November 17, 2020

The Honorable Seema Verma
Administrator, Centers for Medicare &
Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the National Independent Laboratory Association (NILA) we write to express concerns about changes to reimbursement for COVID-19 diagnostic tests announced by the Centers for Medicare and Medicaid Services (CMS) on October 15, 2020. As you may know, NILA members serve a wide variety of communities and patient populations—many of whom are not served by large independent laboratories. NILA member laboratories across the United States have been invaluable to the nation's COVID-19 response by performing laboratory testing for physicians, hospitals, skilled nursing facilities (SNFs), and other health care professionals.

Swift test results are critical in isolating infected patients and mitigating the spread of COVID-19. In a recent survey, NILA's community and regional laboratories reported that they can often provide test results within one to two days—significantly faster than the reported wait times experienced by many Americans in recent weeks and months. We agree with your assertion that "prompt testing and turnaround times are more important than ever," and NILA's member laboratories work tirelessly toward that goal. However, it is unacceptable that under the new policy, the two-day window in which a test must be completed to be eligible for additional payment begins at the time of specimen collection. Once a COVID-19 specimen is collected many factors affect when it arrives in a laboratory. We therefore urge CMS to reconsider this policy and instead begin the two-day clock when the specimen arrives in the laboratory.

This timing is particularly problematic for patients and laboratories in rural areas where it can take hours for the specimen to get to the laboratory after collection. Many NILA member laboratories in rural communities have staff who drive long distances to collect specimens from clinics and doctors' offices. In fact, it can take up to 24 hours for laboratories to receive samples from nursing homes in rural areas. Additionally, major national shipping companies have experienced delays throughout the pandemic that may continue or worsen during the holiday season and as winter weather begins in many regions. If laboratories will be penalized for turnaround time, the time clock should start when the specimen actually arrives in the laboratory, NOT when it is collected from the patient.

The ability of NILA laboratories to return test results in a two-day timeframe also hinges on laboratories' access to proper testing supplies. NILA members are facing severe shortages of test kits, reagents, and other materials, such as plastic pipette tips, without which they cannot perform needed COVID-19 tests.

We have asked the federal government to increase transparency of testing supply availability and to act to increase production of currently limited supplies. Mitigating supply shortages will serve the dual goals of helping to increase the number of tests provided as well as the speed with which test results are delivered. Without better and more consistent access to testing supplies, laboratories will not be able to consistently meet patients' testing demand within the two-day timeline for the $25 add-on payment.

As laboratories across the country are hamstrung by testing supply shortages, CMS's decision to lower the base reimbursement rate for COVID-19 diagnostic testing is a punitive measure in response to a problem that is largely outside of our laboratories' control. These punitive measures will leave many laboratories on the front lines of this pandemic without the resources they need to perform sufficient testing in their communities. Further, we believe this reimbursement policy will have the unintended effect of decreasing patient access to testing by encouraging laboratories to turn away patient samples so that they can maintain higher reimbursement rates under the new payment policy. With many laboratories already at maximum testing capacity for their available testing supplies, this will greatly decrease testing availability for patients. Before this policy is implemented in January 2021, we encourage CMS to consider the impact of specimen transport and supply shortages on its newly announced reimbursement policy.

Thank you for your consideration of these comments. NILA respectfully requests a virtual meeting with you and your staff to further discuss the impact of this policy on community and regional laboratories across the country. Meghan Riley (mriley@dc-crd.com) is available to schedule a meeting and answer any questions you may have.

Sincerely yours,

Mark S. Birenbaum

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