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, and the Governor's Executive Orders

No. MDH 2020-11-17-01

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 November 10, October 1, August 6, July 1, June 19, June 12, May 19, May 6, April 5, March 23; 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**

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

   With testing now broadly available, Marylanders who believe they should be tested for COVID-19 should contact their healthcare provider. **Healthcare providers 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.

Any individual who is in one of the following categories should contact their healthcare provider to arrange to be tested:

i. Any symptomatic individual;

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, child care, 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; and

iii. All Marylanders who travel outside of Maryland, or who have traveled to or returned to Maryland, are strongly advised to:

   a. Immediately get a COVID-19 test upon arrival in Maryland or within 72 hours before travel to Maryland. A list of test sites can be found at http://covidtest.maryland.gov;

   b. Any Marylander who travels to a state with a COVID-19 test positivity rate above 10% or with a case rate over 20 per 100,000 in the past 7 days should get tested and self-quarantine at home until the test result is received. The District of Columbia, the Commonwealth of Virginia, the Commonwealth of Pennsylvania, and the States of Delaware and West Virginia are exempt from this recommendation.

Note: A list of state COVID-19 test positivity rates can be found here: (https://www.cdc.gov/covid-data-tracker/index.html#testing) (COVID-19 Tests Performed by State - Commercial and Reference, Public Health, and Hospital).

Note: A list of state COVID-19 case rate per 100,000 over the past 7 days can be found here: https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

c. Employee commuters who leave/enter the state on a daily basis and have work-based COVID-19 screening procedures do not need to quarantine. Employees who occasionally travel to or from Maryland for work-related purposes should, to the extent reasonably practicable, comply with the quarantine and testing recommendations above.

iv. 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 Nursing Homes and Assisted Living Programs.

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.

iii. 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.

D. **Point of Care Testing**

Any healthcare provider or healthcare facility, subject to the following terms and conditions, may perform point of care COVID-19 test analysis pursuant to Executive Order 20-03-23-02 (initiating a process for authorization of laboratories in Maryland to develop and perform COVID-19 testing):

Note: This order supersedes, for the duration of the State of Emergency and Catastrophic Health Emergency, any and all other directives from the Maryland Office of Health Care Quality (OHCQ) on the subject of point of care COVID-19 testing.

i. The following devices, which have been given FDA emergency-use authorization (EUA) for COVID-19 testing are approved for COVID-19 point-of-care testing:

a. Cepheid Xpert Xpress
b. Mesa Biotech Accula
c. Abbott ID Now
d. Cue Health Inc. Cue Covid Test
e. Quidel Sofia
f. BD Veritor System
g. LumiraDx
h. Abbott BinaxNOW
i. Other devices as approved by the U.S. Food and Drug Administration for either antigen or molecular testing for COVID-19.

ii. COVID-19 test analysis may be performed at a clinical laboratory if:

a. Existing Maryland laboratory license and CLIA certificate that includes COVID testing: No action required.

b. Existing Maryland laboratory license and CLIA certificate that does not include COVID tests: Complete a change form to add COVID testing before testing commences below:

https://health.maryland.gov/ohcq/Labs/docs/LabsApps/Laboratory_Licensing_Change_Form.pdf

c. No Maryland laboratory license or CLIA certificate, apply for both below:

https://health.maryland.gov/ohcq/Labs/docs/LabsApps/State_Compliance_Application_2019.pdf

https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf

Note: A list of labs that are certified to perform COVID-19 testing can be found here: https://health.maryland.gov/ohcq/Documents/COVID_Testing_List.pdf

Note: Additional information about the CLIA Certificate of Waiver can be found here: https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf

Note: Healthcare providers include, but are not limited to physicians, nurses, pharmacists, and dentists, and other individuals licensed, certified, or registered by MDH or a Maryland health occupations board.

Note: Any individual designated by the laboratory director who has a high school diploma or passed the General Educational Development test (GED) may perform point-of-care tests after the appropriate training.

Note: The licensed laboratory must disclose to the OHCQ within 30 days any changes in ownership, name, address, or laboratory director.

iii. A laboratory enrolled in the CLIA program and possessing a Maryland laboratory license to conduct COVID-19 testing shall follow all manufacturers' instructions for usage, disposal, and infection control of the Point of Care testing device(s).

Note: The Centers for Disease Control and Prevention has published recommendations for good laboratory practices for waived testing sites: https://www.cdc.gov/labquality/images/waived-tests/RST-Booklet_Dec-2019.pdf

iv. Surveys of laboratories will be conducted consistent with CLIA and State licensure requirements and for the purpose of investigating a complaint.

v. 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_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.

Each licensed healthcare provider shall exercise individual independent professional judgment in determining what procedures and appointments are urgent and nonelective.

All hospitals should see additional information and directives in Section 9 of this order regarding hospital patient surge preparedness.

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 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.

iii. The licensed healthcare facility or healthcare provider must ensure that there is adequate capacity to meet the needs of the COVID-19 and Non-COVID-19 patients prior to resumption of elective and non-urgent surgical services.

iv. All licensed healthcare providers and healthcare facilities shall exercise individual independent professional judgment in determining what procedures and appointments are urgent and nonelective. MDH recommends that healthcare providers and facilities using an algorithm and/or methodology (e.g. MeNTS protocol supported by the American College of Surgeons) on how they will curtail and/or suspend elective and non-urgent cases when additional patient capacity is required. https://www.facs.org/media/press-releases/2020/covid-scoring-system0414. https://www.facs.org/media/press-releases/2020/covid-scoring-system0414/worksheet

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 Equipment Conservation Order**

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.

