AMERICAN CLINICAL LABORATORY ASSOCIATION

September 18, 2020

Via Electronic Mail

Chairman Michael Chernow, Ph.D.
Medicare Payment Advisory Commission
425 I St., N.W., Suite 701
Washington, DC 20001

RE: Public Comments on September 3, 2020 Session on Medicare Clinical Laboratory Fee Schedule

Dear Dr. Chernow,

On behalf of the American Clinical Laboratory Association (ACLA), I am submitting comments in response to the Medicare Payment Advisory Commission (MedPAC or Commission) September 3, 2020 session regarding the Congressionally-mandated report on changes to the Medicare Clinical Laboratory Fee Schedule (CLFS) under Section 216 of the *Protecting Access to Medicare Act of 2014* (PAMA). 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 41 million COVID-19 diagnostic tests to date. ACLA works to advance the next generation of health care delivery through policies that expand access to lifesaving testing services.

Virtually every healthcare provider uses laboratory test results to guide treatment decisions for their patients. Laboratory tests have allowed the promise of personalized medicine to become a reality and have been a major component of innovations in diabetes treatment, infectious disease identification, and cancer care, among other improvements in health care. We hope that MedPAC's recommendations will recognize the value of Medicare beneficiary access to accurate, reliable, and high-quality laboratory testing and acknowledge the importance of ensuring adequate reimbursement for laboratories developing and performing innovative tests.

This letter includes information about flaws in PAMA's implementation that led to CLFS rates not reflecting private market rates and some of the factors that contributed to the unrepresentative data collected from laboratories; an examination of the assertion that inclusion of a broader variety of labs in data reporting would not have an appreciable effect on Medicare CLFS rates; and information for the Commission on why competitive bidding and other commodity-focused pricing mechanisms are not appropriate for clinical laboratory services.

A. Background

According to section 105(b) of Division N of the *Further Consolidated Appropriations Act, 2020*, MedPAC is required to review the methodology CMS has implemented for private payor-based CLFS rates. The Commission also is required to consider how to implement the least burdensome data collection process that would result in a representative and statistically-valid data sample of private market rates from all laboratory market segments, including hospital outreach laboratories, physician office laboratories, and independent laboratories, and consider the variability of private payor rates across market segments. Furthermore, MedPAC is required to consider appropriate statistical methods for estimating Medicare payment rates that are representative of the market.

As you know, Section 216 of PAMA made significant changes to the methodology for establishing Medicare clinical laboratory reimbursement rates in order to ensure that Medicare payment better reflects the market served by Medicare. PAMA requires "applicable laboratories" to report "applicable information"—each private payor rate and the associated volume of payments at each such rate for almost every code on the CLFS—every three years, and it sets the Medicare rate for each test code equal to the weighted median of the rates reported, subject to applicable phase-in limits. (For a small subset of tests, designated as Advanced Diagnostic Laboratory Tests (ADLTs), a performing laboratory reports price and volume information annually.) PAMA establishes a single national fee schedule that applies to all clinical laboratories regardless of the laboratory's geographic location or the type of clinical laboratory—hospital outreach laboratory, physician office laboratory, or independent laboratory.

B. CMS's Flawed Implementation of PAMA Resulted in Medicare Payment Rates that Do Not Reflect the Broad Private Market that Serves Medicare

ACLA supports the intent of the statutory changes made in Section 216 of PAMA, which is for CLFS rates to reflect private market rates. If implemented effectively, this creates predictability for market-based reimbursement of clinical laboratories that provide the services. Further, a framework following private market rates would allow Medicare to benefit from common market dynamics such as competition and efficiency. However, the Centers for Medicare & Medicaid Services (CMS) has failed to implement these changes in accordance with legislative intent. In particular, the agency's flawed implementation of data collection under Section 216 of PAMA has resulted in Medicare CLFS rates that do not reflect the market and threaten Medicare beneficiary access in the long-term.

