STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS

ADMINISTRATIVE ORDER AND NOTICE OF RULE ADOPTION AND WAIVER PURSUANT TO P.L. 2020, c. 18

PHARMACIST PARTICIPATION IN COVID-19 TESTING

DCA Administrative Order No. 2020-06 and DCA Waiver No. W-2020-10

Administrative Order and Temporary Rule Adoption and Waiver adopted by Paul R. Rodríguez, Acting Director, Division of Consumer Affairs

Date: May 13, 2020

Authority: P.L. 2020, c. 18

Effective Date: May 13, 2020

Expiration Date: Concurrent with the end of the state of emergency or public health emergency declared pursuant to Executive Order No.103 (EO 103), whichever is later.

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WHEREAS, on March 9, 2020, through EO 103, the facts and circumstances of which are adopted by reference herein, the Governor declared both a public health emergency and a state of emergency throughout the State due to the public health hazard posed by Coronavirus Disease 2019 (COVID-19); and

WHEREAS, through EO 103, on March 9, 2020 Governor Murphy authorized the executive head of any agency or instrumentality of the State government to waive, suspend, or modify any existing rule, where the enforcement of which would be detrimental to the public welfare during this emergency, subject to prior approval and in consultation with the State Director of Emergency Management and the Commissioner of Health; and

WHEREAS, through Executive Order No. 109, on March 23, 2020, the facts and circumstances of which are adopted by reference herein, Governor Murphy authorized the Director of the Division of Consumer Affairs to issue orders expanding the scope of practice for any category of health care professional licensed by a board in the Division of Consumer Affairs; and

WHEREAS, on April 7, 2020, through Executive Order No. 119, the facts and circumstances of which are adopted by reference herein, the Governor declared that the public

health emergency declared in EO 103 pursuant to the Emergency Health Powers Act (EHPA), N.J.S.A. 26:13-1 et seq., continues to exist throughout the State of New Jersey; and

WHEREAS, on April 14, 2020, Governor Murphy signed into law P.L. 2020, c. 18, which permits the Director to issue administrative orders to suspend temporarily any provision of Title 45 of the Revised Statutes or suspend or modify temporarily any rule adopted pursuant to such authority or to adopt temporarily any rule relating to the practice of any profession licensed by a board in the division, upon concurrence by the Attorney General, after determining that such order is necessary to promote the public welfare and further such other purposes of the state of emergency or public health emergency declared in EO 103; and

WHEREAS, on May 6, 2020, through Executive Order No. 138, the facts and circumstances of which are adopted by reference herein, the Governor declared that the public health emergency declared in EO 103 pursuant to the EHPA continues to exist throughout the State of New Jersey; and

WHEREAS, multiple state and federal agencies are involved in the regulation of clinical laboratories and testing, including for the SARs-CoV-2 virus, the virus that causes COVID-19; and

WHEREAS, review and approval or authorization of tests and medical devices is under the jurisdiction of the United States Food and Drug Administration (FDA), pursuant to the agency's authority under the federal Food Drug and Cosmetic Act (FD&C Act); and

WHEREAS, the FDA has expressed a desire to increase the availability of testing for the presence of COVID-19 and to accelerate the development and availability of diagnostic tests by laboratories and commercial manufacturers during the public health emergency; has established a procedure to issue Emergency Use Authorizations (EUAs) for tests to detect COVID-19 or its antibodies; and has developed a policy for development of testing overseen by states; and

WHEREAS, tests that the FDA has authorized can be found on the FDA's website (https://www.fda.gov/media/136702/download), along with a description and an indication of the setting in which the test may be performed; and

WHEREAS, oversight and certification of testing laboratories are under the jurisdiction of the federal Centers for Medicare and Medicaid Services (CMS), which regulates all laboratory testing other than research performed on humans in the United States; and under federal law, as set forth in the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263a (CLIA), specimen analysis and testing is to be conducted by a laboratory with the certificate appropriate for the type of testing to be conducted—e.g., high complexity, moderate complexity, or CLIA waived—and in a manner consistent with any requirements imposed by FDA when the test or medical device was approved for use; and as of this date, CMS has not waived these requirements to facilitate broader testing; and

WHEREAS, the New Jersey Department of Health (NJDOH) also licenses and regulates clinical laboratories and testing for moderate and high complexity tests in the state, pursuant to

N.J.S.A. 45:9-42.27, involving the "collection, processing and transmission of specimens to another facility for the performance of clinical tests;" and laboratories performing moderate and high complexity testing must be certified by CMS, as well as licensed by NJDOH under state law; while laboratories performing only CLIA-waived testing require a CLIA certificate of waiver, but do not require a license from NJDOH; and

WHEREAS, the participation of pharmacists in the testing process is governed by the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40, et seq. and the regulations jointly promulgated by the Board of Pharmacy and the Board of Medical Examiners, at N.J.A.C 13:39-13 and N.J.A.C. 13:35-6.27, pursuant to which pharmacists are prohibited from ordering or performing laboratory tests unless the tests are specifically granted CLIA-waived status and only through the use of a patient-specific collaborative practice agreement, upon prescription or a standing order, with the pre-approval of the Board of Pharmacy; and pharmacists would not be able to provide results of tests to patients without first consulting with the patient's treating physician; and

