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New Jersey Authorizes Pharmacists to Conduct COVID-19 Testing

John Zen Jackson Greenbaum, Rowe, Smith & Davis LLP Client Alert May 20, 2020

There is substantial support for the view that reliable widespread testing is essential to the restoration of a semblance of normalcy in New Jersey when considering the impact of the COVID-19 pandemic. In connection with Governor Phil Murphy's "The Road Back" plan for the state, regulatory action has now been taken to make such testing more readily available by authorizing licensed pharmacists to administer the tests. New Jersey Attorney General Gurbir S. Grewal **announced** the establishment of the program on May 19, 2020.

In his statement, the Attorney General noted that there were 2,239 pharmacies in New Jersey, which should greatly facilitate access to testing. By **Administrative Order No. 2020-06** issued on May 13, the Division of Consumer Affairs (DCA) had promulgated authorization for the testing, establishing conditions and limitations on the activity. The Administrative Order is based on delegation of authority from the Governor's public health emergency declaration and statutory authorization for the Director of the DCA to suspend, modify or adopt on a temporary basis rules pertaining to the various regulated professions.

Effective immediately and until the termination of the public health emergency declared by Executive Order 103, pharmacists can provide COVID-19 testing without a collaborative practice agreement or protocol with a physician. There is no need for a prescription, a standing order or supervision by a physician. There is also no requirement that the individual be symptomatic or have had exposure to the virus.

Subject to the conditions and limitations in the Administrative Order and "to the extent permitted by federal law," pharmacists are authorized to:

- Order testing for the virus that causes COVID-19 or for its antibodies;
- Collect specimens to test for COVID-19 or its antibodies, or oversee or supervise such collection, at or immediately outside of a registered pharmacy;

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- Perform tests for COVID-19 or its antibodies at or immediately outside of a registered pharmacy;
- Interpret and analyze COVID-19 or COVID-19 antibody test results and provide the results to patients;
 and
- Collect, analyze, and monitor patient data relating to COVID-19 or COVID-19 antibody testing.

One of the conditions of this testing activity is that tests used by pharmacists must be approved by the U.S. Food and Drug Administration (FDA) or authorized by the FDA under an Emergency Use Authorization. The analysis of the tests is to be carried out by a laboratory under federal and state law. The testing process is subject to further regulatory requirements that might be issued by the Department of Health.

The pharmacy must have and adhere to safety precautions in terms of physical separation of patients, the use of appointments to control flow and allow for social distancing to be maintained, and the use of appropriate personal protective equipment, sanitation and disposal practices. Pharmacists are to provide patients with truthful and accurate written descriptions of the test and obtain documentation of the patient's informed consent to the testing. They must also ensure that the patient receives the test results and must provide written information on how to obtain the results and when to expect them.

Pharmacists need to notify the New Jersey Board of Pharmacy of their intention to order and administer COVID-19 tests, including whether the testing is diagnostic or for antibodies. The Administrative Order details the information regarding manufacturer and product codes to be provided. The Administrative Order also sets forth several items of demographic data that need to be collected and maintained for "public health" purposes and reported to the Commissioner of Health. Records also need to be maintained identifying the patient, pharmacist administering the test, the test utilized, and the dates of various aspects of the process.

The Administrative Order states that pharmacists are not authorized to perform venipuncture in connection with testing for COVID-19 or antibodies, which would seem to create a significant limitation on testing for COVID-19 antibodies, as those tests are conducted on blood samples.

The Administrative Order also states that the provisions of the Consumer Fraud Act apply to representations made to consumers, to advertisements and sales of tests or collections undertaken pursuant to the Order.

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