

U. S. Department of Justice Drug Enforcement Administration

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Jay Campbell
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North Carolina Board of Pharmacy
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Dear Mr. Campbell:

This is in response to your email dated October 2, 2024, to the Drug Enforcement Administration (DEA) in which you asked if pharmacists may use North Carolina's Rule .1815 to provide an emergency refill for buprenorphine. You stated that "the health consequences of patients being treated for Opioid Use Disorder (OUD) in the Helene-affected areas being unable to continue buprenorphine therapy are, I think obvious (and would likely be true for patients on other controlled substances.)" You asked for DEA to address this emergency issue.

The DEA Administrator is permitted by <u>21 CFR 1307.03</u> to grant an exception to the application of any provision contained in <u>21 CFR</u>, part 1300 to 1399, but in no case shall the Administrator be required to grant an exception to any person which is otherwise required by law or DEA regulation. This authority has been delegated to the Assistant Administrator of the Diversion Control Division.

DEA understands due to the damage from Hurricane Helene, many DEA-registered pharmacy and practitioner locations are flooded and do not have access to internet and/or phone services. Flooded pharmacies are unable to dispense from their stock and without internet are unable to transfer any schedule III-V refills as authorized by 21 CFR 1306.25(a). Many practitioners are without phone capabilities and are unable to contact a pharmacy to authorize a new oral prescription as authorized by 21 CFR 1306.21. DEA has no objection to the North Carolina Board of Pharmacy implementing its rule titled, "Emergency Prescription Refill Due to Interruption of Medical Services" found at 21 NCAC 46.1815. The rule states, "In the event a pharmacist or device and medical equipment permit holder receives a request for a prescription refill and the pharmacist or permit holder is unable to readily obtain refill authorization from the prescriber because of the prescriber's inability to provide medical services to the patient, the pharmacist or permit holder may dispense a one-time emergency supply of up to 90 days of the prescribe medication." Under the rule, the following conditions apply:

- 1. The prescription is not for a schedule II controlled substance;
- 2. The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;

Jay Campbell Page 2

3. In the pharmacist's or permit holder's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences;

- 4. The dispensing pharmacist or permit holder creates a written order entered in the pharmacy's automated data processing system containing all of the prescription information required by section .2300 of these Rules and signs that order;
- 5. The dispensing pharmacist or permit holder notified, or makes a good faith attempt to notify, the prescriber or the prescriber's office of the emergency dispensing within 72 hours after such dispensing.

Based on the definition of an emergency situation as defined by the Secretary of Health and Human Services, these above-mentioned actions are necessary for the proper treatment of the intended ultimate user, no appropriate alternative treatment is available, and it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing. 21 CFR 290.10. Accordingly, contingent on your compliance with the foregoing conditions, DEA **concurs** with your implementation of 21 NCAC 46.1815 for thirty days from the date of this letter, at which time upon request from your office, DEA will consider an extension of this exception should the foregoing emergency conditions continue to exist.

I trust this letter adequately addresses your inquiry. For information regarding the DEA Diversion Control Division, please visit https://.DEAdiversion.usdoj.gov/index.html. If you have any additional questions on this issue, please contact the DEA's Natural Disaster website at Natural.Disaster2@dea.gov.

Sincerely,

Thomas W. Prevoznik Assistant Administrator Diversion Control Division