WHEREAS, by operation of Executive Directive 20-003 issued on March 19, 2020, the Commissioner of Health, under the authority of the EHPA, N.J.S.A. 26:13-18(a), has authorized pharmacists to perform specimen collection by means of swab testing at recognized "testing sites," including county and local sites; and

WHEREAS, the federal Centers for Disease Control and Prevention (CDC) has advised pharmacies that are participating in public health testing for COVID-19 to communicate with local and state public health staff to determine which persons meet the criteria for testing, and that NJDOH and/or local health departments should inform pharmacies about procedures to collect, store, and ship specimens appropriately, and how to address self-collection options, where offered; and

WHEREAS, there is broad recognition that the widespread availability of testing and the collection of data relating to the results of testing will be essential to the State's effort to better inform mitigation strategies and to ultimately control and contain the public health emergency through the exercise of the Commissioner of Health's powers under the EHPA to investigate illness and health conditions under N.J.S.A. 26:13-4 and to identify other individuals who may have had contact with those who have tested positive for COVID-19, as authorized under N.J.S.A. 26:13-5; and

WHEREAS, it is important that patients undergoing testing for COVID-19 or its antibodies have a full understanding of the meaning and value of the tests offered, as a failure to obtain accurate information could result in patients failing to take necessary precautions to prevent the spread of infection; and

WHEREAS, individuals seeking testing should be provided accurate information concerning the testing being undertaken; and

WHEREAS, it is in the public interest to expeditiously expand the availability of testing for the presence of COVID-19 and for antibodies to the virus, and to recognize that pharmacists

have the requisite competencies and skills to collect specimens, order and/or perform some of the tests which are currently authorized and those that may become approved or authorized and available in the future; and

WHEREAS, there are presently statutory and regulatory provisions designed to safeguard the health and safety of the public, limiting the practice of pharmacists in collaborative practice agreements, and these provisions can, in a time of crisis such as this, thwart or delay efforts to respond rapidly to emerging needs by establishing conditions and barriers that deprive the health care system of the agility to best utilize available resources in an effort to stem the spread of COVID-19; and

WHEREAS, at the same time that a relaxation of the provisions relating to collaborative practice are implemented, conditions and restrictions on the exercise of this expanded scope of practice are necessary to ensure that collection of specimens and testing for COVID-19 or its antibodies, is conducted with requisite safety precautions and in laboratories with appropriate certification and licensing; and

WHEREAS the Division has determined, in consultation with the Commissioner of Health, that the public health and safety would be compromised by authorizing pharmacists, or any health care practitioners, to use tests that have not been approved by the FDA or authorized for use by the FDA pursuant to an EUA; and

WHEREAS, the Commissioner of Health and the Attorney General recognize the need to more broadly test for the presence of COVID-19 and its antibodies, and to expand the health care workforce authorized to participate in testing for COVID-19, and they concur in the issuance of this Administrative Order and Rule Adoption and Waiver on a temporary basis as necessary to promote the public welfare; and

NOW, THEREFORE, I, Paul R. Rodríguez, Acting Director of the Division of Consumer Affairs, by virtue of the authority vested in me by the statutes of this State, and upon concurrence by the Attorney General, determine that this ORDER is necessary to promote the public welfare and further such other purposes for which the state of emergency and public health emergency was declared in EO 103, and hereby ORDER as follows:

1. Authorization to Participate in COVID-19 Testing. Notwithstanding any provision of N.J.S.A. 45:14-41, N.J.S.A. 45:14-61, N.J.S.A. 45:14-62, N.J.A.C. 13:39-13.1 to -13.9, or N.J.A.C. 13:35-6.27(k), licensed pharmacists are authorized to do the following, without entering into a collaborative practice agreement or protocol and without a prescription, standing order, or supervision from a physician, subject to the conditions and limitations in paragraph 2 of this Order, and to the extent permitted by federal law:

   a. Order testing for the SARs-CoV-2 virus, the virus that causes COVID-19 (COVID-19), or its antibodies;

   b. Collect specimens to test for COVID-19 or its antibodies, or oversee or supervise such collection, at or immediately outside of a registered pharmacy;

c. Perform tests for COVID-19 or its antibodies at or immediately outside of a registered pharmacy;

d. Interpret and analyze COVID-19 or COVID-19 antibody test results and provide the results to patients; and

e. Collect, analyze and monitor patient data relating to COVID-19 or COVID-19 antibody testing, subject to the conditions and limitations in paragraph 3 of this Order.

