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4729-5-30.2 Prescription requirements for chloroquine and hydroxychloroquine.

(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 or a statement indicating its veterinary medical purpose; and

(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) Unless otherwise approved by the board, the prescription is limited to no more than a fourteen-seven-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 COVID-19, at which time a resolution shall issue.

NOTE: The 7-day supply is based upon prescribing instructions for the drug provided by FDA:

The suggested dose under this EUA for hydroxychloroquine sulfate to treat adults and adolescents who weigh 50 kg or more and are hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible, is 800 milligrams of hydroxychloroquine sulfate on the first day of treatment and then 400 milligrams daily for four to seven days of total treatment based on clinical evaluation.

From: https://www.fda.gov/media/136537/download
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<th>Entity</th>
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<td>OVMA</td>
<td>While we certainly understand the intent and need for parameters relative to prescribing chloroquine or hydroxychloroquine we do have a concern with proposed rule 4729-5-30.02 as drafted. Chloroquine may be used in veterinary aquaculture medicine to treat parasitic infections and could potentially be used to treat Lupus in dogs. As written the rule calls for a “written diagnosis code” which is specific to human medicine and would therefore potentially limit its use for legitimate purposes in veterinary medicine. We would respectfully ask this be modified to add words in (A)(1) to the effect of “or identify the veterinary medical purpose.”</td>
<td>The Board understands the commenters concerns and the proposed language will be incorporated into the rule (see end of this document).</td>
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<td>Paul Groff, MD</td>
<td>It is my opinion that the emergency rule to limit prescriptions of hydroxychloroquine to outpatients with proven covid19 and subsequently amended to include patients with probable covid19 seen in emergency rooms unfairly prohibits treatment options to presumed covid19 patients diagnosed in other outpatient settings to the benefit of rheumatoid arthritis and lupus patients. My first concern is that many medical facilities do not want patients to come to the facility if they are concerned that the patient has covid19 but rather to a testing location. Also testing for covid19 remains limited particularly in Ohio. The intent of this rule appears to prohibit outpatients from taking these medicines if they have symptoms of covid19 but are not yet tested positive creating treatment delay. We recognize that in this health care crisis we do not have enough knowledge on the risks and benefits of these medicines to make perfect decisions. However, an early study from Wuhan demonstrated that while hydroxychloroquine may not reduce viral loads significantly it did provide symptomatic relief in covid19 patients. Are the symptoms of rheumatoid arthritis and lupus patients more important than symptoms in covid19 patients? Moreover, a recent survey indicated 25 percent of physicians believe hydroxychloroquine should be given prophylactically to patients at risk for developing covid19 which this rule also prohibits.</td>
<td>The commenter cites several early studies performed in other countries that were limited in size and scope. A larger study conducted in the United States has emerged in the past few weeks found no benefit from the drug, either alone or given in combination with an antibiotic. In fact, the patients treated with hydroxychloroquine alone had a higher mortality rate. Additionally, the FDA issued a warning strongly recommending limits on the treatment of COVID-19 to hospital settings: <em>To decrease the risk of these heart problems that can be life-threatening, we are warning the public that hydroxychloroquine and chloroquine, either alone or combined with azithromycin, when used for COVID-19 should be limited to clinical trial settings or for treating certain hospitalized patients under the EUA. FDA will continue to investigate risks associated with the use of hydroxychloroquine and chloroquine for COVID-19, and we will communicate publicly when we have more information.</em> Given the science and national warnings, the Board does not feel it is appropriate to expand the current rule beyond hospital and clinical trial settings.</td>
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While I believe the rule to curb prescribing of hydroxychloroquine in Ohio is well intentioned, the result of this rule could in fact cause harm. If hydroxychloroquine turns out to be beneficial in the earlier stages of covid19 by reducing the body's inflammatory response to the infection, the effect of this emergency rules may lead to increased morbidity and mortality. By creating delay and effectively rationing the pills to those later in the course of the covid19 disease and to those with malaria, rheumatoid arthritis or lupus as well as other off label uses of the drug not diagnosed as covid19, early cases of covid19 may progress to a point where the hydroxychloroquine no longer helps. Unfortunately, we just don’t know if that is true, but I believe the Pharmacy Board should not be picking winners and losers based on the advice of the Lupus Foundation during a health care crisis. I suspect covid19 will ultimately have far greater prevalence than lupus. It probably already does. This topic has become overly political and my suggestion would be to strike this rule.

