

**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.

Ashley Snyder
Commission Counsel

21 NCAC 32B .0119 is adopted under temporary procedures with changes 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~~ 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 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 nurse practitioner's agent, and that information is recorded in accordance with 21 NCAC 46 .1819(c). ~~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 Note: Authority G.S. 90-5.1(a)(3); 90-18.2; ~~90-12.5~~.

Emergency Adoption Eff. April 21, ~~2020~~.2020;

Temporary Adoption Eff. June 26, 2020.