2. Conditions and Limitations. The following conditions and limitations apply with respect to pharmacists engaged in conduct authorized by paragraph 1 of this Order:

a. Testing shall be limited to tests approved by the FDA or authorized by the FDA under an Emergency Use Authorization.

b. Testing shall be carried out by a laboratory or site authorized under federal and state law to perform the test, including but not limited to the Clinical Laboratory Improvement Amendments, 42 U.S.C. 263a, the New Jersey Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.26 et seq., and associated regulations.

c. Testing shall be consistent with any Executive Directive, guidance, or other direction issued by the Commissioner of Health to govern prioritization of COVID-19 testing.

d. For locations at which specimen collection occurs, appropriate safety precautions to protect patients, bystanders, and pharmacists, consistent with any orders and guidance issued by federal and state authorities, shall be adopted. Appropriate safety precautions may include but are not limited to: maintaining physical separation between patients before, during, and after specimen collection; requiring that testing be performed by appointment; limiting the number of tests scheduled to an amount that allows for appropriate social distancing; requiring use of appropriate personal protective equipment; cleaning the collection area after each patient; and adhering to appropriate waste-disposal practices.

e. Pharmacists shall provide patients with truthful and accurate written descriptions of the test and its purpose consistent with the approval or authorization provided by the FDA, and obtain the patient's signature on a form indicating the patient's informed consent to the test.

f. All aspects of testing shall be conducted in accordance with the manufacturer's instructions and applicable state and federal laws, rules, and guidance.

g. Pharmacists must ensure that test results are provided to the patient. The patient must be provided with written information explaining how to obtain the test results and when the results can be expected.

h. Pharmacists shall provide information to patients as to the need for follow-up care, consistent with any orders and guidance issued by federal and state authorities.

i. Pharmacists shall notify the Board of Pharmacy of their intent to order and administer COVID-19 tests, including whether the testing is diagnostic or antibody. Such notifications shall include the name, manufacturer, any type of product code uniquely identifying the test as well as any expiration date for any of the test kits or their components, including reagents. Pharmacists shall notify the test kit manufacturer and FDA (via email at CDRH-EUA-Reporting@fda.hhs.gov) of any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test kit. Notification shall also be provided to the Board of Pharmacy, including an explanation of the variances that led to the reporting. Notifications to the Board of Pharmacy may be made via email to NJPharmacist@dca.lps.state.nj.us.

j. Prior to engaging in specimen collection and testing, pharmacists shall review and familiarize themselves with any test, and the test kit manufacturer's instructions, including any package insert.

3. Data Collection. To facilitate both the public health response to COVID-19 and the delivery of test results to individual patients, and as a condition for any testing for COVID-19 or COVID-19 antibodies in which a pharmacist participates pursuant to this Order, pharmacists shall comply with the following data collection, record-keeping, and reporting requirements:

a. The patient must provide to the pharmacist the following information prior to collection of a specimen:

i. Name;
ii. Home address (street address, municipality, county, state, zip code);
iii. Telephone number;
iv. Email address;
v. Date of birth;
vi. Ethnicity;
vii. Race;
viii. Gender;
ix. Name and contact information for the patient's primary care provider, if available; and
x. Any additional information required by the Commissioner of Health.

b. The pharmacist must maintain a record of the following information with respect to every individual for whom a specimen is collected and/or analyzed:

i. All information provided by the patient pursuant to paragraph 3a of this Order;
ii. The name and license number of the pharmacist administering the test;
iii. The test kit name and identifier, including any serial or model number and expiration date;
iv. The date the test was administered;
v. The date the specimen was sent to the laboratory, with the name and address of the laboratory;
vi. If the specimen analysis is performed at the pharmacy, the name of the individual performing the specimen analysis;
vii. Test results;
viii. Documentation of communications with the patient or the patient's primary care provider regarding the test or test results;
ix. Information relating to any billing for testing services provided; and
x. Any additional information required by the Commissioner of Health.

c. Pharmacists shall ensure that all information required to be collected pursuant to paragraph 3.a of this Order, and all information required to be maintained pursuant to paragraph 3.b of this Order, is maintained at the pharmacy, stored in a manner consistent with N.J.A.C. 13:39-7.19, and available to the Board upon request.

d. All information concerning individuals for whom a specimen is collected and/or analyzed shall be reported to the Commissioner of Health in such manner, frequency and format as the Commissioner requires.

4. Relation to Other Provisions of Law.

a. The provisions of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq., shall apply to the representations made to consumers, advertisements, and sales of tests or collections undertaken pursuant to this Order.

b. Pharmacists acting pursuant to the authority granted in this Order, and consistent with its conditions and limitations, are authorized by law to manipulate a patient for the collection of specimens, within the meaning of N.J.A.C. 8:44-2.7(e), for purposes of COVID-19 tests and antibody tests.

c. Nothing in this Order is intended to authorize pharmacists to perform venipuncture in connection with testing for COVID-19 tests and antibody tests.

5. Waiver. To the degree that they are inconsistent with this Order, the provisions of N.J.S.A. 45:14-41, N.J.S.A. 45:14-61, N.J.S.A. 45:14-62, N.J.A.C. 13:39-13.1 to -13.9, and N.J.A.C. 13:35-6.27(k) are waived and suspended. Any provisions of these statutes and rules that are not inconsistent with this Order remain in full force and effect.

This ORDER shall take effect immediately and shall remain in effect until the end of the public health emergency and state of emergency declared in EO 103, whichever is later, unless expressly revoked or superseded by a subsequent Administrative Order issued by the Director of the Division of Consumer Affairs.

Paul R. Rodríguez, Acting Director

Date: May 13, 2020