

GEORGIA BOARD OF PHARMACY
Emergency Conference Call Agenda
2 Peachtree St., N.W., 6th Floor
Atlanta, GA 30303
March 18, 2020
4:30 p.m.

The following Board members were present:

Lisa Harris, President
Mike Faulk, Vice-President
Michael Azzolin
Michael Brinson
Hal Henderson
Bill Prather
Dean Stone

Staff present:

Tanja Battle, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst I

Open Session

President Harris established that a quorum was present and called the meeting to order at 4:32 p.m.

Remote Orders: President Harris stated that there have been numerous inquiries regarding the matter of remote orders. Ms. Battle stated that drafts of Emergency Rules 480-36-.08 and 480-48-.04 have been shared with each member and asked if there were any comments. Ms. Emm stated processing remote orders would require the applicant to apply for a temporary Georgia license. She added that the pharmacist, in this instance, would still have to have a Georgia license. She stated that the Board's emergency policy says that very thing that the individual can apply for a temporary Georgia license. Mr. Henderson asked how long would that process take. Ms. Battle responded that the application for such is on the Board's website under the emergency policy and staff will certainly expedite those as they come in. Mr. Azzolin stated that he believes the federal CMS rules allow for licensed professionals to work across state lines. He asked if the Board could simply mirror that provision if the individual is licensed in another state. Mr. Changus stated that he thinks there is the expectation, nationally, that people will be able to work across state lines. As there does not appear to be legislative authority for such, he stated that individuals should apply under the policy the Board has in place. He further stated that the way this rule is written it clearly contemplates other people working from other jurisdictions. Mr. Changus stated that if there are any issues with the proposed language, the Board will learn of these through the standard review process through the Governor's Office. President Harris commented that, as it stands, the individual has to be licensed in Georgia and if not, he or she would have to get a temporary license, which the board office would expedite. Mr. Prather commented that he thinks the Board should go with what the policy states. Mr. Brinson agreed. Ms. Battle commented that expediting the application does not mean waiving the requirements. She stated that the applicant would still have to meet all the requirements minus the exam.

After proposed changes were discussed, Mr. Prather made a motion to adopt Rule 480-36-0.36-.08 Remote Order Verification for Retail Pharmacy Permits. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Rule 480-36-0.36-.08 Remote Order Verification for Retail Pharmacy Permits

(1) As a response to the current state of emergency as declared by the Governor, the Georgia State Board of Pharmacy finds the potential for imminent peril to the public health, safety, or

welfare of Georgia citizens. This emergency rule shall go into effect based on O.C.G.A. 50-13-4(b) and shall be effective for the duration of the emergency or a period of not more than 120 days, whichever is shorter. During the time this rule is effective, it shall replace Georgia State Board of Pharmacy Rule 480-36.

(2) Definitions. As used in this chapter, the following terms:

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

(b) "Remote prescription drug order processing" shall mean the processing of prescription or patient information from a location other than the location from which the prescription medication is received and dispensed. It shall not include the dispensing of a drug, but may include:

1. Receiving the prescription order from the primary dispensing pharmacy

2. Interpreting, analyzing, or clarifying prescriptions;

3. Entering prescription or patient data into a data processing system;

4. Transferring prescription information;

5. Performing a drug regimen review;

6. Performing a drug allergy review;

7. Performing therapeutic interventions; or

8. Any combination of these order processing functions.

(c) Primary dispensing pharmacy. A primary dispensing pharmacy shall be defined as the retail pharmacy located in this State from which a prescription is physically received and dispensed to the patient or the patient's caregiver.

(d) Secondary remote entry pharmacist. A secondary remote entry pharmacist shall be defined as pharmacist who performs remote prescription drug order processing but does not dispense the medication to the patient or the patient's caregiver. There shall only be one secondary pharmacist to assist the primary dispensing pharmacy with remote prescription drug order processing per prescription.

(3) Policy and Procedures. The primary dispensing pharmacy shall have written policies and procedures regarding remote prescription drug order processing that are available for inspection by the Board or its representative. The policy shall at a minimum include the following:

(a) The responsibilities of the primary dispensing pharmacy and the secondary remote entry pharmacist;

(b) Procedures for protecting the confidentiality and integrity of patient information;

(c) Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

(d) Procedures for maintaining required records;

(e) Procedures for complying with all applicable laws and regulations to include counseling.

(4) Record Keeping.

