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, and Public Safety § 14-3A-03

No. MDH 2020-06-19-02

I, Robert R. Neall, Secretary of Health, finding it necessary for the prevention and control of 2019 Novel Coronavirus ("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 this infectious and contagious disease under the Governor's Declaration of Catastrophic Health Emergency. **This Amended Directive and Order replaces and supersedes the Directives and Orders Regarding Various Healthcare Matters, dated June 12, May 19, May 6, April 5, and March 23, 2020 and the Directive and Order regarding Availability of Testing dated March 20, 2020.**

COVID-19 TESTING & REPORTING

1. **Testing**

   A. **Testing Framework**

   Maryland has increased the availability of COVID-19 testing capacity over the past three months.

   With testing now broadly available, the following populations should be prioritized for testing by healthcare providers:

   i. Any symptomatic individual; and

   ii. Asymptomatic individuals where COVID-19 exposure may be possible, including:

      a. Contacts of confirmed COVID-19 cases (e.g., contact tracing, outbreak or cluster investigation);

      b. Residents and staff of congregate living settings and long-term care facilities (e.g., nursing homes, assisted living facilities, residential programs and group homes serving individuals with developmental disabilities, behavioral health residential programs and group homes, dormitories, housing shelters, detention or correctional facilities);

c. Healthcare workers and first responders (e.g., emergency medical service personnel, home health care workers, and law enforcement personnel);

d. Patients, especially high-risk unstable patients, whose care would be altered by a diagnosis of COVID-19;

e. Individuals employed in close contact settings (e.g., retail, public transport, school, childcare, camp, food service or processing, personal services, or for children attending school, camp, or child care, and manufacturing); and

f. Individuals previously in a large gathering.

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 home residents and staff shall be conducted according to the provisions of the Amended MDH Order and Directive Regarding Nursing Home Matters, No. MDH 2020-06-19-01.

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).

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

D. **Test Sites - Analysis**

i. A COVID-19 test collection site may perform test analysis if it is licensed by federal and state authorities as a Clinical Laboratory Improvement Amendments of 1988 (CLIA)-certified laboratory.

ii. MDH may issue a Certificate of Waiver for certain COVID-19 point-of-care testing systems on a case-by-case basis and in conformity with their emergency use authorization.

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 diagnostic 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 COVID-19 Test Reporting**

A. Pursuant to Health General Article § 18-904, a medical laboratory performing a diagnostic 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 immediately to MDH and the appropriate local health officer in addition to positive test results.

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 ability to pay, type of health insurance, or participation in any particular provider network.

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_Reimbursement.pdf

MDH shall make available appropriate financial support to those providing testing to mitigate outbreak situations or as directed by MDH or local health departments.

HEALTHCARE PROVIDER MATTERS

5. Elective and Non-urgent Medical Procedures - Licensed Healthcare Facilities and All Healthcare Providers

A. Prohibition of Elective and Non-Urgent Medical Procedures

Pursuant to the Executive Order of March 16, 2020 relating to various healthcare matters and in accordance with the guidance issued by MDH and posted on its website at http://coronavirus.maryland.gov, all licensed hospitals, ambulatory surgical centers, and all other licensed healthcare facilities shall cease all elective and non-urgent medical procedures effective at 5 p.m., Tuesday, March 24, 2020 and not provide any such procedures for the duration of the catastrophic health emergency.

Pursuant to the Executive Order of March 16, 2020 relating to various healthcare matters and in accordance with the guidance issued by MDH and posted on its website at http://coronavirus.maryland.gov, all providers of healthcare licensed, certified, or otherwise authorized under the Health Occupations Article shall perform only medical procedures that are critically necessary for the maintenance of health for a patient. All elective and non-urgent medical procedures and appointments shall cease effective at 5 p.m., Tuesday, March 24, 2020 and shall not be performed for the duration of the catastrophic health emergency.

B. Resumption of Elective and Non-Urgent Medical Procedures - Conditions

All licensed healthcare facilities and healthcare providers may resume elective and non-urgent medical procedures and appointments at 7:00 A.M., May 7, 2020 provided all of the following measures are in place:

i. Healthcare providers licensed under the Health Occupations Article shall exercise their independent professional judgment in determining what procedures are appropriate to perform, which appointments should occur, and which patients to see in light of widespread COVID-19 community transmission.

ii. Any licensed healthcare facility or healthcare provider resuming elective and non-urgent medical procedures in a healthcare setting shall have at least one week's supply of PPE for themselves, staff, and as appropriate, for patients.

