

GEORGIA BOARD OF PHARMACY
Conference Call
August 13, 2014
2 Peachtree St., N.W., 36th Floor
Atlanta, GA 30303
2:00 p.m.

The following Board members were present:

Al McConnell, Chairperson
Jim Bracewell
Mike Faulk
Chris Jones
Laird Miller
Bill Prather
Bob Warnock

Staff present:

Tanja Battle, Executive Director
Janet Wray, Senior Assistant Attorney General
Rick Allen, GDNA
Anil Foreman, Legal Officer
Brandi Howell, Business Operations Specialist

Visitor

Michael Melroy

Open Session

Chairperson McConnell established that a quorum was present and called the meeting to order at 2:01 p.m.

Rule 480-48-.01 Definitions: Discussion was held concerning items (d) "Mail order pharmacy" and (e) "Mail order prescription". Laird Miller made a motion to post Rule 480-48-.01 Definitions striking sections (d) and (e) from the proposed version of the rule. Bill Prather seconded and the Board voted unanimously in favor of the motion.

480-48-.01 Definitions

For purposes of this chapter of the Rules and Regulations, the following definitions apply:

(a) "Board" shall mean the Georgia Board of Pharmacy.

(b) "Delivery by Mail" or "delivered by mail" shall mean delivery to a patient by the United States Postal Service or a commercial common carrier. It is not considered to be delivery by mail when a pharmacy uses its own employees or employs a local courier service to deliver filled prescriptions in the same day from the pharmacy to a patient or facility providing care to the patient.

(c) "Pharmacy" means a pharmacy holding a current Board issued license to operate a pharmacy in Georgia, including pharmacy benefit managers required to be licensed pursuant under O.C.G.A. §26-4-110.1, and nonresident pharmacy permit holders.

Rule 480-48-.02 Conditions for Use of Delivery by Mail: Bob Warnock made a motion to post Rule 480-48-.02 Conditions for Use of Delivery by Mail. Laird Miller seconded and the Board voted unanimously in favor of the motion.

480-48-.02 Conditions for Use of Delivery by Mail

(1) Any pharmacy can regularly employ the U.S. Postal Service or a common commercial carrier to deliver a drug which requires a prescription to a patient only after the patient has requested that a pharmacy use this method of delivery for his/her filled prescription drugs. Any pharmacy providing mail order service to its patients is required to follow applicable Georgia laws and rules.

(2) A mail order pharmacy located outside this state is required to follow all applicable pharmacy and drug rules and laws of the state in which the pharmacy is physically located.

(3) A mail order pharmacy shall ensure that all prescription drug order medications are delivered to

the patient in accordance with standards of the drug manufacturer's temperature standards as set by the Food and Drug Administration (FDA). Pharmacy shall insure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by mail order by enclosing in each medication's packaging a USP-recognized method by which the patient can easily detect improper storage or temperature variations.

(4) Any pharmacy using delivery by mail to deliver dispensed prescription drugs shall comply with the following conditions:

(a) Any pharmacy that employs a mailing or shipping party is accountable to the Board to arrange for the appropriate mailing/shipping process.

(b) A mail order pharmacy shall provide a method by which a patient or patient's caregiver can notify the mail order pharmacy as to any irregularity in the delivery of their medication to include but not be limited to:

1. Timeliness of delivery

2. Condition of the prescription drug upon delivery; and

3. Failure to receive the proper prescription drug.

(c) Medications designated as requiring special handling by this rule must be signed for upon delivery by the patient or patient's designee. In the event that the medication cannot be delivered, the package will not be left behind and shall be returned to the mailing or shipping service to be held for pickup until signed for by the patient or the patient's designee, or redelivered to the patient if so requested by the patient or the patient's caregiver. The Board has designated the following drugs as requiring special handling:

1. All Schedule II, III, IV, and V controlled substances.

(d) A mail order pharmacy shall provide a process by which, if the delivery of a prescription medication is in any way compromised, the pharmacy will replace the patient's medication, to be delivered by next-day delivery or the mail order pharmacy will immediately contact the patient's prescriber to arrange for a prescription for a minimum seven (7) day supply of the medication to be dispensed to the patient by a licensed pharmacy of the patient's choice.

(e) A pharmacy that employs delivery by mail must provide written information, set forth in Board Rule 480-31-.01, for each drug that is delivered, and a method of electronic or telephonic communications for a pharmacist or a Georgia-licensed pharmacy intern under direct supervision of the pharmacist to provide consultation or counseling in accordance with the obligations of O.C.G.A. §26-4-85. All such counseling will be documented in the pharmacy's patient records. It is sufficient proof to show counseling was refused if a patient or patient's caregiver does not contact the pharmacy.

(f) The pharmacy shall provide information to the patient on the procedure that the patient should follow if any prescription drug does not arrive in a timely manner, or if the integrity of the packaging or medication has been compromised during shipment and delivery by mail.

(g) A pharmacy using delivery by mail shall document in its records when the prescription drug was sent to the patient.

(h) A pharmacy using delivery by mail shall document the instances when prescription drugs have been compromised during shipment and delivery by mail or when drugs do not arrive in a timely manner, and shall maintain such documentation for two (2) years. In addition, the mail order pharmacy shall maintain reports of patient complaints and internal/external audits about timeliness of deliveries, condition of the medication when received by patient including medication that was compromised in delivery, misfills of prescriptions, and the failure of a patient to receive medication. Such records shall be provided to the Board, upon request.

