Maryland
DEPARTMENT OF HEALTH

AMENDED DIRECTIVE AND ORDER REGARDING VARIOUS HEALTHCARE MATTERS

Pursuant to Md. Code Ann., Health-Gen. §§ 2-104, 18-102, 18-103, 18-205, 18-902, 18-904, Public Safety § 14-3A-03, COMAR 10.06.01.06A

No. MDH 2021-06-15-03

I, Dennis R. Schrader, Secretary of Health, finding it necessary for the prevention and control of 2019 Novel Coronavirus and the disease that it causes ("SARS-CoV-2" or "2019-NCoV" or "COVID-19"), and for the protection of the health and safety of patients, staff, and other individuals in Maryland, hereby authorize and order the following actions for the prevention and control of the spread of this infectious and contagious disease that endangers public health in this State.

This Amended Directive and Order replaces and supersedes the Directives and Orders Regarding Various Healthcare Matters, dated April 28, March 09, February 11, January 28, 2021, December 17, December 1, November 17, November 10, October 1, August 6, July 1, June 19, June 12, May 19, May 6, April 5, March 23, 2020; and the Directive and Order regarding Availability of Testing dated March 20, 2020; and rescinds the Directive and Order Regarding Office of Health Care Quality Oversight Activities, dated March 16, 2020.

COVID-19 TESTING & REPORTING

1. Testing

A. Testing Framework

Any healthcare providers authorized under their scope of practice to do so shall order a COVID-19 test for any individual who believes it necessary, regardless of symptoms. Specialty healthcare providers may refer a patient to a primary care provider, if a primary care provider is available.

Note: An individual should contact their health plan prior to receiving a COVID-19 test to determine whether testing is covered by the plan in their circumstance. Out-of-pocket expenses may apply if the test is not covered by the health plan.

Note: Maryland Medicaid will cover the costs of COVID-19 testing for its beneficiaries.

Based on a public health cluster, outbreak, or contact tracing investigation, an individual may be directed by the Maryland Department of Health (MDH) or a local health department to be tested.

B. Serial or Retesting:

i. Retesting or serial testing of individuals should be conducted according to clinical or epidemiological indications or as directed by MDH or a local health department.

ii. Testing of nursing homes and assisted living program residents and staff shall be conducted according to the provisions of the appropriate MDH Orders regarding those facilities.

C. Test Sites - Specimen Collection

i. COVID-19 test specimens shall be collected in a manner that is in accordance with the U.S. Centers for Disease Control (CDC) recommended infection prevention and control practices, including use of recommended personal protective equipment (PPE).

A healthcare provider shall follow the CDC's guidelines for collecting, handling, and testing clinical specimens from persons for COVID-19.

ii. In addition to those individuals already authorized to collect COVID-19 specimens for testing, any individual licensed, registered, or certified by MDH or a Maryland health occupations board who has appropriate training and supervision may collect COVID-19 test specimens. Individuals and entities offering to perform COVID-19 specimen collection are responsible for ensuring that individuals collecting specimens for testing have the appropriate training and supervision.

iii. In addition to the above, any individual designated by the laboratory director or supervising clinician at the specimen collection who has a high school diploma or passed the General Educational Development test (GED) may collect COVID-19 test specimens after the appropriate training.

D. Point of Care Testing

i. Point of Care COVID-19 testing devices, which have been given FDA emergency-use authorization (EUA) for COVID-19 antigen or molecular testing are approved for use in Maryland.

ii. Positive, negative, and inconclusive point of care test results shall be reported in accordance with the below test reporting requirements.

E. **At-Home/Self-Collection**: Any FDA-approved test for SARS-CoV-2 Coronavirus that uses at-home or self-collection of test samples may be used in Maryland provided that:

i. The use of the test complies with the test's Emergency Use Authorization;

ii. The analysis of the test is performed in a Maryland licensed laboratory with appropriate CLIA certification; and

iii. The laboratory complies with all reporting requirements under Maryland law and this order.

iv. The effect of any Maryland statute or regulation that is inconsistent with the provisions of this subsection of this order is suspended.

2. Positive COVID-19 Test Reporting

A. Pursuant to Health General Article §§ 18-205 and 18-904, and COMAR 10.06.01.03 and .04, a medical laboratory performing a test for COVID-19 shall report a positive test result of an individual immediately to MDH and the appropriate local health officer.

B. The medical laboratory shall immediately notify the requesting healthcare provider of the positive test result and provide a written or electronic report of the positive test result to the requesting healthcare provider to give to the patient.

3. Negative and Inconclusive COVID-19 Test Reporting

A. Pursuant to Health General Article § 18-904, a medical laboratory performing a test for COVID-19 shall report negative and inconclusive test results in addition to positive test results.

B. A laboratory that is already submitting HL-7 formatted electronic laboratory reports (ELRs) to MDH shall send reports for negative and inconclusive test results in addition to positive test results via HL-7 messaging.

C. A laboratory that does not submit HL-7 formatted ELRs to MDH shall submit reports for negative and inconclusive test results, in addition to positive test results, immediately to MDH when the result can be sent by another electronic format (i.e. a formatted CSV file). If the results cannot be sent by HL-7 format or another approved electronic format, they must be immediately submitted to the appropriate local health officer in a manner designated by MDH. All point of care test results shall be submitted via HL-7 formatted ELRs or another approved electronic format (i.e. a formatted CSV file). If the facility reporting the point of care test results cannot do so via either of those methods, the facility shall report the results through the following portal: https://ulp.crisphealth.org/.

