AMERICAN CLINICAL LABORATORY ASSOCIATION

October 28, 2020

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Rm. 445-G
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency [CMS-3401-IFC]

Dear Administrator Verma,

Please accept the comments of the American Clinical Laboratory Association (ACLA) on the interim final rule with comment period (IFC) published on September 2, 2020.[1] As you know, ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic disease. ACLA members also have been a vital component of the response to the COVID-19 pandemic, having performed more than 50 million COVID-19 diagnostic and serologic tests to date. ACLA works to advance the next generation of health care delivery through policies that expand access to lifesaving testing services.

Our comments are focused on two issue areas: changes to regulations implementing the Clinical Laboratory Improvement Amendments (CLIA) that require laboratories to report COVID-19 test results during the public health emergency (PHE), and limits on COVID-19 testing without an order for Medicare beneficiaries.

A. Requirements for Laboratories to Report COVID-19 Test Results During the PHE

1. Background

Section 18115 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) says a laboratory "shall report the results from each [COVID-19] test…in such form and manner, and at such timing and frequency, as the Secretary may prescribe." In the IFC, CMS amends the regulation at 42 C.F.R. § 493.1100 to require that for the duration of the public health emergency,

[1] 85 Fed. Reg. 54820 (Sept. 2, 2020).

all laboratories performing non-waived COVID-19 testing must "report SARS-CoV-2 test results to the Secretary." It adds a new paragraph to § 493.1834 to set forth the per-day civil monetary penalties that may be imposed as a result of COVID-19 test reporting requirements ($1,000 for the first day and $500 for each subsequent day), and it makes other regulatory changes to allow it to impose civil monetary penalties on a laboratory holding only a Certificate of Waiver. It also adds a new paragraph to § 493.555 to specify that an accrediting organization or an exempt state must notify CMS within 10 days of a laboratory's failure to report COVID-19 test results to the Secretary.

CMS's justification for amending CLIA regulations to require COVID-19 test reporting is that it "does not know the complete universe of laboratories performing SARS-CoV-2 testing or which tests are being performed" and that by collecting that information, the CLIA programs "will be able to identify quality and accuracy issues" with laboratories performing the testing.[2]

2. CLIA and its implementing regulations are not designed to effectuate CMS's goals, and amendments to CLIA regulations are not the appropriate vehicle for doing so.

ACLA members agree that the federal government should have access to data about COVID-19 testing and the number of infections in order to inform its response strategy and allow it to deploy its resources timely and where they are most needed. We also agree that it is important for the CLIA program to be able to identify quality and accuracy issues with laboratories and to survey laboratories as needed.

We do not believe that it is appropriate to amend CLIA regulations for CMS's stated purposes. In the CARES Act, Congress could have amended the CLIA statute at 42 U.S.C. § 263a to include the reporting requirements, but it did not, indicating that Congress did not intend for the CLIA program to be the primary enforcer of the requirement. CLIA's purpose is to authorize the Secretary to issue standards to ensure consistent performance of laboratory testing, including standards regarding quality control; maintenance of records, equipment, and facilities; qualifications of personnel; and qualifications under a proficiency testing program.[3] Submitting test reports about COVID-19 testing falls far outside of these primary purposes. We are not aware of another time that CMS has promulgated a CLIA regulation this is specific to testing for one disease state and that applies only for a limited time (in this case, for the duration of the current public health emergency). There are no other CLIA regulations whose effect is dependent on a temporary proclamation that is unrelated to the accuracy and reliability of laboratory testing.

Public health functions such as reportable disease reporting falls far outside of CLIA's primary purposes. Laboratories are required to report test results to public health authorities for scores of diseases, yet CLIA regulations never have been used to enforce laboratories' obligation to do so. State and local health authorities already are empowered to enforce reportable disease

[2] *Id*. at 54826.

[3] Congressional Research Service Summary of the Clinical Laboratory Improvement Amendments of 1988, Pub.L. 100-578, *available at* https://www.congress.gov/bill/100th-congress/house-bill/5471/titles.

reporting requirements applicable to laboratories.[4] Here, HHS chose to delegate the task of receiving reports for COVID-19 tests to state and local health departments, and those entities should retain the authority to enforce their existing reporting requirements, without the awkward and inappropriate overlay of potential civil monetary penalties under CLIA.

We are concerned about the precedent set by using CLIA regulations for the first time to enforce requirements that are unrelated to the quality of testing or the operations of a laboratory. We believe it is inappropriate to use CLIA regulations in this way.

3. Without amending CLIA regulations, CMS already is empowered to identify quality and accuracy issues with SARS-CoV-2 testing.

CMS has alleged that amending CLIA regulations to add a condition-level requirement for test reporting is essential to its ability to "identify quality and accuracy issues with laboratories performing SARS-CoV-2 testing" and it will allow the program "to survey these laboratories to determine if they are performing testing within their appropriate CLIA certification."[5]

Without amending CLIA regulations, CMS already knows the complete universe of laboratories performing SARS-CoV-2 testing and which tests are being performed. The agency announced on October 9, 2020 that in the previous two months, it had "issued 171 cease and desist letters to entities across the U.S. that were testing for COVID-19 without an appropriate CLIA certificate, and 66 percent were issued to laboratories performing COVID-19 testing outside the scope of the existing CLIA certification."[6] The agency was able to identify the laboratories conducting COVID-19 testing, determine which COVID-19 tests each laboratory performs, and determine whether each laboratory is permitted to perform certain tests under its CLIA certificate. CMS was able to take this decisive action even prior to amending CLIA regulations. (If needed, CMS also can get information about laboratories doing COVID-19 testing from state and local heath agencies that already are receiving test reports on COVID-19 tests.)

