



**STATE OF
OHIO**
BOARD OF PHARMACY

Emergency Rule for Dispensing Chloroquine and Hydroxychloroquine

Updated 4/24/2020

IMPORTANT ADVISORY: On April 24, 2020, the FDA issued a [statement](#) cautioning against the use hydroxychloroquine or chloroquine for the treatment of COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems. For the full statement, click [here](#).

Please be advised that while Board of Pharmacy rules permit the limited use of chloroquine and hydroxychloroquine outside of hospital and clinical trial settings for the treatment of COVID-19, prescribers are encouraged to review this [statement](#).

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:

4729-5-30.2 – Prescription requirements for chloroquine or hydroxychloroquine
(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.

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 any of the following:

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1. 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. **(Authorized 3/26/2020)**
2. 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 seven-day supply (no refills authorized)**. **(Authorized 3/26/2020, Updated 4/14/2020)**
3. For patients discharged from an emergency department, for a probable COVID-19 diagnosis based upon [case classifications established by the Ohio Department of Health](#). The prescriber shall be required to notate on the prescription that the patient has been discharged from the emergency department with a probable COVID-19 diagnosis and the prescription shall be for **no more than a seven-day supply (no refills authorized)**. **(Authorized 4/14/2020)**

NOTE: Emergency department includes emergency departments in hospitals and free-standing emergency departments. It does not include urgent care facilities.

REMINDER: Rule [4729-5-30](#) of the Ohio Administrative Code states 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.

Prescribers are strongly recommended to familiarize themselves with dosing standards and contraindications provided by FDA under its [Emergency Use Authorization](#) as well as its [statement](#) on using these medications outside of a hospital setting or clinical trial.

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.)?

No. At this time, the rule only applies to prescriptions that are dispensed for outpatient use, as [CDC has stated](#) 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.

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>

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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.

Q4) Am I able to prescribe chloroquine or hydroxychloroquine for other conditions? – UPDATED 4/14/2020

Yes, as long as the prescriber includes a diagnosis code on the prescription. The limitations set forth in rule are only for the off-label prescribing of these medications for COVID-19. Other off-label uses (e.g. dermatomyositis, cutaneous disease, etc.) are still permitted.

Q5) Are urgent cares included in the definition of emergency department? – UPDATED 4/16/2020

Emergency department includes emergency departments in hospitals and free-standing emergency departments. It does not include urgent care facilities.

Q6) Are pharmacists required to review clinical assessments or patient progress notes to confirm the patient meets the requirements of the rule? – UPDATED 4/24/2020

No. The responsibility of the pharmacist is to confirm that the prescription contains all of the additional information required by the rule to dispense the prescription (i.e. diagnosis, notation from prescriber about emergency department/hospital discharge, etc.).