4. Other Testing Items

A. **Availability**: All healthcare providers, facilities, and entities that offer community COVID-19 testing shall make that testing available to any person presenting at the testing site without regard to that person's race, color, religion, sex, age, national origin, marital status, sexual orientation, gender identity, disability, ability to pay, type of health insurance, or participation in any particular provider network.

i. This section does not prohibit a health care provider from refusing, withholding from, or denying any person services for failure to conform to the usual and regular requirements, standards, and regulations imposed by the health care provider.

ii. All testing centers shall be accessible and provide reasonable accommodations, including meaningful language access, in accordance with State and federal law.

B. **Costs**: Laboratories processing COVID-19 tests for Maryland residents must accept reimbursement from the patients' insurance - private, Medicare, Medicaid or other payers. If a patient is uninsured, providers and laboratories should use this process for reimbursement: https://phpa.health.maryland.gov//Documents/covid19_FAQ_Uninsured_Reimburse ment.pdf

HEALTHCARE FACILITIES

5. Off-Campus Hospital Facilities

Notwithstanding the provisions of COMAR 10.07.01.06, off-campus hospital facilities may be used for inpatient hospital care if the proposed off-campus facility would be operated by an existing licensed Maryland hospital under the terms of that hospital's license and such use would not adversely affect the safety and health of patients served at the off-campus facility.

6. Hospital Surge Plans, Hospital Bed Capacity Increases, and Patient Transfer

A. All licensed acute care hospitals ("hospitals") shall provide to MDH their emergency plan for pandemics that will add available staffed medical-surgical and ICU bed capacity in the event that the statewide census of all adult, medical-surgical and ICU hospitalized patients reaches certain thresholds.

i. Each hospital's plan shall indicate how the hospital will use its best efforts to add staffed bed capacity equal to ten percent (10%) of that hospital's physical bed capacity, within seven (7) calendar days after each time the state hits the following thresholds:

a. When the statewide number of total hospitalized medical-surgical and ICU adult patients reach 8,000;

b. When the statewide number of total hospitalized medical-surgical and ICU adult patients reach 9,000; and

c. When the statewide number of hospitalized medical-surgical and ICU adult patients reach 10,000.

ii. When each threshold is reached, as indicated in the CRISP Reporting System at 8 a.m. each day, each hospital shall use its best efforts to make available additional staffed capacity equivalent to at least 10% of its designated physical bed capacity.

iii. Any additional staffed bed capacity that is created shall be prioritized for the treatment of COVID-19 patients.

Note: Hospitals in a system may submit a pandemic plan for all hospitals in the system.

Note: Adding capacity may include, but is not limited to, hospital capacity adjustments such as bringing additional staffed beds into service, staff re-deployment or altered staffing models, reducing non-urgent and elective procedures and surgeries, and transferring patients to alternate care sites (ACSs). In addition, hospitals are encouraged to consider bringing idle clinical or administrative space on-line or other space conversions for clinical care.

Note: Hospitals should strongly consider rescheduling elective and non-urgent procedures that have any likelihood of requiring inpatient beds and/or a ventilator unless clinically warranted.

B. In order to maintain adequate hospital capacity for patient care, and to ensure that COVID-19 and non-COVID-19 patients have access to appropriate medical care, hospitals are directed to execute the following measures:

i. Daily Patient Transfer Reporting

Each hospital and freestanding emergency medical facility shall report daily to the Maryland Institute for Emergency Medical Services System (MIEMSS) with regard to COVID-19 patients transfer to COVID-19 alternate care site (ACS) or other treatment locations.

ii. Transfers

With respect to all patient transfers, all reasonable efforts shall be made to transfer patients with their informed consent to an appropriate, clinically indicated hospital, emergency medical facility, COVID-19 ACS, or other treatment location that is located closest to their originating healthcare facility and to notify the patient's authorized decision maker or family member, if applicable.

OTHER HEALTHCARE MATTERS

7. Quarantine and Isolation Orders

Pursuant to Health General Art. §§ 3-306, 18-208, 18-906, the Baltimore City Commissioner of Health and the local health officers for each of the twenty-three counties in the State of Maryland are authorized to issue, as a designee of the Health Secretary, quarantine and isolation orders for the prevention and control of 2019 Novel Coronavirus ("SARS-CoV-2") and the disease that it causes - Coronavirus Disease 2019 ("COVID-19").

8. Termination

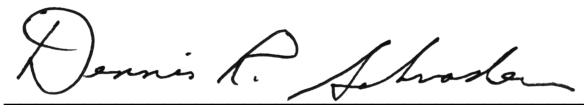
This Directive and Order shall cease to have effect and be rescinded at 11:59 P.M. on December 31, 2021 or when the federal Declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 is terminated, whichever condition comes first.

9. Severability

If any provision of this Directive and Order or its application to any person, entity, or circumstance is held invalid by any court of competent jurisdiction, all other provisions or applications of this Directive and Order shall remain in effect to the extent possible

without the invalid provision or application. To achieve this purpose, the provisions of this Directive and Order are severable.

THESE DIRECTIVES AND ORDERS ARE ISSUED UNDER MY HAND THIS 15TH DAY OF JUNE 2021 AND ARE EFFECTIVE IMMEDIATELY.



Dennis R. Schrader
Secretary