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Lieutenant Governor

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MARYLOU SUDDERS Secretary MONICA BHAREL, MD, MPH Commissioner

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ORDER OF THE COMMISSIONER OF PUBLIC HEALTH CLIA-WAIVED COVID-19 TESTING IN CONGREGATE CARE SITES

On March 10, 2020, Governor Charles D. Baker declared a State of Emergency in the Commonwealth to respond to the spread of COVID-19. The Public Health Council has approved and authorized me to take such actions, incur such liabilities, and establish such rules, requirements, and procedures which are necessary to prepare for, respond to, and mitigate the spread of COVID-19 in order to protect the health and welfare of the people of the Commonwealth, consistent with the Governor's declaration.

As of December 6, 2020, the Department has reported 250,022 confirmed cases of COVID-19 and 10,793 deaths among confirmed cases in the Commonwealth. Maximizing access to COVID-19 testing for Massachusetts residents is a critical component of the Commonwealth's comprehensive strategy to mitigate and slow the spread of COVID-19. This is particularly important in congregate care settings, which are at higher risk for COVID-19 transmission than other settings, and whose residents are at higher risk for more severe illness due to underlying chronic conditions and diagnoses.

Accordingly, pursuant to the authority granted by G.L. c. 17, § 2A and with the approval of the Governor and the Public Health Council, and in order to assure the maintenance of the public health during the continuing public health emergency, I issue the following Order:

For purposes of this Order, congregate care settings are defined as group homes, residential treatment programs or homeless shelters operated pursuant to a contract with the Department of Developmental Services (DDS), the Division of Housing and Community Development (DHCD), the Department of Public Health (DPH), the Department of Mental Health (DMH) or the Department of Youth Services (DYS).

To increase access to COVID-19 testing, notwithstanding G.L. c. 111D, §§ 4 and 5 congregate care settings may participate in a testing program sponsored by the Commonwealth to conduct CLIA-waived COVID-19 tests of their staff and residents without applying for or receiving state clinical laboratory licensure, provided that any such setting must:

- apply for and receive a federal Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver;
- comply with G.L. c. 111D, § 6, 105 CMR 300; and

• comply with the direction of their contracting agency.

This Order applies only for the purposes of conducting CLIA-waived COVID-19 tests of the congregate care setting's staff and residents.

All other applicable statutes, regulations, and guidance not inconsistent with this Order remain in effect.

This Order shall remain in effect the State of Emergency is terminated by the Governor, or until rescinded by me, whichever shall happen first.

IT IS SO ORDERED.

Monica Bharel, MD, MPH

Commissioner, Massachusetts Department of Public Health

November 7, 2020