9. **Hospital Visitation**

All hospital visitation is prohibited except for the following situations:

A. Compassionate Care;

B. Parents/Guardians with minor children patients;

C. Obstetrics; and

C. Support persons for individuals with disabilities.

With respect to the four situations listed above, hospitals shall limit visitation to only those visitors who are essential for the patient's physical or emotional well-being, and shall comply with all CDC guidance regarding visitation.

10. **Hospital Surge Plans and Patient Transfer**

A. Having reached 85% of the statewide number of hospital staffed beds (6,600), and 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. **Informed Consent**

A hospital shall attempt to secure the informed consent of an individual or the authorized decision maker of the individual prior to the transfer and transport of the individual as described below. All discussions with the individual or the individual's authorized decision maker shall be documented in the medical record, including the clinical rationale for the transfer.

ii. **Emergency Departments.**

An individual that presents to a hospital's emergency department, or a hospital's affiliated alternate screening site, or a freestanding emergency medical facility who:

a. Receives a medical screening examination; and

b. Has received stabilizing treatment for an emergency medical condition and

c. Is either:

I. Under investigation for a COVID-19 infection; or

II. Diagnosed with COVID-19; and

d. Meets the admission criteria of a COVID-19 alternate care site (ACS) or other treatment location designated by the State:

I. As determined by the hospital or freestanding emergency medical facility's attending physician; and

II. As confirmed by the COVID-19 ACS or other treatment location's Attending Physician or Chief Medical Officer,

May be transported to the COVID-19 ACS or other treatment location notwithstanding the refusal of the patient to consent to such transport and admission upon acceptance of the patient for admission by the receiving facility, regardless of whether the hospital has the capacity to treat the patient.

With respect to all transfers pursuant to this Order, the effect of any State statute or regulation that is inconsistent with the provisions of this subsection of this order is suspended.

iii. **COVID-19 Inpatients**

A diagnosed COVID-19 patient:

a. Who is admitted to a hospital as an inpatient; and

b. Who meets the admission criteria of a COVID-19 ACS or other treatment location

May be transferred and transported to the COVID-19 ACS or other treatment location, notwithstanding the refusal of the patient to consent to such transfer and admission, upon acceptance of the patient for admission by the receiving site, when the hospital is unable to admit patients requiring inpatient care and who do not meet the admission criteria for a COVID-19 ACS or other treatment location.

c. With respect to all transfers pursuant to this Order, the effect of any State statute or regulation that is inconsistent with the provisions of this subsection of this order is suspended.

iv. **Non-COVID-19 Inpatients**

a. Non-COVID-19 patients, whether they present to the emergency department or are an inpatient, may be transferred to another hospital or healthcare facility to match their clinical condition with the required appropriate level of care. Transfers may also be initiated to create space for higher acuity patients, COVID-19, and Non-COVID-19, who need the space that is currently occupied by the patient who will be transferred to another site of care.

b. With respect to all transfers pursuant to this Order, the effect of any State statute or regulation that is inconsistent with the provisions of this subsection of this order is suspended.

v. **Pandemic Plan**

All hospitals shall implement their emergency plan for pandemics. Hospitals and healthcare systems shall provide up-to-date surge planning efforts to MDH that are dedicated to expansion of their capacity. This expansion may be a result of adding staff and/or physical space to meet the demand for services. The expanded care model is another component of these efforts to grow capacity.

vi. **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 ACS or other treatment locations.

vii. **Transfers**

With respect to all transfers made pursuant to this Order, all reasonable efforts shall be made to transfer patients 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.

vii. **End Date**

Unless renewed or extended, this subsection and its provisions shall end on January 31, 2020.

B. MIEMSS may:

i. Develop an intensive care bed surveillance system that:

a. Maintains an ongoing assessment of available intensive care beds in the State;

b. Requires hospitals to accurately report availability of intensive care resources;

c. Serves as a clearinghouse of resources to facilitate necessary patient transfers;

d. Requires hospitals to receive intensive care-level patients identified by MIEMSS with appropriate consultations.

ii. MIEMSS may appoint or designate a director to coordinate statewide efforts under this section.

iii. Pursuant to Education Article § § 13-509, 13-510, and 13-516, MIEMSS may implement procedures to route COVID-19 positive patients to a specific, clinically appropriate care setting and away from an emergency room and utilize tele-triage procedures to assist the transporting EMS clinicians.

C. Upon the Statewide Total Hospital Bed Census reaching the total statewide number of beds, including elective surgery beds, hospitals shall put into place a triage system for elective and non-urgent medical procedures in accordance with Section 5 of this directive. The hospital shall put this system into place 24 hours after the statewide number of beds is reached.

OTHER HEALTHCARE MATTERS

11. **Prescription Devices**

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.

12. **Nursing Home and Hospital Mutual Aid in Nursing Home Outbreak Situations**

A. When an outbreak occurs in a nursing home, a nursing home shall coordinate with hospital(s) located in the nursing home's corresponding MIEMSS region to ensure adequate staffing support from the hospital**,** including direct clinical care, and infection control technical assistance where appropriate to ensure adequate continued care and infection control; such support may include the provision of a certified infection control (CIC) professional to the nursing home. When contacted, a hospital shall render all assistance possible.

B. All nursing homes shall establish at least one mutual aid arrangement with another nursing home facility to ensure continuity of operations, to include ensuring adequate staffing support.

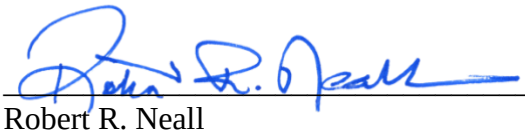
13. **Penalties**

Persons who violate this Order and Directive may face administrative and criminal sanctions to include imprisonment not exceeding one year or a fine not exceeding $5,000 or both.

14. **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 17th DAY OF NOVEMBER 2020 AND ARE EFFECTIVE IMMEDIATELY.



Robert R. Neall
Secretary