First, CMS received data about a very small portion of payments to laboratories made by private payors. CMS reported receiving 4.9 million records representing 248 million laboratory tests from 1,942 clinical laboratory reporting entities. But more than 40 times as many laboratories submitted claims to Medicare in 2016 than the number that reported data in the first round of PAMA data reporting. This means that less than three percent of clinical laboratories that currently serve Medicare patients, and less than one percent of all laboratories in 2016, submitted private payor rates that were used to establish rates for all Medicare laboratories. Private payor data

reported by laboratories form the foundation of the new Medicare clinical laboratory reimbursement framework under PAMA, so the anemic data collection is a fundamental flaw in implementation.

Second, the reported data clearly are unrepresentative of the laboratory market as a whole and cannot be used for an accurate and unbiased estimate of rates paid by private payors. Important market segments effectively were excluded from the group of clinical laboratories that reported private payor data to CMS: only 21 hospital laboratories (approximately 0.2 percent of all hospital laboratories in 2016) reported data to CMS, which left out a robust set of data with payment rates that differ markedly from the rates reported by independent laboratories.

As MedPAC staff acknowledged in their presentation to the Commission, independent clinical laboratories were significantly overrepresented among clinical laboratories that reported data. According to CMS, data reported by independent clinical laboratories made up around 90 percent of the total data used to determine reimbursement rates under PAMA, but these laboratories received only 56 percent of total Medicare payments for clinical laboratory services in 2016. Data from the three largest, lowest cost laboratories alone made up around 60 percent of the total data used to determine PAMA reimbursement rates, but these laboratories received only 16 percent of total Medicare payments for clinical laboratory services in 2016.

MedPAC staff also recognized that physician office laboratories and hospital outreach laboratories were underrepresented in the data used to determine PAMA reimbursement rates, with data from physician office laboratories and hospital outreach laboratories making up just eight percent and one percent respectively of total data submitted. However, physician office laboratories and hospital outreach laboratories received 18 percent and 26 percent of total Medicare payments for clinical laboratory services respectively in 2016. Clearly, the underrepresentation of laboratories that play a significant role in providing laboratory services to Medicare beneficiaries resulted in reimbursement rates that are not reflective of the broad scope of the laboratory market.

The following factors contributed to the flawed data collection that resulted in the new Medicare CLFS payment rates.

1. Burdensome Data Collection and Reporting Requirements

Section 216 of PAMA requires clinical laboratories to report the rates actually paid by each and every private payor and the test volume at each rate, including data from paper remittances. While paper claims represent a small percentage of remittances, they represent a large percentage of the cost of reporting. In fact, one ACLA member estimated that complying with the first round of PAMA data reporting cost over $1 million and involved roughly 21,000 man-hours. This crushing administrative burden also serves as a disincentive to more clinical laboratories reporting data. Paired with the agency's lack of enforcement of the reporting requirements, this enormous burden will lead to CMS receiving unrepresentative data over and over again. A less burdensome data reporting method therefore is fundamental to successful reform of Section 216 of PAMA.

2. CMS's Regulatory Definition of "Applicable Laboratory" Effectively Excluded Hospital Outreach Laboratories from Reporting

CMS blocked the vast majority of hospital outreach laboratories from reporting their private payor data. During the first round of data reporting, to qualify as an "applicable laboratory", a hospital outreach laboratory must have received more than $12,500 in Medicare CLFS payments in the first half of 2016 (low-revenue threshold), and the ***hospital's*** Medicare revenue from the Physician Fee Schedule and Clinical Laboratory Fee Schedule combined must have made up more than 50 percent of the ***hospital's*** total Medicare revenue during the same time period. Of course, unless a hospital outreach laboratory had its own National Provider Identifier (NPI), it could never meet the second criteria, because the hospital's Part A revenue would overwhelm its Part B revenue. Over 7,000 hospital laboratories submitted claims to Medicare in 2016, and 3,043 hospital outreach laboratories provided more than $12,500 in Medicare CLFS services in the first half of 2016, yet only 21 reported data to CMS for PAMA rate-setting purposes. Also, it appears that many of the handful of hospitals that did report are large academic hospitals, whose private payor rates are not representative of the thousands of hospitals throughout the country providing laboratory services to a wide variety of Medicare beneficiaries, including those in rural or underserved areas.

