

TITLE 21 - OCCUPATIONAL LICENSING BOARDS AND COMMISSIONS

CHAPTER 46 – BOARD OF PHARMACY

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to adopt the rule cited as 21 NCAC 46 .1819.

Link to agency website pursuant to G.S. 150B-19.1(c): www.ncbop.org/rulemakings.htm

Proposed Effective Date: February 1, 2021

Public Hearing:

Date: December 16, 2020

Time: 10:00 a.m.

Location: The public can participate on Teams at <https://tinyurl.com/y27ovmlt>, or may call 336-604-5350, conference ID 755 889 266#.

Reason for Proposed 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, the Board of Nursing 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. This rule was adopted as an emergency and then a temporary rule. The State Health Director has requested that the rule be adopted as a permanent rule because the state of emergency and corresponding potential drug shortages now may potentially extend beyond the expiration of the temporary rule. The Board intends to repeal the rule upon the conclusion of the state of emergency. The State Health Director has determined that the State is unlikely to suffer future shortages of two of the drugs previously listed in the temporary and emergency rule, and that those drugs may be removed from the list, while the others should remain.

Comments may be submitted to: Jay Campbell, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517; fax (919) 246-1056; email ncboprulemaking@ncbop.org

Comment period ends: December 17, 2020 at 12:00 noon

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

- State funds affected
- Local funds affected
- Substantial economic impact (\geq \$1,000,000)
- Approved by OSBM
- No fiscal note required

SECTION .1800 - PRESCRIPTIONS

21 NCAC 46 .1819 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) Darunavir.

(b) 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 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) 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 prescriber or the prescriber's agent, and that information is recorded in writing by the pharmacy, along with the identity of the prescriber or prescriber'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. 90-85.6; 90-85.26; 90-85.32;
Emergency Adoption Eff. April 1, 2020;
Temporary Adoption Eff. June 26, 2020;
Adoption Eff. February 1, 2021.*