

## DEPARTMENT OF HEALTH

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### NOTICE OF EMERGENCY AND PROPOSED RULEMAKING

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The Director of the Department of Health, pursuant to the authority set forth in section 19(a)(3) of the District of Columbia Pharmacist and Pharmacy Regulation Act of 1980, effective September 16, 1980 (D.C. Law 3-98; D.C. Official Code § 47-2885.18 (a)(3)); Mayor's Order 98-48, dated April 15, 1998; section 4902 of the Department of Health Functions Clarification Act of 2001, effective October 3, 2001 (D.C. Law 14-28; D.C. Official Code § 7-731); section 15 of the District of Columbia Drug Manufacture and Distribution Licensure Act of 1990, effective June 13, 1990, (D.C. Law 8-137; D.C. Official Code § 48-714(a)); and Mayor's Order 98-88, dated May 29, 1998, hereby gives notice of the adoption, on an emergency basis, of the following amendments to Chapter 13 (Prescriptions and Distribution) of Title 22, Subtitle B of the District of Columbia Municipal Regulations (DCMR).

This emergency rulemaking is necessary to protect the health, safety, and welfare of the District's residents by ensuring the continued availability of hydroxychloroquine, chloroquine, and azithromycin to patients who rely on these prescription medications for treatment of FDA-approved medical conditions and diseases to avoid disability, illness, and early death.

The purpose of this rulemaking is to require that pharmacists only dispense hydroxychloroquine, chloroquine, and azithromycin for FDA-approved conditions and treatment or pursuant to the exceptions set forth in this rulemaking.

This emergency rulemaking was adopted on April 2, 2020, and became effective immediately on that date. The emergency rule will expire one hundred twenty (120) days from the date of adoption, July 31, 2020, or upon publication of a Notice of Final Rulemaking in the *D.C. Register*, whichever occurs first.

The Director also gives notice of her intent to adopt this rule, in final in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

#### **CHAPTER 13 (PRESCRIPTIONS AND DISTRIBUTION) of Title 22 (HEALTH), Subtitle B (PUBLIC HEALTH AND MEDICINE) of the DCMR is amended as follows:**

**A new section 1318 (Prescriptions for Hydroxychloroquine, Chloroquine, and Azithromycin) is added to read as follows:**

#### **1318 Prescriptions for Hydroxychloroquine, Chloroquine, and Azithromycin**

1318.1 Prescription drug orders for Hydroxychloroquine, Chloroquine, or Azithromycin shall only be dispensed as follows:

- (a) If the prescriber has provided a diagnosis code for an FDA-approved use for the drug; or
- (b) If the prescription is written for a COVID-19 diagnosis:
  - (1) The diagnosis shall have been confirmed by a positive test result, which must be documented on the prescription:
  - (2) The prescription shall be limited to not more than a fourteen (14) day supply of Hydroxychloroquine or Chloroquine, and not more than a ten (10) day supply of Azithromycin; and
  - (3) The prescription shall not be refilled. The prescriber must provide a new prescription order.

1318.2 The dispensing of Hydroxychloroquine, Chloroquine, or Azithromycin for patients who are presumptive positive for COVID-19 is prohibited except for use as part of a documented institutional review FDA-approved clinical trial to evaluate the safety and efficacy of the drugs to treat COVID-19. Prescriptions issued pursuant to this exception shall be accompanied by documentation that the patient is enrolled in a clinical trial.

All persons desiring to comment on the subject of this proposed rulemaking should file comments in writing not later than thirty (30) days after the date of the publication of this notice in the *D.C. Register*. Comments should be sent to the Department of Health, Phillip L. Husband, General Counsel, Office of the General Counsel, 899 North Capitol Street, N.E., 6<sup>th</sup> Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained during the hours of 9 a.m. to 5 p.m., Monday through Friday, excluding holidays, at the address listed above, or by contacting Angli Black, Paralegal Assistant, at [Angli.Black@dc.gov](mailto:Angli.Black@dc.gov), (202) 442-5977.