DEPARTMENT OF HEALTH
NOTICE OF THIRD EMERGENCY AND SECOND PROPOSED RULEMAKING

The Director of the Department of Health, pursuant to the authority set forth under §§ 102(11), 302 (14), and 1006 of the District of Columbia Health Occupation Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §§ 1201.02(11), 3-1203.02 (14)), and 3-1210.06, D.C. Official Code § 47-2885.01, D.C. Official Code § 47-2885.18, Mayor's Order 98-48 dated April 15, 1998, Mayor's Order 98-140, dated August 20, 1998, Mayor's Order 2020-045, dated March 11, 2020; Mayor's Order 2020-050, dated March 20, 2020, and Mayor's Order 2020-079, dated July 22, 2020, gives notice of the adoption, on an emergency basis, of the following amendment to chapter 65 of Title 17 of the District of Columbia Municipal Regulations (DCMR) (Pharmacists) adding a new § 6516 (COVID-19 Testing by Pharmacists).

This emergency rulemaking is necessary to continue to protect the health, safety, and welfare of the District's residents by reducing the spread of COVID-19 by establishing minimum standards for the safe and effective operation of pharmacies where pharmacists, pharmacy interns, and pharmacy technicians under the direct supervision of a pharmacist, participate in COVID-19 testing. This rulemaking defines and addresses the location standards, distancing requirements, and use of personal protection equipment standards for the different types of COVID-19 testing, and expands the authority to participate in COVID-19 testing to pharmacy technicians.

A Notice of Emergency rulemaking was published in the *D.C. Register* on June 19, 2020 at 67 DCR 007783. Those emergency rules were adopted on June 5, 2020, and expired one hundred twenty (120) days from the date of adoption, on October 3, 2020. Mayor's Order 2020-079, issued July 22, 2020, extended the declared public emergency and public health emergency in the District of Columbia through October 9, 2020. The Mayor's Order included the finding that the spread of COVID-19 remains a continued threat to the health, safety, and welfare of District residents. This emergency rulemaking action is necessary to maintain the continuity of these provisions through the extended period of the public emergency and public health emergency.
A Notice of Second Emergency and First Proposed Rulemaking was published in the D.C. Register on October 23, 2020 at 012538. Those emergency rules were adopted on October 15, 2020, and became effective immediately on that date. The emergency rule will expire one hundred twenty (120) days from the date of adoption (February 12, 2021), or upon publication of a Notice of Final Rulemaking in the *D.C. Register*, whichever occurs first. Mayor's Order 2020-127, issued December 18, 2020, extended the declared public emergency and public health emergency in the District of Columbia through March 31, 2021. The Mayor's Order included the finding that the District of Columbia, like the rest of the country, is confronting a surge in COVID-19 cases. The spread of COVID-19 remains a continued threat to the health, safety, and welfare of District residents. This emergency rulemaking action is necessary to maintain the continuity of these provisions through the extended period of the public emergency and public health emergency.

In response to the Notice of Second Emergency and First Proposed Rulemaking, the National Community Pharmacists Association, National Grocers Association, The Food Industry Association, and National Association of Chain Drug Stores submitted a joint comment letter.

- The comment letter requested that the provisions pertaining to personal protective equipment (PPE) be amended to follow the Centers for Disease Control and Prevention (CDC) guidelines. Upon further consideration, the Department of Health elected to amend the PPE provisions to be consistent with CDC guidelines.
- The comment letter requested that the provisions pertaining to testing locations be amended to permit indoor testing in pharmacies. The Department did not accept this request as it is inconsistent with CDC guidelines and poses a risk to the public.
- The comment letter requested that the provisions pertaining to testing locations be amended to permit off-site testing. Upon further consideration, the Department elected to amend the testing locations provisions to permit off-site testing locations subject to Department approval and inspection.
- The comment letter requested that the provisions pertaining to expand the role of pharmacy technicians to include administering diagnostic COVID-19 tests. The Department elected to amend this provision to be consistent with the actions taken by the U.S. Department of Health and Human Services' Declarations pertaining to pharmacy technicians administering COVID-19 testing.
- The comment letter requested that the provisions pertaining to testing appointments be amended to remove the requirement to make an appointment. Upon further consideration, the Department elected to remove the requirement of an appointment, which was able to be made on the same day and on site.