(i) A pharmacy or a pharmacist shall refuse to deliver by mail a prescription drug which, in the professional opinion of the pharmacy or pharmacist may be clinically compromised by delivery by mail.

(j) A mail order pharmacy shall make available to the patient or the patient's caregiver contact information of the Board of Pharmacy.

Rule 480-6-.02 Nonresident Pharmacy Permit: Discussion was held regarding the wording throughout the rule concerning “business days” and “calendar days”. The Board agreed that the language needed to be consistent.

Mr. Warnock asked the Board about the proposed effective date of 01/01/2015. He expressed his concerns with how this date would impact staff trying to process renewals. Mr. Miller responded by stating that he felt board staff could handle processing non-resident permits first and delay processing pharmacists’ renewals. He encouraged the Board to implement this as written. Mr. Jones agreed with Mr. Miller.

Chairperson McConnell stated that the Board can stress to pharmacists to renew early and submit the required information to the Board as soon as possible. Ms. Battle responded by stating that delaying renewals for pharmacists was not a practical option as some facilities, especially hospitals, would not allow pharmacists to continue working. She indicated that staff would work on both renewals and non-resident pharmacy applications simultaneously and allocate additional time and resources to ensure completion of both.

Mr. Faulk asked Ms. Battle how far in advance can a pharmacist renew his/her license. Ms. Battle responded by stating that she is currently working with the vendor now and hopes to have this function available online by September 1st. Mr. Prather suggested the Board contact all hospitals and drug store chains to request they submit the affidavit for citizenship and secure and verifiable documentation to the Board office as soon as possible.

Mike Faulk made a motion to post Rule 480-6-.02 Nonresident Pharmacy Permit. Laird Miller seconded and the Board voted unanimously in favor of the motion.

480-6-.02 Nonresident Pharmacy Permit.

(1) Effective 01/01/2015, it shall be unlawful for any person, pharmacy, or facility located outside this state to ship, mail, or deliver prescription drugs orders into this state or to advertise its services, personally or through an in-state third party, unless such person, pharmacy or facility holds a pharmacy license pursuant to O.C.G.A. Section 26-4-110.1, or holds a non-resident pharmacy permit pursuant to O.C.G.A. Section 26-4-114.1, or is otherwise exempt from Georgia registration as a matter of Georgia law.

(2) Application for a non-resident pharmacy permit:

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

(b) The Board requires information from each applicant for a nonresident pharmacy permit on its application, including but not limited to, the following:

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 each facility used by the applicant for the records, storage, handling, and distribution of prescription drugs into this state;

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 receives and dispenses prescription drug orders;

9. The names and license numbers of the pharmacist-in-charge of each facility involved in dispensing drugs to residents of this state and evidence that the pharmacist(s) 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 that is no older than two (2) years 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 an owner or pharmacist of a felony involving the practice of pharmacy 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 if 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 a completed 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 not paid before September 1st of the odd-numbered year, the permit shall lapse and shall not be renewed, and an application for a new permit shall be required.

(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 the state in which they are located and licensed for all prescriptions shipped, mailed or delivered to patients or practitioners in the State of Georgia, but shall be maintained a minimum of two (2) years. 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 within fifteen (15) business days, upon written request.

(10) In addition to labeling requirements required by the state where the nonresident pharmacy is located, the permit holders shall label the drugs dispensed with the following minimum information:

- (a) The name and address of the dispenser;
- (b) The serial number and date of the prescription or of its filling;
- (c) The name of the prescriber;
- (d) The name of the patient;
- (e) The name of the drug dispensed;
- (f) The direction for use and cautionary statements; and
- (g) Identification of the pharmacist filling the prescription.
- (11) Nonresident pharmacy permit holders shall comply with the Board's rules and regulations on delivery of prescriptions by mail in Board Chapter 480-48.
- (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 federal compounding laws as required in Board Chapter 480-11.
- (14) 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.
- (15) Nonresident pharmacy permit holders must notify the Board within five (5) business 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.
- (16) Within 72 hours, nonresident permit holders must update the Board of any change in pharmacist-in-charge of shipping into Georgia by completing forms provided by the Board and including such pharmacist licensure information and criminal history. Where a criminal background check cannot be completed within the 72 hours contemplated by this section, nonresident pharmacy permit holders must still update the Board of any change in pharmacist-in-charge of shipping into Georgia by completing forms provided by the Board and including such pharmacist licensure information, but shall have up to fifteen (15) business days to provide criminal history information.
- (17) 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 holder's compounding practices. The permit holder shall respond within ten (10) business 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.
- (18) 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.
- (19) If, in the course of investigation of a nonresident pharmacy permit holder or applicant, an onsite inspection by the Board or its designee is required, the permit holder or applicant shall be responsible for the cost of such onsite inspection.
- (20) 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 as provided herein.

A motion was made by Bill Prather, seconded by Jim Bracewell, and the Board voted that the formulation and adoption of these amendments 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 the relevant code sections.

In the same motion, the Board voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed at O.C.G.A§ 50-13-9 16 5 4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rules will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, August 20, 2014, at 9:00 a.m. at South University College of Pharmacy, 709 Mall Blvd, Savannah, GA 31406.

The Board meeting adjourned at 2:39 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist
Minutes edited by Tanja D. Battle, Executive Director