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 32M .0119 COVID-19 Drug Preservation Rule

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

4. Was this an Emergency Rule: ☒ **Yes** ☐ **No** **Effective date:** 04/21/2020

5. Provide dates for the following actions as applicable:

a. Proposed Temporary Rule submitted to OAH: 04/13/2020

b. Proposed Temporary Rule published on the OAH website: 04/13/2020

c. Public Hearing date: 04/28/2020

d. Comment Period: 04/20/2020-05/11/2020

e. Notice pursuant to G.S. 150B-21.1(a3)(2): Yes

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 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.

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**

9. Rule-making Coordinator: Lynne Taylor
1203 Front Street
Raleigh, NC 27609
Phone: 919-326-1109, Ext. 237

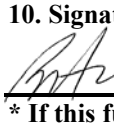
E-Mail: lynne.taylor@ncmedboard.org

Agency contact, if any: Marcus Jimison
Senior Board Attorney

Phone: 919-326-1109, Ext. 226

E-Mail: marcus.jimison@ncmedboard.org

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

Title: President

E-Mail: bryant.murphy@ncmedboard.org

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

TEMPORARY RULE
RRC STAFF OPINION

Please Note: This communication is either 1) only the recommendation of an RRC staff attorney as to action that the attorney believes the Commission should take on the cited rule at its next meeting, or 2) an opinion of that attorney as to some matter concerning that rule. The agency and members of the public are invited to submit their own comments and recommendations (according to RRC rules) to the Commission.

AGENCY: Medical Board

RULE CITATION: 21 NCAC 32M .0119

RECOMMENDED ACTION:

X Approve, but note staff's comment

Object, based on:

Lack of statutory authority

Unclear or ambiguous

Unnecessary

Failure to comply with the APA

COMMENT:

Staff recommends approval because the agency substantially complied with the APA. On April 13, 2020, the agency submitted the proposed Rule to the Codifier for publication on OAH's website. The agency adopted the Rule on May 21, 2020, 28 business days after submission to the Codifier. The temporary rulemaking process requires submission to the Codifier 30 business days prior to adoption.

§ 150B-21.1. Procedure for adopting a temporary rule.

(a3) Unless otherwise provided by law, the agency shall:

(1) At least 30 business days prior to adopting a temporary rule, submit the rule and a notice of public hearing to the Codifier of Rules, and the Codifier of Rules shall publish the proposed temporary rule and the notice of public hearing on the Internet to be posted within five business days.

(2) At least 30 business days prior to adopting a temporary rule, notify persons on the mailing list maintained pursuant to G.S. 150B-21.2(d) and any other interested parties of its intent to adopt a temporary rule and of the public hearing.

(3) Accept written comments on the proposed temporary rule for at least 15 business days prior to adoption of the temporary rule.

(4) Hold at least one public hearing on the proposed temporary rule no less than five days after the rule and notice have been published.

§ 150B-18. Scope and effect.

This Article applies to an agency's exercise of its authority to adopt a rule. A rule is not valid unless it is adopted in substantial compliance with this Article. An agency shall not seek to implement or enforce against any person a policy, guideline, or other interpretive statement that meets the definition of a rule contained in G.S. 150B-2(8a) if the policy, guideline, or other interpretive statement has not been adopted as a rule in accordance with this Article.

Ashley Snyder
Commission Counsel

The agency contends it substantially complied with the temporary rulemaking process. Staff agrees and therefore recommends approval. The agency's explanation is provided below:

The Board adopted the rule prior to 30 business days for the following reasons. The rule at issue was requested by the Secretary of the NC DHHS and the State Medical Director to prevent hoarding of certain drugs which may be used to treat COVID-19. Because of this unprecedented pandemic and because of the need to act quickly to prevent shortages of certain medications that may effectively treat COVID-19 (the Board did receive information that some prescribers were issuing more prescriptions for these drugs than normal and at larger quantities), the Board acted quickly to adopt the preservation rules. The Board acted responsibly and quickly on the Secretary's request and passed an emergency rule. Temporary rule-making began at the same time the emergency rule was adopted per the APA. The comment period ended prior to the Board's adoption and a public hearing was held. The Board did not receive any public comments prior to the end of the comment period or at the public hearing. No one appeared at the scheduled virtual public hearing. The Board meets during the third week of each odd-numbered months. These meetings are set far in advance. The Board's May 2020 meeting fell on business day 28, just two business days short of the 30-business day. We are in the middle of an unprecedented global pandemic where boards are enacting emergency rules and issuing emergency orders to deal with possible healthcare provider shortages as well as potential shortages of medications. Although the Board could call a special meeting, the Board is comprised of practicing healthcare professionals who work full time, and doing so would impose additional costs and detract from other duties and responsibilities during a time of an unprecedented public health crises.

TEMPORARY RULE
REQUEST FOR TECHNICAL CHANGE

AGENCY: Medical Board

RULE CITATION: 21 NCAC 32M .0119

DEADLINE FOR RECEIPT: June 12, 2020

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

On your Findings of Need Form, please review the date in Box 5(a). Does submission on April 13, 2020 meet the requirements of G.S. 150B-21.1(a3)(1) given your adoption date of May 21, 2020?

On your Findings of Need Form, please provide a date in Box 5(e). Did your notice meet the requirements of G.S. 150B-21.1(a3)(2) given your adoption date of May 21, 2020?

In (c)(2), please use "14-day." See 26 NCAC 02C .0108(9), which requires the use of figures for numbers over nine.

In (e), where is your statutory authority to require the pharmacy to record this information in writing?

At line 30, please change "History Authority:" to "History Note:"

In your history note, why is 90-12.5 listed? Are you waiving a statute in this Rule? If so, which one?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: June 3, 2020

21 NCAC 32B .0119 is adopted under temporary procedures as follows:

21 NCAC 32M .0119 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 nurse practitioner 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 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 nurse practitioner 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 nurse practitioner or the nurse practitioner's agent, and that information is recorded in writing by the pharmacy along with the identity of the nurse practitioner or the nurse practitioner'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 Authority: Authority G.S. 90-5.1(a)(3); 90-18.2; 90-12.5.
Emergency Adoption Eff. April 21, ~~2020.~~2020;
Eff. _____.