CLIA representatives acknowledged on a September 15, 2020 stakeholder call that the program will enforce the reporting requirements only through routine inspections and inspections resulting from complaints about non-compliance with other CLIA regulations. Without making any changes to CLIA regulations, the agency already is empowered to conduct routine and complaint surveys of any laboratory, including one conducting COVID-19 testing.[7] CMS may use its usual inspection processes and procedures to evaluate the quality and accuracy of a laboratory's

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[4] *See, e.g.*, New York State Department of Health Communicable Disease Reporting Requirements, *available at* https://www.health.ny.gov/forms/instructions/doh-389_instructions.pdf; North Carolina Department of Health and Human Services Communicable Disease Surveillance and Reporting, *available at* https://epi.dph.ncdhhs.gov/cd/report.html; Arizona Department of Health Communicable Disease Reporting – Clinical Labs, *available at* https://www.azdhs.gov/preparedness/epidemiology-disease-control/index.php#reporting-labs.

[5] 85 Fed. Reg. 54827.

[6] CMS Takes Action to Protect Integrity of COVID-19 Testing, *available at* https://www.cms.gov/newsroom/press-releases/cms-takes-action-protect-integrity-covid-19-testing (last visited October 28, 2020).

[7] *See* 42 C.F.R. § 493.1773.

COVID-19 testing. It will be obvious during routine and/or complaint inspections whether a laboratory is doing COVID-19 testing. This calls into question why it is necessary to amend CLIA regulations that already allow the agency to do what it plans to do.

Efforts to append a COVID-19 test reporting requirement onto existing CLIA regulations do not help CMS identify laboratories conducting COVID-19 testing, and do not enhance the program's ability to identify quality and accuracy issues in those labs. CMS currently has all the tools it needs to effectuate its stated goals.

We do not believe it is necessary to issue federal regulations to implement state reportable disease reporting requirements, but if CMS chooses to do so, it should do so outside of the context of CLIA regulations. It also should make clear that the requirement is limited to reporting test results and information integral to the test report.

B. Limits on COVID-19 and Related Testing Without an Order

CMS is revising the policy at 42 C.F.R. § 410.32(a)(3) that removed the requirement that certain COVID-19-related diagnostic tests are covered based only on the order of a treating physician or non-physician practitioner (NPP). As of September 2, 2020, only one COVID-19 diagnostic test and only one test for influenza and/or respiratory syncytial virus (RSV) performed in conjunction with a COVID-19 test to establish or rule out a COVID-19 diagnosis will be considered "reasonable and medically necessary" without the order of a treating physician or NPP. Many details of this policy and its underpinnings are confusing, and we ask the agency to clarify the policy and its rationale.

When CMS implemented this policy in May, it did so because of the importance of testing as many Medicare beneficiaries as possible and to do so quickly, and because the agency was concerned that not all Medicare beneficiaries have access to a doctor to obtain a COVID-19 laboratory test.[8] It <u>still</u> is important to test as many Medicare beneficiaries as possible, given the vulnerability of the Medicare population and because the pandemic is far from over. Additionally, Medicare beneficiaries still may be reluctant to visit a physician's office to obtain an order or provide a specimen, for fear of encountering others who may or may not be infected with the coronavirus. We do not believe the original justifications for the policy have changed, nor that the policy should change.

The "one test without an order" limitation should apply to the laboratory testing a particular Medicare beneficiary, <u>not</u> to the Medicare beneficiary himself or herself. There is no way for a laboratory to know whether a Medicare beneficiary previously received a COVID-19 test and/or influenza and RSV test from another laboratory without a physician or NPP order. There is no centralized database for a laboratory to consult to determine whether a Medicare beneficiary who presents for a COVID-19 test without an order from a physician or NPP has had a test performed in the past by a different lab without an order.

[8] 85 Fed. Reg. 27550, 27558 (May 8, 2020).

Even if a laboratory is furnishing a repeat test to a Medicare beneficiary, in many cases it will be extremely difficult for a laboratory to comply with this policy change. As you know, the circumstances under which many specimens are collected for COVID-19 testing differ markedly from specimen collection for more routine tests. A Medicare beneficiary may present at a drive-through or walk-up specimen collection station for a COVID-19 test and have a specimen collected, long before the laboratory testing the specimen is able to determine whether a physician's or NPP's order is required for that particular beneficiary—even if the same lab furnished a test to the beneficiary in the past. If the beneficiary already received a test without an order, a second test without an order would not be "reasonable and medically necessary" and the laboratory could not be paid for it. And because laboratories generally are not collecting specimens for COVID-19 tests and therefore have little face-to-face interaction with beneficiaries being tested for COVID-19, they have no way to obtain signed Advance Beneficiary Notices of Non-Coverage (ABN). The operational infeasibilities of this policy shift place an unfair burden on testing laboratories that may be forced to provide uncompensated testing for Medicare beneficiaries.

We disagree with this policy, but if allowed to stand, the policy should be that it is reasonable and medically necessary for the same laboratory to furnish only one COVID-19 test and/or influenza and RSV test for the same Medicare beneficiary without an order from a physician or NPP. We ask the agency to clarify this for stakeholders. If the limitation applies to the Medicare beneficiary himself or herself, we urge the agency to inform laboratories how they can determine whether a Medicare beneficiary previously received COVID testing and/or influenza and RSV testing from a different laboratory without a physician's or NPP's order.

CMS also should state unequivocally that Medicare will pay for any COVID-19 test ordered by an authorized provider that meets coverage criteria, regardless how many tests the beneficiary has had in the past.

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Thank you for consideration of ACLA's comments and thank you in advance for responding to our questions and requests for clarification.

Sincerely,

Sharon L. West
Vice President, Legal and Regulatory Affairs