TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY
VOLUME:
ISSUE:

1. Rule-Making Agency: Medical Board

2. Rule citation & name: 21 NCAC 32B .1708 COVID-19 Drug Preservation Rule

3. Action: ☒ **Adoption** ☐ **Amendment** ☐ **Repeal**

4. Was this an Emergency Rule: ☒ **Yes** ☐ **No** **Effective date:** 04/06/2020

5. Provide dates for the following actions as applicable:

a. Proposed Temporary Rule submitted to OAH: 03/27/2020

b. Proposed Temporary Rule published on the OAH website: 03/27/2020

c. Public Hearing date: 05/18/2020

d. Comment Period: 04/01/2020-05/04/2020

e. Notice pursuant to G.S. 150B-21.1(a3)(2): March 30, 2020

f. Adoption by agency on: 05/21/2020

g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]:

h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]:

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

☒ **A serious and unforeseen threat to the public health, safety or welfare.**
☐ **The effective date of a recent act of the General Assembly or of the U.S. Congress.**
Cite:
Effective date:
☐ **A recent change in federal or state budgetary policy.**
Effective date of change:
☐ **A recent federal regulation.**
Cite:
Effective date:
☐ **A recent court order.**
Cite order:
☐ **State Medical Facilities Plan.**
☐ **Other:**

Explain:
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 a 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. They subsequently asked the Board of Nursing to adopt the same rule.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

According to the Centers for Disease Control, COVID-19 has caused over 90,000 deaths in the United States. There are no FDA-approved vaccines or treatments for COVID-19. As health care providers and public health officials try to combat the spread of COVID-19, a number of drugs are being tested for preventing or treating COVID-19. As these drugs undergo tests, publicity of their potential effects on COVID-19 spread, and some prescribers have prescribed these drugs for patients as off-label medications for the prevention or treatment of COVID-19. While such off-label prescribing is not prohibited, it has had the effect of causing shortages in these drugs for the treatment of the conditions for which they are approved. As the most prominent example, hydroxychloroquine is the subject of clinical trials at the National Institute of Health and other testing to determine if it can treat COVID-19. Those involved in the COVID-19 fight, including the President, have publicized these ongoing hydroxychloroquine tests as a potential cure for COVID-19. As a result, there have been shortages of hydroxychloroquine for its approved uses, including lupus and rheumatoid arthritis patients, and the drug has been placed on the FDA Drug Shortage list. In addition to hydroxychloroquine, other drugs covered in the rule have already been placed on the FDA Drug Shortage list, including chloroquine, lopinavir-ritonavir, and ribavirin.

The COVID-19 Drug Preservation Rule does not prohibit prescribing any drug for off-label use for COVID-19. Instead, it provides that a prescriber must include a written diagnosis on the prescription supporting the prescription. If that diagnosis is COVID-19, the initial prescription is limited to 14 days (though a subsequent prescription may be issued). This helps to prevent and alleviate the shortages for existing (and newly diagnosed) patients who have conditions for which the drugs are approved.

If the Board were to have approved a rule on the normal permanent rule-making timeline, the rule could not have been effective until August 1, 2020, at the earliest. Given the pandemic nature of COVID-19, this would have allowed COVID-19 to rage for months and shortages to persist and deepen during the height of the pandemic.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

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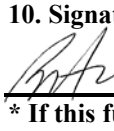
10. Signature of Agency Head*:



*** If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**
Typed Name: Bryant A. Murphy

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RULES REVIEW COMMISSION USE ONLY	
Action taken: ☐ Date returned to agency:	Submitted for RRC Review:

21 NCAC 32B .1708 is adopted under temporary procedures with changes as follows:

21 NCAC 32B .1708 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) Darunavir; and

(7) Azithromycin.

(b) A physician or physician assistant shall prescribe 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 that the patient has been diagnosed with COVID-19;

(2) Be limited to no more than a ~~fourteen-day~~ 14-day supply; and

(3) Not be refilled, unless a new prescription is issued in conformance with this Rule, including not being refilled through an emergency prescription refill.

(d) A physician or physician assistant shall not prescribe 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 in accordance with 21 NCAC 46 .1819(e). ~~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.

History Note: *Authority G.S. ~~90-5.1(a)(3), 90-12.5;~~ 90-5.1(a)(3);*
Emergency Adoption Eff. April 6, 2020;
Temporary Adoption Eff. June 26, 2020.