



Interim Guidance for Dispensing Hydroxychloroquine or Chloroquine During the COVID-19 Public Health Emergency

April 19, 2020

Background: In December 2019, a new respiratory disease called the novel coronavirus (COVID-19) was detected. COVID-19 is caused by a virus (SARS-CoV-2) that is part of a large family of viruses called coronaviruses. Recently, community-wide transmission of COVID-19 occurred in the United States, including New York where there have been more than 11,000 deaths and 213,000 positive cases, as of April 14, 2020. In response to this public health emergency, clinicians commenced studies of different therapeutics, including hydroxychloroquine and chloroquine, to treat people who have contracted COVID-19 to determine potential effect.

Executive Order: [Executive Order 202.10](#), as modified by [Executive Order 202.11](#) provides that:

“No pharmacist shall dispense hydroxychloroquine or chloroquine except when written: as prescribed for an FDA-approved indication; for an indication supported by one or more citations included or approved for inclusion in the compendia specified in 42 U.S.C. 1396r-8(g)(1)(B)(i); for patients in inpatient settings and acute settings; for residents in a subacute part of a skilled nursing facility; or as part of a study approved by an Institutional Review Board. Any person authorized to prescribe such medications shall denote on the prescription the condition for which the prescription has been issued.”

Guidance: In March 2020, Governor Cuomo [announced](#) that the New York State Department of Health (DOH) recommended trials for new drug therapies to help combat COVID-19. Subsequently, New York State obtained a supply of hydroxychloroquine from the federal government, as well as donations from pharmaceutical companies. New York’s health care institutions have also continued to procure and distribute additional doses to people who are confirmed or suspected to be infected with COVID-19 through their health care providers and facilities, including through several new [clinical trials](#).

Based upon the FDA’s [emergency use authorization](#) (EUA), it is the Department’s position that hydroxychloroquine can be used to treat adults and adolescents who weigh 50 kilograms or more with COVID-19, despite this and other medications not yet being finally approved by the FDA for this particular purpose. Thus, emergency use authorization provided by the FDA and authorized by Executive Order 202.11 allow health care practitioners to prescribe hydroxychloroquine for the treatment of most confirmed COVID-19 patients and permit pharmacists to fulfill such prescriptions in retail or other non-hospital pharmacies and inpatient settings.

Practitioners who prescribe hydroxychloroquine are required to submit reports on the safety and outcome data for each patient that receives this medication through the FDA’s [MedWatch Adverse Event Reporting](#) program and the [Biomedical Advanced Research Development Authority](#), pursuant to the EUA. Further, prescribers are required to denote the condition(s) for which hydroxychloroquine or chloroquine are being used, pursuant to Executive Order 202.11.

Additionally, pharmacists can dispense prescriptions for hydroxychloroquine and chloroquine when they are used for a condition which has been previously approved by the FDA; for a condition that is compendia supported as specified in 42 U.S.C. 1396r–8(g)(1)(B)(i); or for the treatment of COVID-19 patients involved in:

- an inpatient and acute settings,
- a subacute part of a skilled nursing facility, or
- a study approved by an Institutional Review Board (IRB).

However, these restrictions should not be interpreted to prohibit a practitioner from prescribing hydroxychloroquine or chloroquine for COVID-19 in an outpatient setting if such practitioner has determined that the patient meets the criteria which authorizes such medication(s) for treatment of COVID-19 (e.g. adults and adolescents who weigh 50 kilograms or more).

Additional Information:

New York State Department of Health COVID-19 Website

<https://coronavirus.health.ny.gov/>

United States Centers for Disease Control and Prevention (CDC) COVID-19 Website

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

FDA COVID-19 EUA Information

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization# covid19euas>

FDA Fact Sheet for Health Care Providers EUA of Hydroxychloroquine Sulfate Supplied from the Strategic National Stockpile for Treatment of COVID-19 in Certain Hospitalized Patients

<https://www.fda.gov/media/136537/download>

FDA Fact Sheet for Patients and Parent/Caregivers EUA of Hydroxychloroquine Sulfate for Treatment of COVID-19 in Certain Hospitalized Patients

<https://www.fda.gov/media/136538/download>

FDA Frequently Asked Questions on the EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate for Certain Hospitalized COVID-19 Patients

<https://www.fda.gov/media/136784/download>