



EMERGENCY RULE-MAKING FINDINGS OF NEED [G.S. 150B-21.1A]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: North Carolina Board of Pharmacy	
2. Rule citation(s): 21 NCAC 46 .1819	
3. Adoption by agency on: March 24, 2020	4. Date agency requests entry of emergency rule in the Code: April 1, 2020
5. What is the need for an emergency rule? On March 10, 2020, the Governor of North Carolina, by issuing Executive Order No. 116, declared a state of emergency to coordinate a response and enact protective measures to help prevent the spread of COVID-19. COVID-19 is respiratory disease that can result in serious illness or death. COVID-19, previously unidentified in humans, spreads easily from person to person. Once an outbreak of COVID-19 begins, it is difficult to contain. The World Health Organization, the Center for Disease Control and Prevention, and the United States Department of Health and Human Services have declared COVID-19 a public health threat and emergency. The search for potential treatments for COVID-19 has caused shortages and threatens to cause further shortages in certain drugs. On March 24, 2020, the North Carolina Secretary of Health and Human Services and the State Health Director requested that the Medical Board and the Board of Pharmacy adopt the COVID-19 Drug Preservation Rule in order to alleviate shortages and ensure that these drugs are available to patients who need them.	
6. Has the agency provided the public with abbreviated notice? If so, describe. Yes. On March 24, 2020, approximately three hours before the hearing and approximately 30 minutes after the Secretary of Health and Human Services and State Health Director communicated (through their agents) a request for this rule, the Board provided the following notice: (1) Notice by e-mail (the same method used to notify the Board members) to each local newspaper, local wire service, local radio station and local television station that has filed a written request for notice; (2) notice to the Board's interested persons' list; (3) notice through Twitter; (4) notice placed on the Board's website; and (5) notice posted on the door of the Board's office.	
7. Why is adherence to notice and hearing requirements contrary to the public interest and that the immediate adoption of the rule required by a serious and unforeseen threat to the public health or safety? This emergency rule is adopted in accordance with N.C. Gen. Stat. 150B-21.1A. The Board has determined that adherence to the notice and hearing requirements of Article 2A of Chapter 150B of the North Carolina General Statutes would be contrary to the public interest and that the immediate adoption of the rule is required by a serious and unforeseen threat to the public health or safety due to the COVID-19 crisis. Under the unprecedented circumstances of the COVID-19 pandemic, shortages and potential shortages of these drugs are continuously increasing. Without immediate action, the drugs will not be available to patients who need them. This was the basis of the Secretary of Health and Human Services and State Health Director's request that the Board specifically adopt an emergency rule. Their letter is attached.	

[Emergency Rule-making Findings of Need Continued]

<p>8. Does the agency have specific statutory authority for the adoption of an emergency rule? If so, has the agency met the statutory criteria for adoption? (attach copy of statutory authority) The Board has general rulemaking authority, including through G.S. 90-85.21A, 90-85.26 and 90-85.32. None of those specifically mention emergency rulemaking. The Board does, however, have specific authority to waive the requirements of the Pharmacy Practice Act during a state of emergency under G.S. 90-85.25(a), which is attached.</p>	
<p>9. Has the agency submitted the proposed temporary rule for publication on the Internet in accordance with G.S. 150B-21.1(a3)?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>10. Rule establishes or increases a fee? (See G.S. 12-3.1)</p> <p><input type="checkbox"/> Yes Agency submitted request for consultation on: Consultation not required. Cite authority:</p> <p><input checked="" type="checkbox"/> No</p>	
<p>11. Rule-making Coordinator: Clinton R. Pinyan</p> <p>Phone: (336) 373-8850</p> <p>E-Mail: cpinyan@brookspierce.com</p>	<p>12. Signature of Agency Head*:</p> <p align="center"></p> <hr/> <p>* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.</p> <p>Typed Name: Keith A. Vance</p> <p>Title: President</p> <p>E-Mail: kvance@ncbop.org</p>
<p>Agency contact, if any: Jay Campbell</p> <p>Phone: (919) 246-1050</p> <p>E-Mail: jcampbell@ncbop.org</p>	

REVIEW BY THE CODIFIER OF RULES	
<p>Approved. Entered into the North Carolina Administrative Code on: _____</p>	
<p>Reviewed By: _____</p>	<p>Date: _____</p>
<p>Comments:</p>	
<p>Statement does not meet the criteria.</p>	
<p>Reviewed By: _____</p>	<p>Date: _____</p>
<p>Comments:</p>	



STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

March 24, 2020

R. David Henderson
Chief Executive Officer
North Carolina Medical Board
PO Box 20007
Raleigh, NC 27619-0007

Jack W. (Jay) Campbell
Executive Director
North Carolina Board of Pharmacy
6015 Farrington Road
Suite 201
Chapel Hill, NC 27517

Dear Dr. Henderson and Mr. Campbell:

On March 10, 2020, the Governor of North Carolina, by issuing Executive Order No. 116, declared a state of emergency to coordinate a response and enact protective measures to help prevent the spread of COVID-19. The search for potential treatments for COVID-19 has caused shortages and threatens to cause further shortages in certain drugs. Please accept this letter as a formal request that the Medical Board and the Board of Pharmacy adopt emergency rules to assist in alleviating shortages and ensure that these drugs are available to patients who need them.

Attached to this letter you will find suggested language to be used in issuing your respective emergency rules. We believe it is important to address the issues we are seeing in the community related to shortages of these investigational medications for COVID-19 treatment at both the prescribing and dispensing level.

We appreciate your prompt attention and action in this matter.

Sincerely,

A handwritten signature in cursive script that reads "Mandy K. Cohen".

Mandy K. Cohen, MD, MPH
Secretary

A handwritten signature in cursive script that reads "Elizabeth Cuervo Tilson".

Elizabeth Cuervo Tilson, MD, MPH
State Health Director and Chief Medical Officer

Emergency and Proposed Temporary Rule

Reason for Action: On March 10, 2020, the Governor of North Carolina, by issuing Executive Order No. 116, declared a state of emergency to coordinate a response and enact protective measures to help prevent the spread of COVID-19. COVID-19 is respiratory disease that can result in serious illness or death. COVID-19, previously unidentified in humans, spreads easily from person to person. Once an outbreak of COVID-19 begins, it is difficult to contain. The World Health Organization, the Center for Disease Control and Prevention, and the United States Department of Health and Human Services have declared COVID-19 a public health threat and emergency. The search for potential treatments for COVID-19 has caused shortages and threatens to cause further shortages in certain drugs. On March 24, 2020, the North Carolina State Health Director requested that the Medical Board and the Board of Pharmacy adopt the COVID-19 Drug Preservation Rule in order to alleviate shortages and ensure that these drugs are available to patients who need them.

COVID-19 DRUG PRESERVATION RULE

(a) The following drugs are “Restricted Drugs” as that term is used in this Rule:

- (1) Hydroxychloroquine;
- (2) Chloroquine;
- (3) Lopinavir-ritonavir;
- (4) Ribavirin;
- (5) Oseltamivir;
- (6) Daurunavir; and
- (7) Azithromycin

(b) [Medical Board: A physician shall prescribe] [Pharmacy Board: A pharmacist shall fill or refill a prescription for] a Restricted Drug only if that prescription bears a written diagnosis from the prescriber consistent with the evidence for its use.

(c) When a patient has been diagnosed with COVID-19, any prescription of a Restricted Drug for the treatment of COVID-19 shall:

- (1) Indicate on the prescription order that the patient has been diagnosed with COVID-19;
- (2) Be limited to no more than a fourteen (14) day supply; and
- (3) Not be refilled, unless a new prescription order is issued in conformance with this Rule,

including not being refilled through an emergency prescription refill.

(d) [Medical Board: A physician shall not prescribe] [Pharmacy Board: A pharmacist shall not fill or refill a prescription for] a Restricted Drug for the prevention of, or in anticipation of, the contraction of COVID-19 by someone who has not yet been diagnosed.

(e) A prescription for a Restricted Drug may be transmitted orally only if all information required by this Rule is provided to the pharmacy by the physician or the physician’s agent, and that information is recorded in writing by the pharmacy, along with the identity of the physician or physician’s agent transmitting the prescription.

(f) This Rule does not affect orders for administration to inpatients of health care facilities.

(g) This Rule does not apply to prescriptions for a Restricted Drug for a patient previously established on that particular Restricted Drug on or before March 10, 2020.

§ 90-12.5. Disasters and emergencies.

In the event of an occurrence which the Governor of the State of North Carolina has declared a state of emergency, or in the event of an occurrence for which a county or municipality has enacted an ordinance to deal with states of emergency under G.S. 166A-19.31, or to protect the public health, safety, or welfare of its citizens under Article 22 of Chapter 130A of the General Statutes, G.S. 160A-174(a) or G.S. 153A-121(a), as applicable, the Board may waive the requirements of this Article in order to permit the provision of emergency health services to the public. (2002-179, s. 20(a); 2007-346, s. 7; 2012-12, s. 2(ff).)