(a) The primary dispensing pharmacy and the secondary remote entry pharmacist shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.

(b) In addition to any other required records, the primary dispensing pharmacy and the secondary remote entry pharmacist shall maintain retrievable records which show, for each prescription remotely processed, each individual processing function and identity of the person who performs a processing function and the pharmacist who checked the processing function.

(c) The record keeping required by this rule is in addition to the record keeping required under Rule Chapter 480-10 and any other Board rules and state and federal laws.

(5) Patient Counseling.

(a) It shall be the responsibility of the pharmacist on duty at the primary dispensing pharmacy to perform patient counseling of all prescriptions, as required, including those assisted by remote processing.

Signatures: Ms. Battle stated that a draft of 480-48-0.37-.04 Delivery by Mail has been shared with the Board. She stated that the board office has received information that UPS and FedEx have directed their drivers not to require signatures. She added that hospice pharmacies are concerned about the same thing. After further discussion, Mr. Brinson made a motion to adopt Chapter 480-48-0.37-.04 Delivery by Mail. Mr. Henderson seconded and the Board voted unanimously in favor of the motion.

Chapter 480-48-0.37-.04 DELIVERY BY MAIL

(1) As a response to the current state of emergency as declared by the Governor, the Georgia State Board of Pharmacy finds the potential for imminent peril to the public health, safety, or welfare of Georgia citizens. This emergency rule shall go into effect based on O.C.G.A. 50-13-4(b) and shall be effective for the duration of the emergency or a period of not more than 120 days, whichever is shorter. During the time this rule is effective, it shall replace Georgia State Board of Pharmacy Rule 480-48.

(2) 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" or "delivery by mail" shall mean delivery to a patient or the patient's designee by the United States Postal Service or by a commercial common carrier from the pharmacy which fills the prescription.

(c) "Delivery by Pharmacy" shall mean delivery directly to a patient or patient's designee from the pharmacy by contract or private carrier or by an employee of the pharmacy.

(d) "Mail order pharmacy" shall mean a pharmacy that uses delivery by mail as a means of delivery of a prescription drug to a patient or the patient's designee.

(e) "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.

(3) Conditions for Use of Delivery by Mail

(a) 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 deliver by mail his/her filled prescription drugs. Any pharmacy providing delivery by mail to its patients is required to follow applicable Georgia laws and rules.

(b) 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.

(c) A mail order pharmacy shall ensure that all prescription medications are delivered to the patient in accordance with standards of the manufacturer, United States Pharmacopeia, Federal Food and Drug Administration and other recognized standards. A pharmacy shall ensure integrity of any drug requiring temperature control other than "room temperature storage" that is delivered by mail order and provide a notification to the patient of the timeliness in addressing the proper storage of the medication.

1. The shipping method may include the use of temperature tags, time temperature strips, insulated packaging, or a combination of these.

2. The notification method may be by verbal, written, electronic, or other technological means. If verbal, then the pharmacy must document the notification and maintain such documentation.

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

1. Any pharmacy that uses delivery by mail is accountable to the Board to arrange for the appropriate mailing/shipping process.

2. 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:

(i) Timeliness of delivery;

(ii) Condition on the prescription drug upon delivery; and

(iii) Failure to receive the proper prescription drug.

(e) 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.

(f) 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.

(g) 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.

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

(i) 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.

(j) 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.

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

(4) Delivery by Pharmacy

Any pharmacy may provide for delivery by pharmacy upon the request of the patient or the patient's designee. The Board will hold the pharmacy responsible for any problems in the service of delivery by pharmacy. In order for a delivery to be considered delivery by pharmacy, the delivery must be on a continuous route from the pharmacy to the patient or the patient's designee. All medications shall be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed.

President Harris stated that she has received questions about concerns related to touching the signature pad at the point of sale in the drug store where patients have to sign that they picked up the prescription or request counseling. She asked can the Board waive that. Director Troughton responded that is not something that is require by law or rule. He stated that requirement is based on insurance contracts. He added that he does not believe the Board has the authority to waive that as it is up to the individual merchant and their insurance contracts.

Pursuant to O.C.G.A. § 50-14-1(3), the Board declares that special circumstances exist warranting the holding of this meeting on less than 24 hours' notice, those circumstances being the COVID-19 pandemic.

There being no further business to discuss, the meeting was adjourned at 5:23 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, April 15, 2020 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I
Minutes edited by Tanja D. Battle, Executive Director