



STATE OF GEORGIA DRUGS AND NARCOTICS AGENCY

254 Washington Street, SW – Suite G2000
Atlanta, Georgia 30334
404-656-5100 fax 404-651-8210 800-656-6568

Dennis M. Troughton Sr., PharmD/RPh, Director

In recent days it has become evident that, not only are ventilators in great demand and short supply, but hospitals are facing looming shortages of critical medications that are necessary to safely and effectively maintain the ventilation of patients. For various reasons, hospitals have had difficulty obtaining the medications through the normal supply chain. Data is showing that the COVID-19 pandemic has not reached its peak in Georgia and hospitals have yet to experience the number of patients that will require treatment. The consequence of these medications not being available is that ventilating patients becomes more difficult or even impossible. As a result, supportive treatment could decline and patients could suffer.

Our understanding is that some non-hospital pharmacies in Georgia have these needed medications in stock or available to them. The medications are in an original state that would require the pharmacies to compound them into a final form that the hospitals can use. As you know, the practice of compounding in licensed pharmacies is legal in Georgia and is regulated by the Georgia Board of Pharmacy whose laws and rules are enforced by the Georgia Drugs and Narcotics agency.

An issue that has prevented pharmacies from compounding these medications for the hospitals is that federal and state regulations do not allow pharmacies to compound and provide the compounded product to physicians or hospitals. The regulations require that the pharmacies only compound and dispense the products as a result of a patient specific prescription.

Unfortunately, the ferocity of this virus precludes many hospitals from providing patient names to the compounding pharmacy as they are preparing the medication. Also, the pharmacies that have the medications to compound are often hundreds of miles from the hospitals that are in desperate need of the compounded medications. Given the urgent need in this time of crisis, GDNA is working to link pharmacies that can compound the needed medications with hospitals and specifically identified patients during this emergency, paying heed to the intent of the federal and state guidelines on compounding practice. The ultimate goal is to have patient-specific prescriptions that can be documented in the record, while expediting the compounding process and provision of the medications to the hospitals as rapidly as possible, so as not to impact emergency patient care.

Pharmacies are required to be in compliance with United States Pharmacopeia (USP) standards. The agents with the Georgia Drugs and Narcotics Agency are responsible for the inspections of such pharmacies and are all trained in USP standards. As such any licensed pharmacy compounding these medications would have been inspected by the agency and held to the requirements of USP. This is to ensure that these compounded products are properly and safely prepared for the Georgia patients who so desperately need them.

The joint mission of the Georgia Board of Pharmacy and the Georgia Drugs and Narcotics Agency is to protect the health, safety and welfare of Georgia citizens. It is our duty as State entities under the leadership of our

Governor to work to ensure that the prescription medications needed to help COVID-19 patients are available to the frontline healthcare professionals who are treating them. It is our belief that this compounding can be done within the laws and rules of Georgia. The Georgia Board of Pharmacy and the Georgia Drugs and Narcotics Agency intend to use their authority to support the Governor in his efforts to allow healthcare professionals to provide Georgia citizens with the best possible health care during this state of emergency.

With the support of the Board I have created a guidance document for the record keeping requirements for outside pharmacies compounding sterile preparations for hospitalized patients during the COVID-19 Georgia declared State of Emergency. This document accompanies this letter. This allowance and guidance will remain in place until the end of the Governor's declared State of Emergency or the Board of Pharmacy changes it.

Dennis M. Troughton Sr., Director
Georgia Drugs and Narcotics Agency
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Record keeping requirements for outside pharmacies compounding sterile preparations for hospitalized patients during the COVID-19 Georgia declared STATE OF EMERGENCY:

Record keeping requirements for the outside pharmacy:

- A master formulation for each different preparation to be compounded in anticipation for hospital patient specific use to include the CSP (compounded sterile preparations) microbial contamination risk level in accordance with USP-NF standards.
- A compounding record for each preparation or batch made detailing all information required in 480-11-.05(e) and:
 - The pharmacy's identification of risk level of sterile compounding conducted for each batch or preparation (low, medium or high)
 - The storage requirements (e.g. temperature)
 - Identify the specific methodology used to deliver the CSPs to the hospitals. Ensure compliance with GA Board of Pharmacy Rule 480-48 and USP guidance for packing and transporting CSPs.
- Each CSP shall be labeled with the following:
 - The pharmacy's name, address and telephone number
 - The name of the active ingredients and strengths contained in the CSP
 - The lot number or identification number of the CSP
 - The quantity, amount, size, or weight of the CSP in the container
 - An appropriate beyond-use date of the CSP as determined by the pharmacist in compliance with and USP-NF standards for pharmacy compounding
- An 'invoice' of all transactions to individual hospitals that lists, at minimum:
 - All lot or batch numbers being provided and the total number of each preparation
 - Storage/temperature requirements of each preparation/batch
 - The date such preparations are being delivered to the hospital
 - Identification of the outside pharmacy and hospital pharmacy, including DEA #s if controlled substances were prepared
- A record identifying individual patients who received a CSP from the outside pharmacy to include the drug description and the lot number of that CSP. This information may be received from the hospital pharmacy after the CSP has been prepared and delivered to the hospital pharmacy.
- All sterile compounding shall be conducted in compliance with USP-NF standards
- All records associated with this process shall be maintained by the outside pharmacy for a minimum of two years in a form that can be printed, copied, or electronically provided upon request for examination by the Board, GDNA, U.S. Food and Drug Administration, U.S. Drug Enforcement Administration, etc.

Record keeping requirements for outside pharmacies compounding sterile preparations for hospitalized patients during the COVID-19 Georgia declared STATE OF EMERGENCY: (continued)

Record keeping requirements for the hospital pharmacy receiving CSPs from outside pharmacy:

- Invoices of receipt from the outside pharmacy
 - Shall be verified, signed and dated by a pharmacist, including time delivered/received
- A record identifying each individual patient receiving a CSP from an outside pharmacy
 - Record to include outside pharmacy's assigned lot number for each CSP within either the pharmacy records or the individual patients' records
 - This information must be relayed back to the outside pharmacy at least every 7 days for all CSPs administered to patients
 - Any/all CSPs not administered shall be wasted per hospitals SOPs/P&Ps
- Any further or additional sterile compounding by the hospital pharmacy, utilizing CSPs from an outside pharmacy, shall be conducted in compliance with USP-NF standards
- All records associated with this process shall be maintained by the hospital pharmacy for minimum of two years in a form that can be printed, copied, or electronically provided upon request for examination by the Board, GDNA, U.S. Food and Drug Administration, U.S. Drug Enforcement Administration, etc.