

GEORGIA BOARD OF PHARMACY
Emergency Conference Call
2 Peachtree St., NW, 6th Floor
Atlanta, GA 30303
March 13, 2020
4:00 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
Eric Lacefield, Deputy Executive Director
Dennis Troughton, Director, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney

Open Session

President Harris established that a quorum was present and called the meeting to order at 4:01 p.m.

Policy #14 Emergency Policies: Ms. Battle stated that the policy cannot move forward until a State of Emergency is declared by the Governor. She stated, because we are approaching a weekend, she wanted to be prepared to act swiftly. President Harris stated that Policy 14 defines “State of Emergency” as a governmental declaration issued by the Governor or President.

Discussion was held regarding a request from Mr. Stephen Snow, Bendin Sumrall & Ladner, for an emergency rule waiver allowing compounding of hand sanitizer gel without patient-specific prescriptions due to supply shortages as a result of COVID-19. Mr. Changus commented that he spoke with Director Troughton regarding whether or not the compounding would require a rule waiver. Mr. Azzolin suggested, due to the current situation and to simplify, waiving the rule during this time. Mr. Brinson commented that he has received several questions from compounders and does not see any issues as long as the ingredients are there. Director Troughton stated that it is not compounding if it is just over-the-counter (OTC) products. He stated that it comes down to proper labeling. He added that he does not think there is any action the Board needs to take. Lastly, he stated when pharmacies did that, GDNA said they had to abide by FDA rules as there is no drug. Mr. Azzolin commented that they say a manufacturing permit is needed. Director Troughton responded that a manufacturing permit is only needed if there is a prescription drug or listed chemical. He added that this is regarding OTC products. Mr. Changus commented that the other aspect is they are asking for a rule waiver. He stated that he thinks this needs to be communicated to the Governor’s office as his office holds the emergency power. President Harris asked how this can be communicated. Ms. Battle responded that the Board can work a statement into what it is doing to address the emergency. Mr. Changus suggested a statement saying that the Board voted to recommend to the Governor’s office to waive Rule 480-11-.02 in order to allow for the compounding of alcohol based hand sanitizer in a pharmacy. Mr. Azzolin commented that there are likely multiple ways to make the hand sanitizer. He stated that he agreed with Ms. Battle’s recommendation of a statement including language stating that as long as all ingredients are OTC it would be permitted.

Mr. Stone commented that the language Mr. Changus has suggested is telling the public that this is what the Board wants to do. He added that people will see the Board’s thought process. Mr.

Changus stated that they are looking for a safe harbor statement. He added that he has already spoken with Mr. Snow and the statement would be viewed as favorable to them. Ms. Battle asked if there is any reason why the Board cannot just issue a statement. Mr. Changus responded by stating that a statement can be done as well. He added that the Governor may be interested in knowing what rules may need to be suspended. Mr. Azzolin suggested keeping a record of rules to be waived during emergencies and provide him a list later. He stated that there have been three rules brought to his attention, one being remote order entry.

Mr. Brinson made a motion for the Board to issue the following statement:

The Board does not have the authority to approve an emergency rule waiver. The Board's position is that a rule waiver allowing the compounding of hand sanitizer gel is not required given that the components are all over-the-counter products. Please be advised labels will need to comply with FDA requirements.

Mr. Stone seconded and the Board voted unanimously in favor of the motion.

The Board discussed Policy #14: Public Emergencies and stated that the policy needed no changes. Mr. Brinson made a motion to post the policy and the statement of interpretation upon a State of Emergency being declared. Mr. Henderson seconded the motion and the Board voted unanimously in favor of the motion.

STATEMENT OF INTERPRETATION RELATING TO EMERGENCY PRESCRIPTION REFILLS FOR EMERGENCIES DURING the COVID-19 STATE OF EMERGENCY

Policy #14 of the Georgia Board of Pharmacy ("Board") provides for the refills of certain medication for up to 30 days for persons in the areas covered by a State of Emergency declared by the Governor of the State of Georgia. This policy is consistent with O.C.G.A. Section 26-4-80(j) and the Governor's Emergency Declaration. The Board is clarifying that persons who are located in emergency areas may also receive a 30-day refill of medication by a Georgia pharmacy or pharmacist without risk of disciplinary action by the Board so long as:

- The refill is not for a controlled substance;
- In the pharmacist's professional judgment, the prescription drug is essential to the maintenance of the patient's life or to the continuation of therapy;
- The pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "emergency refill prescription," and maintains the record as required by state and federal law and as required by state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency;
- The pharmacist informs the patient or the patient's agent at the time of dispensing that the prescription drug is being provided without the practitioner's authorization and that authorization of the practitioner is required for future refills; and
- As emergency conditions permit, the pharmacist notifies the practitioner that the refill occurred.

Policy #14: Public Emergencies

Section 1. Purpose and Scope

The primary purpose of this policy is to enable pharmacists and pharmacies to assist in the management and containment of a public emergency or similar crisis within the confines of a regulatory framework that serves to protect the welfare and health of the public. The Board will consider petitions for rule waivers or variances regarding recordkeeping, minimum physical area, and minimal equipment requirements related to the state of emergency in the declared disaster areas and affected areas on an emergency basis, pursuant to a written request in a manner consistent with the Board's authority under state law and/or the Governor's State of Emergency.

Section 2. Definitions.

