May 13, 2021

James E. Mathews, Ph.D.
Executive Director, MedPAC
425 I Street, NW
Suite 701
Washington, DC 20001

Dear Dr. Mathews:

On behalf of the National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB), thank you for the opportunity to respond to the Medicare Payment Advisory Commission's (MedPAC) recent public meeting, held virtually on April 2, 2021. These comments relate to the discussion entitled *Mandated report: Assessing the impact of recent changes to Medicare's clinical laboratory fee schedule payment rates.*

As we have shared with MedPAC through previous conversations and meetings, NILA and AAB member laboratories have experienced significant, unanticipated cuts in CLFS payment rates due to the Centers for Medicare and Medicaid Services' (CMS) flawed implementation of the Protecting Access to Medicare Act (PAMA). The PAMA data collection process implemented by CMS did not adequately represent the laboratory marketplace as required under statute and as intended by Congress. We were pleased that in its recent meeting MedPAC acknowledged the overrepresentation of independent laboratories in data reporting relative to the proportion of independent laboratories across the market. According to slides from your April 2nd presentation, 90% of reported data came from independent laboratories, a sector of the laboratory market representing only 48% of the utilization of Medicare CLFS tests. Conversely, hospital outpatient and physician office laboratories together made up 51% of utilization, but only 9% of data reported.

This lack of representative data reporting from all segments of the industry resulted in skewed rates that disproportionately harm community and regional laboratories. As we have noted in the past, fewer than one percent—a mere 0.7 percent of laboratories paid under Medicare Part B on the CLFS—reported applicable data to CMS, resulting in radically skewed payment rate calculations with test volume and rate data dominated by the two largest national independent laboratories. Private payer rates to hospitals have historically been much higher than rates for independent laboratories, particularly the largest independent laboratories. NILA has long maintained that the implementation of PAMA, which excluded hospital rates while focusing on rates for a small number of very large laboratories, skewed the data significantly and made cuts to independent laboratories—which serve a unique population of

Medicare beneficiaries not always reached by large national laboratories—much deeper than they should have been.

As such, we are pleased that MedPAC examined survey methodologies that would result in reporting from a representative sample of the laboratory market. In fact, NILA recommended in our September 2020 letter that MedPAC explore other data collection options to ensure a statistically valid, stratified random data sample that represents all segments of the laboratory market, accounting for geographic diversity, is collected by CMS. This would guarantee that each type of laboratory is adequately represented, yet reduce the number of laboratories required to submit data. NILA agrees with MedPAC's assertion that surveying a representative sample of the laboratory industry will produce accurate estimates of private payer rates for independent, hospital outpatient, and physician office laboratories. Consequently, it will mitigate the draconian cuts that have been thrust upon the laboratory industry by faulty data collection methods.

Without representative sampling of private payer rates across the laboratory industry, we are left with a lack of a true private market rate for laboratory testing and, instead, a constant downward pressure towards rates that are only sustainable for the largest national laboratories. This is a dangerous threat to the nation's laboratory infrastructure. If severe cuts continue, we will see further market consolidation and poorer service for Medicare beneficiaries. Already, the number of independent laboratories has significantly decreased and laboratories that remain did not have the resources or reserves in place to act quickly when COVID-19 emerged. Thus, we saw very limited access to COVID-19 testing and long wait times (particularly from the largest national laboratories) in the early months of the COVID-19 pandemic.

The COVID-19 pandemic and the associated crisis of testing availability and fast turnaround times demonstrate the pitfalls that await Medicare and its beneficiaries if patients can only turn to large, national chain laboratories with limited community reach.

We appreciate MedPAC's work to analyze and adjust the flawed implementation of PAMA and are grateful that MedPAC is considering methods to collect data from a representative sample of the laboratory market. We urge MedPAC to make a strong recommendation to Congress to implement a statistically valid survey methodology that will ensure access to essential clinical laboratory services for Medicare patients. Thank you for consideration of our comments. NILA and AAB look forward to reviewing MedPAC's forthcoming report on this subject. If you require further information, please contact Erin Morton at emorton@dc-crd.com.

Sincerely yours,

Mark S. Birenbaum

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Executive Director
National Independent Laboratory Association