United States Senate

April 8, 2020

The Honorable Brett Giroir
Assistant Secretary for Health
Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Assistant Secretary Giroir and Administrator Verma:

We call on you to provide additional regulatory flexibility to hospitals and private laboratories across the nation to enable them to scale-up testing capacity for the novel coronavirus. Even as rapid testing is becoming more available, hospitals are still facing delays in obtaining their patients' results.[1] One of the nation's largest diagnostics companies faced a backlog of 160,000 coronavirus tests on March 25, 2020, delaying results in some cases up to ten days.[2] Additional flexibility in staffing and license requirements for hospital and private testing laboratories can enable them to rapidly and effectively increase testing capacity in a way that meets the urgency of this crisis.

Under the authority of the Clinical Laboratories Improvement Amendments of 1988 (CLIA), CMS regulates all laboratories that perform diagnostic testing for health-related reasons.[3] CLIA certification is based on the level of complexity of testing that a laboratory performs. Laboratories that perform high-complexity testing must meet specific personnel requirements.[4] The Department of Health and Human Services (HHS) and the Centers for Medicare and

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[1] Andrew Ryan and Kay Lazar, *Long backlogs for coronavirus test results frustrate Mass. doctors*, Boston Globe (Mar. 18, 2020), https://www.bostonglobe.com/2020/03/18/nation/national-shortage-swabs-limits-coronavirus-tests-seriously-ill-beth-israel-lahey/; Rachel Becker and Ana Ibarra, *48,600 coronavirus test results still pending in California*, Cal Matters (Mar. 25, 2020), https://calmatters.org/health/2020/03/california-coronavirus-test-results-delayed-backlog/; J. Scott Trubey, *No timetable for widespread virus testing amid ongoing test scarcity*, Atlanta Journal-Constitution (Mar. 25, 2020), https://www.ajc.com/news/local-govt--politics/timetable-for-widespread-virus-testing-amid-ongoing-test-scarcity/oKpCMimtpgDidMAoCThROO/.

[2] Drew Griffin, Curt Devine, Scott Bronstein and Nelli Black, *Documents show backlog of 160,000 coronavirus tests at just one lab company*, CNN (April 1, 2020), https://www.cnn.com/2020/04/01/politics/testing-backlog-coronavirus-quest-invs/index.html.

[3] 42 U.S.C § 263a.

[4] 42 C.F.R. Part 493, Subpart M – Personnel for Nonwaived Testing.

Medicaid Services (CMS) have recently taken steps to provide flexibility to clinical labs and remove regulatory bottlenecks that delayed expanded testing.[5] As CMS oversees laboratories running COVID-19 diagnostics, CMS can and should continue to issue transparent, flexible, and real-time guidance that can help increase testing to meet the growing demands for it.

By way of example, CMS could provide further guidance on the use of "waived tests." The Centers for Disease Control and Prevention outline that "waived tests include test systems cleared by the FDA [Food and Drug Administration] for home use and those tests approved for waiver under the CLIA criteria."[6] CMS can waive certain tests if they are simple and have a low risk for erroneous results.[7] In those cases, as long as laboratories have a CLIA certificate and follow the manufacturer's instructions, there are no additional requirements (such as for personnel training, site inspections, and specific quality standards). In some cases, it is unclear to CLIA laboratories whether coronavirus tests that receive FDA Emergency Use Authorizations can be treated as waived tests under CLIA. CMS should encourage test developers to provide instruction directly to laboratory administrators on whether a test is waived for CLIA purposes.

Similarly, CMS should ensure that COVID-19 testing laboratories do not face unnecessary restrictions on CLIA license requirements. Under CLIA, laboratories must meet certification requirements for specific subspecialties of tests.[8] These requirements for subspecialties add additional testing requirements.[9] CMS could provide flexibility to CLIA laboratories by removing any requirements for specific subspecialties (such as "virology"), allowing CLIA labs that have the general specialty of "microbiology" or a similar broad category of the CLIA license to perform COVID-19 testing.

CMS should also ensure that requirements for testing personnel do not serve as a barrier to expanded testing capacity. Specifically, CMS should provide flexibility to testing laboratories by allowing CLIA Laboratory Directors to accept sufficiently qualified staff that may not meet existing requirements.[10] High-complexity CLIA labs attempting to expand coronavirus diagnostic testing face the challenge of quickly bringing on additional staff to ramp up capacity and to replace staff sidelined by the virus. CLIA laboratories could recruit well-qualified personnel, with experience in laboratory settings, to fill shortages and increase testing capacity. But current regulations prevent experienced personnel from filling the critical need for testing staff. CLIA personnel regulations require high-complexity laboratory testing personnel to have a medical degree, an associate degree in laboratory science, or a high school degree with a medical

[5] Ctrs for Medicare & Medicaid Servs., Ctr. for Clinical Standards and Quality, Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency (Mar. 26, 2020), https://www.cms.gov/files/document/qso-20-21-clia.pdf-0.
[6] Ctrs. for Disease Control & Prevention, Waived Tests, https://www.cdc.gov/labquality/waived-tests.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fclia%2Fwaived-tests.html (last updated Dec. 16, 2019).
[7] Ctrs. for Disease Control & Prevention, Test Complexities, Clinical Laboratory Improvement Amendments (CLIA), https://www.cdc.gov/clia/test-complexities.html (accessed Mar. 30, 2020).
[8] 42 C.F.R. § 493.801.
[9] *See id.* §§ 493.821-.865.
[10] *See id.* Subpart M – Personnel for Nonwaived Testing.

laboratory training.[11] These requirements can prevent PhD-level scientists or post-doctoral research fellows from working in CLIA laboratories, despite years of laboratory experience. CMS could also issue guidance identifying specific tasks that new staff — who do not meet existing personnel qualifications — may be permitted to perform. CMS must ensure the safety and quality of the laboratory setting, but we also must recognize the urgent needs in this moment of crisis.

In this time of crisis, it is imperative to provide flexibility for CLIA laboratories and respond to urgent needs in a responsible way. Supporting regulatory flexibility can help ensure that we marshal all our available resources to respond to the crisis.

Sincerely,

Edward J. Markey
United States Senator

Richard J. Durbin
United States Senator

Tammy Duckworth
United States Senator

[11] *See id.* § 493.1489.