October 30, 2020

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3401-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Administrator Verma:

On behalf of the National Independent Laboratory Association (NILA), thank you for the opportunity to submit comments in response to the interim final rule with comment period CMS-3401-IFC (IFC) regarding 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.

NILA represents regional and community clinical laboratories across the United States, virtually all of whom are responding to the COVID-19 pandemic. Despite severe supply shortages and years of inadequate reimbursement for many clinical laboratory tests following the Protecting Access to Medicare Act (PAMA), NILA laboratories have responded swiftly to meet the testing needs of their communities during this unprecedented public health emergency.

While NILA recognizes the integral role that accurate and timely data play in the federal government's response to the COVID-19 pandemic, the June 4, 2020, guidance on laboratory data reporting requirements and the CMS-3401-IFC have imposed significant burdens on clinical laboratories during a time of difficult challenges for community and regional clinical laboratories. NILA laboratories take seriously their obligations to report test results for COVID-19 and all other reportable conditions to state and local public health departments as required by state law. The imposition of civil money penalties for failure to do so, however, is misguided as community and regional clinical laboratories, and public health departments alike, struggle to make the technology investments required to come into compliance with the June 4, 2020, COVID-19 data reporting guidance. As noted in our July 9, 2020, letter to Secretary Azar, NILA's clinical laboratories have struggled to interpret these ambiguous data reporting requirements, collect required data elements from providers who fail to give laboratories complete information, and report required data elements to public health departments, some of whom do not have the capacity to receive the information.

Additionally, the implementation of CMS-3401-IFC has been marred by confusion and contradictory guidance from the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC). In an October 9, 2020, email to members of the laboratory community, CMS staff informed laboratory partners that, with regard to the IFC, CLIA surveyors would assess laboratories on whether laboratories "have, or have not, reported SARS-CoV-2 test results to state and local health

departments *in which the laboratory is located*." This directly contradicts the June 4, 2020, reporting guidance that states that laboratories must "report data for all testing completed . . . to the appropriate state or local public health department *based on the individual's residence*." NILA respectfully urges CMS to issue clear, unambiguous guidance detailing the form and manner in which community and regional clinical laboratories are expected to report COVID-19 test results and how this requirement differs, if at all, from CDC reporting requirements.

As noted by Dr. Raj Dash during his presentation to the Clinical Laboratory Improvement Advisory Committee (CLIAC) on October 28, 2020,[1] reporting to all fifty state health departments based on a patient's location is inefficient and challenging for smaller community and regional laboratories, many of whom do not have the resources to do so. CMS and CDC should collaborate and work with community and regional clinical laboratories to implement and fund a laboratory reporting mechanism that relieves community and regional laboratories from this burden and funds the reporting requirements for both the CDC, and subsequently, this IFC requirement.

One example of such a platform is the AIMS laboratory reporting system, which would allow laboratories to report to one central repository for public health reporting. However, the startup and connectivity costs for laboratories to connect to and use the AIMS platform is prohibitive for most community and regional clinical laboratories. NILA encourages CMS to consider finance mechanisms that provide access to the AIMS platform, or another similar mechanism, for all clinical laboratories. Most importantly, this mechanism should ensure that laboratories are fully able to support the federal pandemic response for COVID-19 and future pandemics. Assessing civil monetary penalties during this public health emergency for failure to meet an inefficient data reporting standard works against the ultimate goal of collaboration between clinical laboratories and state and local public health departments to ensure that tests results are reported in a timely manner, consistent with state law.

NILA laboratories are rising to meet the unprecedented challenge of the COVID-19 pandemic. NILA respectfully requests that CMS not impose unneeded confusion and costs on clinical laboratories doing this important work.

Sincerely yours,

Mark S. Birenbaum

Mark S. Birenbaum, Ph.D.
Executive Director
National Independent Laboratory Association

[1] Raj Dash, "COVID-19 Laboratory Reporting Challenges and Opportunities," at: https://www.cdc.gov/cliac/docs/meeting/9_Dash_COVID-Lab-Reporting-Challenges-and-Opportunities.pdf.