Ohio Department of Health

Mike DeWine, Governor
Jon Husted, Lt. Governor

Amy Acton, M.D., MPH, Director

TO: Ohio Hospitals, Ohio Hospital Association

FROM: Mark Hurst, MD, Medical Director

TOPIC: Hydroxychloroquine treatment of COVID-19

DATE: April 7, 2020

Colleagues:

As you are aware, there has been much activity surrounding potential treatments for the individuals affected by COVID-19. As this is a new virus that we have been aware of for only a few months at this point, there has been little time to perform randomized controlled trials of treatments, which is the gold standard for determining effectiveness of a treatment.

Recently, there has been some movement to prescribe chloroquine phosphate and hydroxychloroquine sulfate products for COVID treatment. Although the science is not to the point where we are certain that these medications are effective, early research in the lab and some small studies indicate potential help. In light of that, the Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) for use of chloroquine phosphate and hydroxychloroquine sulfate for the treatment of COVID-19 in a hospital setting. In part, this EUA indicates:

> "Based upon limited in-vitro and anecdotal clinical data in case series, chloroquine phosphate and hydroxychloroquine sulfate are currently recommended for treatment of hospitalized COVID-19 patients in several countries, and a number of national guidelines report incorporating recommendations regarding use of chloroquine phosphate or hydroxychloroquine sulfate in the setting of COVID-19. FDA encourages the conduct and participation in randomized controlled clinical trials that may produce evidence concerning the effectiveness of these products in treating COVID-19. FDA is issuing this EUA to facilitate the availability of chloroquine phosphate and hydroxychloroquine sulfate during the COVID-19 pandemic to treat patients for whom a clinical trial is not available, or participation is not feasible."

The authorization for this use is limited to product supplied from the Strategic National Stockpile (SNS) to Public Health Authorities. The Ohio Department of Health (ODH) has obtained hydroxychloroquine sulfate and is prepared to distribute to healthcare systems upon request through their County Emergency Management Agencies (EMA).

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OBTAINING HYDROXYCHLOROQUINE SULFATE FROM THE OHIO DEPARTMENT OF HEALTH

- When it has been determined that response efforts to an incident has exceeded the medical capabilities of the hospital and the jurisdiction, a medical countermeasure (MCM) request should be made through the local emergency management agency (EMA). The request must be as specific as possible and must include at minimum the type of pharmaceutical (in this case, hydroxychloroquine sulfate), quantity and dosing information. Including as much detail as possible will assure there are no delays in the fulfillment process. Hospitals should not directly contact ODH when there is a need for supplies. If all other avenues of obtaining supplies have been exhausted, hospitals should follow their local jurisdictions plans and procedures in accordance with their local EMA to obtain supplies from the state through the 213 RR request process.

Health systems and healthcare providers should fully acquaint themselves with the FDA EUA prior to obtaining and utilizing these medications to treat COVID-19.

INFORMATION FOR HEALTHCARE SYSTEMS TO WHOM THE AUTHORIZED CHLOROQUINE PHOSPHATE AND HYDROXYCHLOROQUINE SULFATE IS DISTRIBUTED

- Systems and healthcare providers receiving the chloroquine phosphate and/or hydroxychloroquine sulfate from the SNS will track adverse events and report to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or Complete and submit FDA Form 3500 (health professional) or FDA Form 3500B (consumer/patient) by fax (1-800- FDA-0178). These forms can be found via link above. Call 1-800-FDA-1088 for questions. Submitted reports should state "chloroquine phosphate treatment under EUA" or "hydroxychloroquine sulfate treatment under EUA." A copy of the adverse event report should also be sent to ODH at the address listed later in this notice.
- Through a process of inventory control, healthcare systems will maintain records regarding the dispensed authorized chloroquine phosphate and hydroxychloroquine sulfate (i.e., lot numbers, quantity, receiving site, receipt date) and maintain patient information and other relevant data as feasible (e.g., patient name, age, disease manifestation, other drugs administered, outcomes).
- Healthcare systems will ensure that any records associated with this EUA are maintained until notified by SNS and/or FDA. Such records will be made available to FDA, SNS and Biomedical Advance Research and Development Authority (BARDA) for inspection upon request.

INFORMATION FOR HEALTHCARE PROVIDERS

This authorization specifies that the medication shall be used to treat hospitalized adults and adolescents who weigh 50 Kg or more. The prescriber should be fully aware of the effects and side effects of the medication and adhere to the guidance in the healthcare provider fact sheet. The factsheets for healthcare providers and patients/parents/caregivers may be accessed here:

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) of Hydroxychloroquine Sulfate Supplied from the Strategic National Stockpile for Treatment of COVID-19 in Certain Hospitalized Patients

- Fact Sheet for Patients and Parent/Caregivers: Emergency Use Authorization (EUA) of Hydroxychloroquine Sulfate for Treatment of COVID-19 in Certain Hospitalized Patients

ODH does not have a supply of chloroquine phosphate at this point. Should we obtain this, the same procedures outlined in this memo regarding hydroxychloroquine phosphate should be followed. Companion fact sheets for chloroquine phosphate, if and when needed, may be accessed here:

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) of Chloroquine Phosphate Supplied from the Strategic National Stockpile of Treatment of COVID-19 in Certain Hospitalized Patients

- Fact Sheet for Patients and Parents/Caregivers: Emergency Use Authorization (EUA) of Chloroquine Phosphate Supplied from the Strategic National Stockpile of Treatment of COVID-19 in Certain Hospitalized Patients

MANDATORY REQUIREMENTS FOR HEALTHCARE PROVIDERS

In order to mitigate the risks of using this approved product for an unapproved use under EUA and to optimize the potential benefit of hydroxychloroquine sulfate, the following items are required. Use of hydroxychloroquine sulfate under this EUA is limited to the following (all requirements **must** be met):

1. The hydroxychloroquine sulfate must only be administered to 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.
2. The health care providers must communicate to the patient or parent/caregiver information consistent with the "Fact Sheet for Patients and Parents/Caregivers" prior to the patient receiving the medication. Health care providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the patient/caregiver has been:
    a. Given the Fact Sheet for Patients and Parents/Caregivers,
    b. Informed of alternatives to receiving authorized hydroxychloroquine sulfate, and
    c. Informed that hydroxychloroquine sulfate is an approved drug that is authorized for the unapproved use under this Emergency Use Authorization.
3. The prescribing health care provider and/or the provider's designee must provide responses to requests from FDA for information about adverse events and medication errors following receipt of hydroxychloroquine sulfate.
4. The prescribing health care provider and/or the provider's designee must be responsible for reporting medication errors and adverse events (death, serious adverse events*) occurring during hydroxychloroquine sulfate treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "**Hydroxychloroquine Sulfate Treatment under Emergency Use Authorization (EUA).**" in the description section of the report.

5. The prescribing health care provider and/or the provider's designee must submit adverse event reports to FDA MedWatch using one of the following methods:
    a. Online Report: complete the report at www.fda.gov/medwatch/report.htm, or
    b. Mail: complete the Postage-paid Form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or
    c. Phone: call 1-800-FDA-1088 to request a reporting form
6. A Copy of this report should also be sent to ODH at:

Ohio Department of Health
Office of the Medical Director
246 N. High St.
Columbus, Ohio 43215

Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" the statement "**Hydroxychloroquine Sulfate Treatment under EUA"**

Thank you for your continuing efforts in dealing with COVID-19 in Ohio.