



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: NC Board of Nursing
2. Rule citation & name: 21 NCAC 36 .0817 COVID-19 Drug Preservation Rule
3. Action: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal
4. Was this an Emergency Rule: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Effective date: April 21, 2020
5. Provide dates for the following actions as applicable: a. Proposed Temporary Rule submitted to OAH: April 13, 2020 b. Proposed Temporary Rule published on the OAH website: April 14, 2020 c. Public Hearing date: April 28, 2020 d. Comment Period: April 20, 2020 – May 11, 2020 e. Notice pursuant to G.S. 150B-21.1(a3)(2): April 16, 2020 f. Adoption by agency on: May 27, 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. <input checked="" type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input type="checkbox"/> The effective date of a recent act of the General Assembly or of the U.S. Congress. Cite: Effective date: <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> 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. 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 Board of Nursing adopt emergency rules with respect to nurses with prescribing authority to assist in alleviating shortages and ensure that these drugs are available to patients who need them. See attached request from Department of Health and Human Services requesting rulemaking.

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

Request was received from the Department of Health and Human Services on March 31, 2020 to address issues in the community related to shortages of investigational medications for COVID-19 treatment at both the prescribing and dispensing level. See attached request.

In addition, Governor's Executive Order No. 130 Meeting North Carolina's Health and Human Services Needs Section 3 (A)(1)(b)(ii).

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: Angela Ellis, Chief Administrative Officer

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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: Martha Ann Harrell

Title: Chair, NC Board of Nursing

E-Mail: angela@ncbon.com

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

☐ Date returned to agency:

TEMPORARY RULE
REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Nursing

RULE CITATION: 21 NCAC 36 .0817

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(e). Does notice on April 16, 2020 meet the requirements of G.S. 150B-21.1(a3)(2) given your adoption date of May 27, 2020?

On your Findings of Need Form, in Box 7, please explain why the notice and hearing requirements of G.S. 150B-21.2 (the permanent rulemaking process) would be contrary to the public interest and that the immediate adoption of this Rule is required.

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

In (c)(3), line 19, please add a period at the end of the sentence.

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

In your history note, why are 90-171.49 and 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 36 .0817 is proposed for adoption as published in NCR 34:22, pages 2115-2116, as follows:

21 NCAC 36 .0817 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 of 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, and that information is recorded in writing by the pharmacy, along with the identity of the nurse practitioner 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. 90-171.23; 90-171.49, 90-5.1; 90-8.2; 90-12.5

Eff. _____