This emergency rulemaking was adopted on ( ), and became effective immediately on that date. The emergency rule will expire one hundred twenty (120) days from the date of adoption ( ), 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 take final rulemaking action to adopt these proposed rules in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

A new Section 6516 is added to read as follows:

6516 COVID-19 Testing by Pharmacists

6516.1 A pharmacist licensed in good standing in the District of Columbia shall only perform COVID-19 tests as set forth in this section.

6516.2 For purposes of this section, the terms "COVID-19 test" and "COVID-19 testing" shall refer to COVID-19 diagnostic tests, COVID-19 antibody tests, and any other tests and testing mechanisms for COVID-19 that are approved by the United Stated Food and Drug Administration (FDA), or that are authorized under a FDA Emergency Use Authorization (EUA), and for which a waiver has been granted under § 2 of the Clinical Laboratory Improvement Amendments Act (42 U.S.C. § 263a) (CLIA).

6516.3 For purposes of this section, the phrase "administer COVID-19 tests" or "administer COVID-19 testing" shall mean to administer a diagnostic COVID-19 test to a patient.

6516.4 For purposes of this section, the phrase “observe and facilitate collection of self-administered COVID-19 tests” or “observe and facilitate collection of self-administered COVID-19 testing” shall mean to observe a patient self-administer a diagnostic COVID-19 test to himself or herself.

6516.5 For purposes of this section, the phrase “administer COVID-19 antibody test” or “administer COVID-19 serology test” shall mean to obtain a specimen from a patient through fingerstick, nasal swab, or other CLIA-waived point of care test for purposes of testing for COVID-19 antibodies.

6516.6 For purposes of this section, the phrase “processing a COVID-19 antibody test” shall mean to analyze a specimen through the use of a CLIA-waived testing mechanism to detect the presence of COVID-19 antibodies.

6516.7 Only a pharmacist licensed in good standing in the District of Columbia shall administer, or supervise a licensed pharmacy intern, or registered pharmacy technician in administering, diagnostic COVID-19 testing.

6516.8 The location site where diagnostic COVID-19 testing is administered shall meet the requirements set forth in § 6516.9 or § 6516.10 of this chapter.

6516.9 A COVID-19 testing location operated by a pharmacy in a non-institutional pharmacy setting that performs diagnostic COVID-19 testing shall:

(a) Be an outdoor location in close proximity to the pharmacy building, such as a parking lot; which may include drive up, curbside, or walk up access;

(b) Not be located within six (6) feet of the entrance of the pharmacy building;

(c) Have and follow a plan for the safe operation of the testing site, and an infection control plan; and

(d) Maintain a record of all patients who have undergone COVID-19 testing at the testing location. This information shall be maintained by the pharmacy for at least one year unless otherwise directed by the Department of Health.

6516.10 A COVID-19 testing location operated by a pharmacy in an off-site location that performs diagnostic COVID-19 testing shall by approved by the Director, subject to inspection by the Department, and comply with all relevant CDC requirements and guidelines as they may be from time to time amended.

6516.11 All pharmacists, pharmacy interns, and pharmacy technicians involved in administering diagnostic COVID-19 testing shall comply with current CDC requirements and guidelines
for personnel collecting specimens or working within six (6) feet of patients, as

they may be from time to amended.

6516.12 The pharmacist-in-charge of a pharmacy where diagnostic COVID-19 testing will be administered, shall:

(a) Implement appropriate policies and procedures for the safe performance of COVID-19 testing at that location, which shall include ensuring compliance with current CDC requirements and guidelines, as they may be from time to time amended, for appropriate training, collection procedures, availability and use of PPE, and proper disposal of used PPE; and

(b) Staff the pharmacy in a manner to ensure that the pharmacist(s) who is administering or supervising the administration of diagnostic COVID-19 testing is engaged solely in administering or supervising the administration of diagnostic COVID-19 testing and is not dispensing prescriptions or counseling patients in between administering COVID-19 testing. The pharmacist performing COVID-19 testing shall only dispense prescriptions and counsel patients after all COVID-19 testing has been completed for the period during which he or she has been assigned to perform testing, after properly disposing of his or her PPE, and after thoroughly washing his or her hands.

6516.13 Only a pharmacist licensed in good standing in the District of Columbia shall observe and facilitate collection of self-administered COVID-19 testing or supervise a licensed pharmacy intern or registered pharmacy technician in observing and facilitating collection of self-administered COVID-19 testing.

6516.14 The location site where authorized pharmacy personnel observe and facilitate collection of self-administered COVID-19 testing occurs shall meet the requirements set forth in § 6516.10 or § 6516.15 of this chapter.

