

Emergency Rule for Dispensing Chloroquine and Hydroxychloroquine

Updated 3/26/2020

On March 22, 2020, Governor Mike DeWine authorized the State of Ohio Board of Pharmacy to file emergency rule 4729-5-30.2 of the Administrative Code, which reads:

<u>4729-5-30.2</u> – <u>Prescription requirements for chloroquine or hydroxychloroquine</u>

(Effective 3/22/2020)

- (A) Unless otherwise approved by the board's executive director, no prescription for chloroquine or hydroxychloroquine may be dispensed by a pharmacist or sold at retail by a licensed terminal distributor of dangerous drugs unless all the following apply:
 - (1) The prescription bears a written diagnosis code from the prescriber;
 - (2) If written for a COVID-19 diagnosis, the diagnosis has been confirmed by a positive test result, which is documented on the prescription and both of the following apply;
 - (a) The prescription is limited to no more than a fourteen-day supply; and
 - (b) No refills may be permitted unless a new prescription is furnished.
- (B) Prescriptions for either presumptive positive patients or prophylactic use of chloroquine or hydroxychloroquine related to COVID-19 is strictly prohibited unless otherwise approved by the board's executive director in consultation with the board president, at which time a resolution shall issue.

UPDATED 3/26/20: Pursuant to paragraph (B) of rule 4729-5-30.2 of the Administrative Code, the Board's Executive Director, in consultation with the Board President have authorized the dispensing of chloroquine or hydroxychloroquine for presumptive positive patients for either of the following:

- For use as part of a documented institutional review board-approved clinical trial to evaluate the safety and efficacy of the drugs to treat COVID-19. Prescriptions must include documentation that the patient is enrolled in a clinical trial.
- For the continuation of inpatient treatment for COVID-19 using chloroquine or hydroxychloroquine for patients discharged from a hospital. The prescriber shall be



required to notate on the prescription that the patient has been discharged from the hospital and the prescription shall be for no more than a fourteen-day supply.

REMINDER: Rule <u>4729-5-30</u> of the Ohio Administrative Code stats that a prescription, to be valid, must be issued for legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice. Furthermore, an order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient that is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of the law.

Pharmacists have a corresponding responsibility to ensure proper prescribing is for legitimate medical purpose, including prescribing for FDA-approved indication or off-label.

This rule permits <u>up to</u> a fourteen-day supply for treating COVID-19, however, prescribers should familiarize themselves with <u>dosing quidance</u> provided by CDC.

Frequently Asked Questions

To assist licensees in complying with this rule, the Board has developed the following frequently asked questions. This document will be updated as needed. If you need additional information, the most expedient way to have your questions answered is to e-mail the Board by visiting: www.pharmacy.ohio.gov/contact.

Q1) Do the requirements of the rule apply to inpatient prescriptions issued for patients in an institutional facility (i.e. hospital, etc.)? – UPDATED 3/26/2020

No. At this time, the rule only applies to prescriptions that are dispensed for outpatient use, as <u>CDC has stated</u> the following "upon limited in-vitro and anecdotal data, chloroquine or hydroxychloroquine are currently recommended for treatment of hospitalized COVID-19 patients in several countries."

The Board has received questions from nursing homes as to whether this rule applies. An institutional facility includes nursing homes licensed under Chapter 3721. of the Revised Code. Therefore, such facilities are also exempted from the requirements of this rule.

Q2) Does this rule mean the Board endorses the use of chloroquine or hydroxychloroquine to treat patients diagnosed with COVID-19?

No, the Board does not have a formal position on the use of chloroquine or hydroxychloroquine to treat patients diagnosed with COVID-19. The purpose of the rule is to ensure that patients who have conditions such as malaria, rheumatoid arthritis, and lupus that are being treated with these medications do not experience shortages during the COVID-19 outbreak.

While the rule does permit the treatment of a COVID-19 patient with a confirmed diagnosis, the Board defers to the FDA and CDC to determine whether chloroquine or hydroxychloroquine is appropriate in the treatment of COVID-19. For more information on treatment options visit: https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html

Q3) I have a patient who has been taking chloroquine or hydroxychloroquine to treat a chronic condition and the patient's prescriber has not included a diagnosis code on the prescription. What are my options?

To not disrupt patient access, any prescription issued prior to 3/22/2020, including refills, may be dispensed without a documented diagnosis code.

Any new prescriptions must have a diagnosis code, including those issued verbally. For new prescriptions issued on or after 3/22/2020 that do not have a diagnosis code, a pharmacist, pharmacy intern, or certified pharmacy technician must contact the prescriber to obtain the proper diagnosis code and document this information on the prescription or in the patient's profile.