Note: PPE requests to any State or local health or emergency management agency will be denied for elective and non-urgent medical procedures.

Note: The healthcare facility or healthcare provider must be able to procure all necessary PPE for its desired services via standard supply chains.

Note: For hospitals with COVID-19 patients, MDH will determine a daily PPE per patient use rate for PPE requests.

Note: "Healthcare setting" means: (1) the office of a healthcare provider licensed under the Health Occupations Article; or (2) a healthcare facility as defined in § 19-114 of the Health-General Article.

iii. Social distancing requirements must be strictly maintained in all settings where people must wait in order to minimize direct contact between individuals within the healthcare setting and use of non-traditional alternatives is encouraged (*e.g.*, call ahead registration; waiting in a car until called).

iv. All healthcare workers, patients, and others must be screened for COVID-19 symptoms upon arrival for shift or visit. Staff must stay home if they are showing COVID-19 symptoms.

v. All healthcare facilities and healthcare providers must plan for and implement enhanced workplace infection control measures in accordance with the most current CDC guidelines: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html

Note: All healthcare providers and staff shall wear appropriate face coverings, to include cloth face coverings, surgical face masks or N-95 masks, respirators, and/or face shields.

Note: Patients should wear a face covering whenever possible.

vi. Any healthcare facility or healthcare provider who is unable to provide PPE for themselves, staff, and patients where appropriate shall immediately restrict operations to urgent and non-elective procedures and appointments.

C. Certification and Other Matters

i. A healthcare facility's managing authority or the responsible healthcare provider shall certify to MDH via secretary.health@maryland.gov that all of the above conditions for resumption of elective and non-urgent medical procedures have been met prior to resuming operations. A copy of this self-certification notice shall be posted prominently in the facility for the attention of patients and staff.

ii. Complaints about a healthcare facility's implementation of these measures may be directed to the Office of Health Care Quality at https://health.maryland.gov/ohcq/Pages/Complaints.aspx. A healthcare provider's failure to comply with the terms of this order shall be considered to constitute unprofessional conduct, and written complaints about such failures may be directed to the appropriate health occupation board.

iii. MDH does not construe the immunity provisions in Pub. Safety Art. §14-3A-06 or Health Gen. Art. § 18-907 to apply to a healthcare provider or facility performing non-COVID-19 related procedures or appointments.

6. **Personal Protective Order Conservation**

Subject to availability, all healthcare providers are required to implement the U.S. Centers for Disease Control and Prevention's Strategies to Optimize the Supply of PPE and Equipment, to include, but not limited to:

A. Use facemasks beyond the manufacturer-designated shelf-life during patient care activities.

B. Implement limited re-use of facemasks. The healthcare provider must not touch the outer surfaces of the mask during care, and mask removal and replacement must be done in a careful and deliberate manner.

C. Prioritize facemasks for:

i. Provision of essential surgeries and procedures;

ii. During care activities where splashes and sprays are anticipated;

iii. During activities where prolonged face-to-face or close contact with a potentially infectious patient is unavoidable; and

iv. Performing aerosol generating procedures, if respirators are no longer available.

HEALTHCARE FACILITY MATTERS

7. **Hospital Contingency Plans**

All licensed hospitals shall implement the medical staff plans required by COMAR 10.07.01.24G(2) to grant temporary disaster privileges. The plans shall remain in effect for the duration of the catastrophic health emergency.

8. **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.

OTHER HEALTHCARE MATTERS

9. Pursuant to the Executive Order of March 16, 2020 relating to various healthcare matters, manufacturers, wholesale distributors, or other entities engaged in the sale, purchase, distribution or transfer of FDA-approved prescription devices for emergency medical reasons relating to COVID-19 response measures are exempt from Maryland licensure

requirements provided that the manufacturer, wholesale distributor, or other entity is licensed or otherwise authorized to engage in such activity in the state in which it is located.

10. **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 19TH DAY OF JUNE 2020 AND ARE EFFECTIVE IMMEDIATELY.

Robert R. Neall
Secretary