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<th>Tricia Bhat, MD</th>
<th>Rule 4729:5-30.2 would not preclude you from prescribing for a patient who tests positive for COVID-19. If you have a patient who was clinically diagnosed with COVID-19 that you are treating on an outpatient basis, you would just indicate they tested positive for the disease on the prescription and they would be able to obtain a 14-day supply.</th>
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| Spring house health | To whom it may concern (caps are to help highlight important facts for the busy reader, they are not "yelling")

I have a couple of questions regarding outpatient covid-19 management. The hydroxychloroquine prescribing was once available only for INPATIENT patients. It now seems it is available for ER's to prescribe FOR OUTPATIENT MANAGEMENT (ie, patient being discharged home from the ER). Does that mean that if I (a board-certified family medicine doctor) feel I have a high risk patient with clinically diagnosed covid-19 (which is now acceptable as a way to diagnose- no test confirmation needed) that I am trying to manage remotely with home monitoring, that patient would HAVE to go to the ER and incur those costs (for self pay/un- or under-insured patients) and the unnecessary cluttering of ER space in order for them to access this treatment option that has NOW BECOME AVAILABLE IN OHIO FOR OUTPATIENT MANAGEMENT?

Only ER providers, who often are not MD/DOs, can diagnose and treat this clinically? This doesn't make sense to me. If the allowance has expanded from needing to be an inpatient to being an outpatient, it should be recognized that outpatient specialty doctors/primary care providers can also diagnose and treat this outpatient management at least as effectively as an ER provider could.

- **Concerns about inappropriate prescribing and the potential hoarding of medications.** Around mid-March, the Board began receiving a number of complaints from pharmacists regarding a sizable increase in both the number of prescriptions of these medications as well as the quantities being prescribed. From the complaints lodged with the Board and media reports, it became apparent that individuals were attempting to obtain large quantities of the drug that severely disrupted the current supply chain.
  - The issue became such a problem that the Attorney
Mandating ER-only prescribing limits access to uninsured and underinsured (often more vulnerable) patient populations who are often managed by their outpatient primary care providers, outpatient pulmonary, and outpatient infectious disease specialists.

Another approach is to make WHOMEVER is prescribing this medication clearly document and own their justification for needing this prescription. Using ER presence as an indicator of a patient's illness severity is a faulty indicator.

- **Reported shortages for patients taking these medications for chronic conditions.** These medications are proven therapies to treat chronic conditions such as lupus and rheumatoid arthritis.
  - According to a recent report from ProPublica, lupus patients are reporting difficulty in refilling prescriptions for the drug.
  - A recent Columbus Dispatch article, points to concerns that such patients are having regarding access to the medication: Barb Faber, 38, of Belle Center, said a shortage of medicine to treat her lupus is alarming because she could die without treatment. "This medication is the only thing that stopped my body from attacking itself," she said. "People taking it that don’t need it is ridiculous. Doctors taking this med, when they know what patients go through and how dangerous it is if they don’t have it, is disgraceful. I went through years of testing to get my diagnosis, and I
went through many medications to find this one thing that works.”

- The Arthritis Foundation and the Lupus Foundation of America contacted the Board directly requesting the Board “...take action that preserves the ability of people with RA and lupus to access the medications they need to fight their disease.”
- Additionally, the Board has made it clear in its guidance that other off-label uses (dermatomyositis, cutaneous disease, Sjogren’s Syndrome, sarcoidosis, Q fever, etc.) are permissible under the rule.

The Board’s efforts to place measured restrictions on the prescribing of hydroxychloroquine and chloroquine for COVID-19 align with the emergency use authorization (EUA) issued by the U.S. Food and Drug Administration (FDA). As with the Board’s rule, the FDA’s EUA permits the treatment of adults and adolescents with these medications if they are hospitalized with COVID-19. This permits prescribers to conduct the required laboratory and monitoring procedures to screen for arrythmia and other conditions that may lead to serious adverse events.

Furthermore, a larger study conducted in the United States has emerged in the past few weeks found no benefit from the drug, either alone or given in combination with an antibiotic. In fact, the patients treated with hydroxychloroquine alone had a higher mortality rate.

Additionally, the FDA issued a warning strongly recommending limits on the treatment of COVID-19 to hospital settings:

To decrease the risk of these heart problems that can be life-threatening, we are warning the public that hydroxychloroquine and chloroquine, either alone or combined with azithromycin, when used for COVID-19 should be limited to clinical trial settings or for treating certain hospitalized patients under the EUA. FDA will continue to investigate risks associated with the use of hydroxychloroquine and chloroquine for
Catharine Kenny | I thought you’d be interested in this story from the New York Post.


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A larger study conducted in the United States has emerged in the past few weeks found no benefit from the drug, either alone or given in combination with an antibiotic. In fact, the patients treated with hydroxychloroquine alone had a higher mortality rate.

Further, a study out of New York found that those who took hydroxychloroquine, with or without the antibiotic azithromycin, were no more likely to survive their infections than those who did not: [https://nypost.com/2020/04/23/hydroxychloroquine-had-no-effect-on-seriously-ill-in-new-york-study/](https://nypost.com/2020/04/23/hydroxychloroquine-had-no-effect-on-seriously-ill-in-new-york-study/)

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Given the science and national warnings, the Board does not feel it is appropriate to expand the current rule beyond hospital and clinical trial settings.