in mode of operation or the location of the business, the nonresident pharmacy may apply for such change by submitting a Board approved application to the Board, and paying a fee. The permits of nonresident pharmacies will not become void of proper application is made and approved prior to the change.
- (7) Permits are issued for two years and expire on June 30th of each odd numbered Year, and may be renewed for two years upon the payment of the required fee for each place of business and the filing of an application for renewal. Applicants for renewal must submit such evidence as requested by the Board including, but not limited to evidence of certain inspection reports on compounding and the status of the licenses of the pharmacy and pharmacists in the state of location. If the application for renewal is not made and the fee paid before September 1st, of the odd numbered year, the permit shall lapse and shall not be renewed except by application for a new permit.
- (8) The denial of a nonresident pharmacy permit and the denial of the renewal of a nonresident pharmacy permit shall not be considered a contested case under the provisions of O.C.G.A. T. 50, Ch. 13, but the applicant shall be entitled to an appearance before the Board.
- (9) Nonresident pharmacy permit holders shall comply with all the recordkeeping requirements of Rule 480-10 and Rule 480-27 for all prescriptions shipped, mailed or delivered to patients or practitioners in the State of Georgia. Nonresident pharmacy permit holders shall notify the Board of each location where the required records are being maintained and such records must be readily retrievable and produced to the Board immediately, upon written request. Records shall be maintained for a minimum of two (2) years.

- (10) Nonresident pharmacy permit holders shall comply with the minimum labeling requirements required by O.C.G.A. Section 26-3-8 and other Board laws, rules and regulations.
- (11) Nonresident pharmacy permit holders shall comply with the Board's rules and regulations on delivery of prescriptions by mail in Board Chapter 480-39.
- (12) Nonresident pharmacy permit holders shall comply with the laws and rules and regulations of the state where such pharmacies are located.
- (13) Nonresident pharmacy permit holders who compound drugs must comply with the Board's rules on compounding found in Board Chapter 480-11.
- (14) Nonresident pharmacy permit holders shall comply with the patient counseling laws and rules for all prescriptions shipped, mailed or delivered into this State.
- (15) Nonresident pharmacy permit holders shall maintain a toll-free telephone number operational during the permit holder's regular hours of operation, but not less than six days per week for a minimum of 60 hours per week in order to provide patient counseling. Such toll-free number shall be capable of receiving inbound call from patients to the permit holder and such number shall be on file with Board and shall be included on the label affixed to each container of all dispensed and distributed drugs sent into the State of Georgia.
- (16) Nonresident pharmacy permit holders shall maintain the following information and shall provide such information to the Board, upon request:
- (a) Normal delivery protocols and times;
 - (b) The procedure to be followed if the a patient's prescription drug is not available from the nonresident pharmacy or if the delivery will be delayed beyond the normal delivery time;
 - (c) The procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the nonresident pharmacy permit holder at the earliest possible time so that the patient does not miss a scheduled dose; and
 - (d) The procedure to be followed when the nonresident permit holder is advised that the patient's medication has not been received within the normal delivery time and the patient is out of medication and requires interim dosages until the medication becomes available or delivery by mail.
- (17) Nonresident pharmacy permit holders must comply with all the USP and FDA requirement for the storage, packaging and shipping of prescription drugs and devices.
- (18) Nonresident pharmacy permit holders must notify the Board within five (5) days of the receipt of any final order or decision by any other licensing board or federal agency of the imposition of disciplinary action or restriction by such other licensing board or federal agency. A final order or decision includes a consent order or agreement and is any decision, regardless whether there still exists an appellate right to the state or federal courts. Any revocation or suspension of a state or federal license or permit will result in the immediate suspension of the nonresident pharmacy permit pending a final decision by the Board.
- (19) Nonresident pharmacy permit holders shall cooperate with the Board in any investigation involving prescription drugs distributed by such permit holder into this state or related to the permit holders compounding practices. The permit holder shall respond within ten (10) calendar days to all communications from the Board or its designee. Failure to respond or cooperate with the Board shall be grounds for the immediate suspension of the nonresident pharmacy permit, pending a hearing on further disciplinary action by the Board. Failure to cooperate with the Board is grounds for disciplinary action by the Board.
- (20) Notices to nonresident pharmacy permit holders shall be made on the agent of record with the Board. If notices are returned as undeliverable or unclaimed, service shall be made on the

Executive Director and any disciplinary proceedings shall proceed, or if a final decision, the decision shall become effective.

(21) If, in the course of investigation of a nonresident pharmacy permit holder, an onsite inspection by the Board or its designee is required, the permit holder shall be responsible for the cost of such onsite inspection.

(22) A nonresident pharmacy permit may be revoked or suspended or otherwise disciplined for any reason that a permit may be denied, for failure to comply with this rule, for disciplinary action by other states and federal agencies, for conduct causing bodily or psychological injuries to a resident of this state, and for failure to comply with Board laws and other applicable rules.

(23) This rule shall not apply to nonresident pharmacies, facilities or entities licensed under Title 33, and shall not apply to pharmacies licensed pursuant to O.C.G.A. Section 26-4-110.1.

Authority: O.C.G.A. §§ 26-3-8, 26-4-5, 26-4-27, 26-4-28, 26-4-60, 26-4-80, 26-4-82, 26-4-83, 26-4-85, 26-4-110, 26-4-110.1, 26-4-114.1.