6516.15 Except as provided in § 6516.10 or § 6516.16, a COVID-19 testing location operated by a pharmacy in a non-institutional pharmacy setting where authorized pharmacy personnel observe and facilitate collection of self-administered COVID-19 testing shall:

(a) Be an outdoor location in close proximity to the pharmacy building, such as a parking lot; which may include drive up, curbside, or walk up access;

(b) Not be located within six (6) feet of the entrance of the pharmacy building;

(c) Have and follow a plan for the safe operation of the testing site, and an infection control plan; and

(d) Maintain a record of all patients who have undergone COVID-19 testing at the testing location. This information shall be maintained by the pharmacy for at least one year unless otherwise directed by the Department of Health.

6516.16 A COVID-19 testing location operated by a pharmacy in a non-institutional setting where authorized pharmacy personnel observe and facilitate collection of self-administered COVID-19 testing may perform the observation through a drive through window only if the pharmacy complies with the requirements set forth below:

(a) The pharmacy implements procedures for a contactless and one-way directional observation and collection process, which shall ensure that nothing passes from the patient into the pharmacy including identification cards, payment, testing orders, or writing utensils;

(b) All pharmacy personnel shall remain greater than six (6) feet from the patient or behind a closed glass window at all times during the observation and collection; and

(c) The patient places the sealed specimen directly into an outdoor collection bin without aid or assistance from any pharmacy personnel.

6516.17 All pharmacists, pharmacy interns, and pharmacy technicians who observe and facilitate collection of self-administered COVID-19 testing shall comply with current CDC requirements and guidelines for PPE for personnel who are handling specimens but not directly involved in collection and who are not working within six (6) feet of the patient as they may be from time to time amended.

6516.18 The pharmacist-in-charge of a pharmacy where authorized pharmacy personnel observe and facilitate collection of self-administered COVID-19 testing, shall implement appropriate policies and procedures for the safe performance of COVID-19 testing at that location, which shall include ensuring compliance with current CDC requirements and guidelines, as they may be from time to time amended, for appropriate training, collection procedures, availability and use of PPE, proper disposal of used PPE,
and appropriate staffing levels.

6516.19 Only a pharmacist licensed in good standing in the District of Columbia shall administer or supervise a licensed pharmacy intern, or registered pharmacy technician to administer a COVID-19 antibody or serology test.

6516.20 The location site where COVID-19 antibody or serology testing is administered which requires removal of a patient's mask, or in which the patient's sputum or other bodily fluids may potentially become aerosolized, shall meet the requirements set for in § 6516.9 or § 6516.10 of this chapter.

6516.21 The location site where COVID-19 antibody or serology testing occurs using fingerstick or other point of care testing in which there is no potential for the

patient's bodily fluids to become aerosolized, shall meet the requirements set forth in § 6516.22 of this chapter.

6516.22 A COVID-19 testing location operated by a pharmacy in a non-institutional setting where authorized pharmacy personnel administer COVID-19 antibody or serology testing in which there is no potential for the patient's bodily fluids to become aerosolized shall:

(a) Ensure patient privacy;

(b) Have and follow a plan for the safe operation of the testing site, and an infection control plan; and

(c) Maintain a record of all patients who have undergone COVID-19 testing at the testing location. This information shall be maintained by the pharmacy for at least one year unless otherwise directed by the Department of Health.

6516.23 All pharmacists, pharmacy interns, and pharmacy technicians who administer COVID-19 antibody or serology testing shall comply with current CDC requirements and guidelines for PPE for personnel who are handling specimens but not directly involved in collection and who are not working within six (6) feet of the patient as they may be from time to time amended.

6516.24 The pharmacist-in-charge of a pharmacy where authorized pharmacy personnel administer COVID-19 antibody or serology testing, shall implement appropriate policies and procedures for the safe performance of COVID-19 testing at that location, which shall include ensuring compliance with current CDC requirements and guidelines, as they may be from time to time amended, for appropriate training, collection procedures, availability and use of PPE, proper disposal of used PPE, and appropriate staffing levels.

6516.25 Prior to performing COVID-19 testing, a pharmacist shall review and familiarize himself/herself with the Center for Disease Control's "Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)" and ensure that the pharmacist and authorized pharmacy personnel have appropriate PPE to safely perform the testing.

6516.26 The health care practitioner who orders the COVID-19 test, who may be the same pharmacist who administers the test, shall be responsible for receiving the test results and directing a patient with a positive test result to receive care and monitoring.

Repealed.

Repealed.
Repealed.
Repealed.
Repealed.

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., 6th 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, (202) 442-5977.