UPDATED JOINT STATEMENT FROM THE:

IOWA BOARD OF PHARMACY
IOWA BOARD OF NURSING
IOWA DENTAL BOARD
IOWA BOARD OF PHYSICIAN ASSISTANTS
IOWA BOARD OF MEDICINE

DATE, September 11, 2020

On March 26, 2020 the Iowa Boards of Medicine, Nursing, Physician Assistants, Dentistry and Pharmacy issued a joint statement after receiving reports of prescriptions being issued for hydroxychloroquine, chloroquine, and azithromycin for preventative purposes in response to the COVID-19 outbreak. At that time, pharmacies in Iowa were reporting shortages of the identified medications, which posed a risk for patients in need. The joint statement was issued to provide immediate information to prescribers and pharmacies to ensure these medications would be available to patients who needed them. The Boards now issue this updated joint statement to replace the original to update prescribers and pharmacies on developments related to chloroquine and hydroxychloroquine as the COVID-19 pandemic continues to progress.

On March 31, 2020, the Federal Food and Drug Administration (FDA) placed chloroquine and hydroxychloroquine on its shortage list. A drug shortage exists "when the demand or projected demand for the drug within the United States exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2). "Drug shortages can have serious and immediate effects on providing needed therapies to patients . . . . Shortages can delay or deny needed care for patients, creating a potential lapse in medical care. Shortages can also lead prescribers to use second-line alternatives, which may be less effective or pose additional risks." Food & Drug Admin., Report on Drug Shortages for Calendar Year 2019, at 2 (April 23, 2020).

Chloroquine phosphate remained on the FDA shortage list until May 8, 2020. Hydroxychloroquine remained on the FDA shortage list until June 26, 2020. During that time, the FDA and other regulatory authorities continued to examine the medications' efficacy for treating COVID-19. On June 15, 2020, the FDA revoked its emergency use authorization for the emergency use of oral formulations of chloroquine phosphate (CQ) and hydroxychloroquine sulfate (HCQ).[1] In the supporting memorandum, the FDA concluded "it is unlikely that CQ and HCQ may be effective in treating COVID-19. Further, in light of the ongoing reports of serious

[1] Food & Drug Admin., Letter of Revocation and Memorandum Explaining Basis for Revocation of Emergency Use Authorization for Emergency Use of Chloroquine Phosphate and Hydroxychloroquine Sulfate (June 15, 2020), https://www.fda.gov/media/138945/download.

cardiac adverse events and several newly reported cases of methemoglobinemia in COVID-19 patients, the Agency has concluded that the known and potential benefits of CQ and HCQ do not outweigh the known and potential risks for authorized uses." The FDA presently continues to advise that "[h]ydroxychloroquine and chloroquine have not been shown to be safe and effective for treating or preventing COVID-19."[2]

Currently, there is not a shortage of chloroquine and hydroxychloroquine, which is likely due to new information and evidence indicating the medications may be unsafe or ineffective for the prevention or treatment of COVID-19. Prescribers and pharmacies are encouraged, as always, to keep abreast of drug shortages and FDA guidance as the pandemic continues. Licensees are also still reminded of the following:

- Prescriptions should only be issued in the context of a valid prescriber-patient relationship for a legitimate medical need.

- Prescribers should not attempt to stockpile medications by issuing prescriptions for themselves or their families or friends in the absence of a legitimate medical need.

- Pharmacists are encouraged to contact prescribers if there are questions or concerns about any prescription. Prescribers may wish to consider adding additional information to prescriptions to prevent questions from the pharmacist and to avoid delays in patient care.

- Prescribers should limit the amount prescribed to the necessary quantity, particularly for drugs that are in short supply.

This updated joint statement does not impose any mandatory requirements on prescribers or pharmacies or create any new legal requirements. Failure to adhere to the guidelines provided in this statement will only result in discipline to licensees if the licensee is in violation of any existing disciplinary grounds already established in rule. The purpose of this joint statement is to provide up-to-date information about an ever-changing landscape for the treatment and prevention of the novel COVID-19 virus. The purpose of this joint statement is in no way meant to act as a deterrent for prescribers to use the identified medications in the manner in which they have been verified to be effective. Rather, prescribers and pharmacies are encouraged to continue to utilize good professional judgment in making patient care decisions during these extraordinary times.

[2] *See* Food & Drug Admin., Drug Safety & Availability (July 1, 2020), https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or.