For the purposes of this policy, the following definitions apply:

- (a) "Affected Areas" include areas covered by the state of emergency.
- (b) "Declared Disaster Areas" are areas designated by state or federal authorities as those that have been adversely affected by a natural or man-made disaster and require extraordinary measures to provide adequate, safe, and effective health care for the affected population.
- (c) "Mobile Pharmacy" means a pharmacy that is self-propelled or movable by another vehicle that is self-propelled.
- (d) "State of Emergency" means a governmental declaration issued by the Governor of the State of Georgia or the President of the United States which may suspend certain normal functions of government, alert citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.
- (e) "Temporary Pharmacy Facility" means a facility established as a result of a state of emergency to temporarily provide pharmacy services within or adjacent to declared disaster areas.

Section 3. Emergency Refill Dispensing

- (a) For the duration of the state of emergency issued in the affected area and consistent with O.C.G.A. §26-4-80(j), a pharmacist may dispense a 72 hour refill supply of a prescription drug repeatedly to a patient, but in total not more than a thirty (30) day supply, without practitioner authorization if:
 - (1) The refill is not for a controlled substance;
 - (2) In the pharmacist's professional judgment, the prescription drug is essential to the maintenance of the patient's life or to the continuation of therapy;
 - (3) The pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "emergency refill prescription," and maintains the record as required by state and federal law and as required by state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency;
 - (4) The pharmacist informs the patient or the patient's agent at the time of dispensing that the prescription drug is being provided without the practitioner's authorization and that authorization of the practitioner is required for future refills; and
 - (5) When emergency conditions permit, the pharmacist notifies the practitioner that the refill occurred.

Section 4. Temporary Recognition of Non-Resident Licensure

- (a) When a state of emergency is declared and consistent with O.C.G.A. §26-4-43:
- (1) A pharmacist not licensed in this state, but currently licensed in another state, may obtain a temporary license to dispense prescription drugs in areas affected by the declared disaster during the time that the state of emergency exists if:
 - (i) The Board can verify current licensure in good standing of the pharmacist directly with the state or indirectly via a third-party verification system; and
 - (ii) The pharmacist is engaged in a documented relief effort.
 - (2) A pharmacy technician or pharmacy intern not registered or licensed in this State, but currently registered or licensed in another state, may assist the pharmacist in dispensing prescription drugs in affected disaster areas during the time that the state of emergency exists if:
 - (i) The Board can verify current registration or licensure in good standing of the pharmacy technician or pharmacy intern directly with the state or indirectly via a third-party verification system; and
 - (ii) The pharmacy technician or pharmacy intern is engaged in a documented relief effort.
- (b) The temporary recognition of non-resident pharmacist licensure and pharmacy intern licensure shall cease at end of the month following the third board meeting conducted after the issuance of such license and shall not be renewed. The temporary recognition of non-resident pharmacy technician registration shall registration shall cease with the termination of the state of emergency.

Section 5. Temporary Pharmacy Facilities or Mobile Pharmacies

- (a) Consistent with the authority in O.C.G.A. §26-4-110, and if necessary to provide pharmacy services during a state of emergency, pharmacies located in declared disaster areas and non-resident pharmacies may arrange to temporarily locate or relocate to a temporary pharmacy facility or mobile pharmacy if the temporary pharmacy facility or mobile pharmacy:
- (1) Is under the control and management of the pharmacist-in charge or designated supervising pharmacist;
 - (2) Is located within the declared disaster area or affected areas;
 - (3) Notifies the Board of its location, subject to approval by the Board in accordance with (b);
 - (4) Is properly secured to prevent theft and diversion of drugs;
 - (5) Maintains records in accordance with laws and regulations of the state in which the disaster occurred; and
 - (6) Ceases the provision of services with the termination of the state of emergency, unless it is successfully licensed by the Board of Pharmacy in accordance with the Georgia Pharmacy Practice Act and applicable rules.
- (b) The Board shall have the authority to approve or disapprove temporary pharmacy facilities and mobile pharmacies and shall make arrangements for appropriate monitoring and inspection of the temporary pharmacy facilities and mobile pharmacies on a case-by-case basis. Approval of temporary pharmacy facilities and mobile pharmacies will be based on the need, type, and scope of the state of emergency, as well as the ability of the temporary pharmacy facilities or mobile pharmacies to comply with state and federal drug law.
- (c) A temporary pharmacy facility wishing to permanently operate at its temporary site must be licensed by the Board in accordance with the Georgia Pharmacy Practice Act and applicable Board rules.

- (d) Mobile pharmacies, placed in operation during a state of emergency, may not operate permanently, unless approved by the Board.

Mr. Henderson stated that he would like to keep looking into the remote information. Mr. Azzolin stated he would submit additional information on this matter to the Board to review. Mr. Henderson commented that his company services a facility in Washington and they are dealing with this all over the country. He stated that their consultants are now doing remote consulting and the delivery drivers have to deliver outside the building. President Harris asked Mr. Changus for suggestions on what to do. Mr. Changus responded by stating that the Governor can waive rules, if it is brought to his attention after a State of Emergency is declared. He stated that it sounds like there are other items that may need to be addressed and suggested the Board can discuss those on another call and amend the policy if necessary.

Ms. Battle stated that if there are any other issues the Board has, to please send them and staff can review to see if the Board has the authority. Ms. Battle stated that she would respond to Mr. Snow's request.

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 4:45 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 Kimberly Emm, Attorney
Minutes edited by Tanja D. Battle, Executive Director