Although Congress did not bar voluntary reporting in Section 216 of PAMA, CMS's regulations did: Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory. An example of a hospital laboratory that was barred from reporting PAMA data is Intermountain Healthcare in Utah. Intermountain Healthcare provides approximately 60 percent of the clinical laboratory services for non-hospital patients in Utah – more than 8 million tests in 2016 – yet it was prohibited from reporting private payor rate and volume data during the first data reporting period. The 21 hospitals that submitted PAMA data cannot be assumed to be representative of the over 3,000 hospital outreach laboratory's NPI's that otherwise had revenues above the low-revenue threshold.

Since the first data reporting cycle, CMS has made a regulatory change regarding the definition of "applicable laboratory" that potentially impacts hospital outreach laboratory reporting. Specifically, a hospital that uses bill type 14x to submit Medicare claims for hospital non-patients is considered an applicable laboratory if it meets the low-revenue threshold during the relevant data collection period. According to an ACLA analysis, in future data reporting periods, an additional 1,765 hospitals could be subject to the PAMA reporting requirements as a result of this change. However, given the cost and burden of reporting, and the absence of any penalties for not reporting, we expect few hospital outreach laboratories to report private payor rate and volume information for their non-patient services. As a result, it is possible that without further changes, weighted medians calculated after the second round of data reporting also will be unrepresentative of the clinical laboratory market as a whole.

3. Physician Office Laboratories Also are Largely Excluded from Reporting

There are approximately 60,000 physician office laboratories that provide services paid for under the CLFS, and around 6,000 physician office laboratories exceeded the $12,500 low-revenue threshold in the first half of 2016. Yet only about 1,100 physician office laboratories reported data to CMS. While 18 percent of Medicare CLFS payments went to physician office laboratories in 2016, only eight percent of the PAMA data reported came from physician office laboratories. Physician office laboratories have different payment rates than currently are reflected in CLFS rates, and ACLA believes that the inclusion of data from physician office laboratories would have had an impact on the payment rates under PAMA. Like hospital outreach laboratories, private payor rates paid to physician office laboratories are higher than those paid to independent laboratories and higher than the 2017 weighted medians.

C. MedPAC Should Examine CMS's Claims that Increases in Reporting from Hospital Outreach Laboratories and Physician Office Laboratories Would Only Modestly Increase Payment Rates under PAMA

ACLA strongly disagrees with CMS's claims that increases in reporting from hospital outreach laboratories and physician office laboratories would increase payment rates under PAMA only modestly. Such a claim runs counter to general knowledge concerning payment rates among different types of clinical laboratories. It is generally accepted that private payor rates paid to hospitals (as well as POLs) are significantly higher than the 2017 weighted medians. We believe that the vast underrepresentation of hospital laboratories and physician office laboratories skewed the data to such an extent that the weighted medians do not represent private market rates. We also are concerned about the lack of transparency of the agency's methodology and analysis. Although CMS released some data and information on this issue, the agency did not present an adequate explanation on the analyses performed to reach its conclusions, nor did it make available sufficient data for outside stakeholders to replicate the analyses. As we discuss above, it is unreasonable to assume that data reported by just 21 hospital NPIs are representative of the more than 3,000 hospital outreach labs that exceeded the low-revenue threshold of $12,500 in CLFS revenue in the first six months of 2016. We urge MedPAC to conduct an independent analysis to evaluate CMS's claims, including examination of claims databases such as FAIR Health. We stand ready to offer our assistance to explore this issue further.

D. Laboratory Services Are Not "Widgets"

In light of the discussion among Commissioners about competitive bidding and other rate-setting methods for interchangeable commodities, ACLA is providing additional background on the services we provide to Medicare beneficiaries and the history of competitive bidding proposals for Medicare reimbursement of clinical laboratory services in particular. We also are available to provide additional context and data to MedPAC on the information below.

Ensuring high quality clinical laboratory testing depends on a combination of complex inputs, including high precision instruments, testing supplies, a highly trained workforce, biosafe facilities, and biosafe and cold transport chains. Subjecting clinical laboratory services to competitive bidding or another strategy focused primarily on price undervalues these essential and complex inputs and risks sacrificing the quality, accuracy, efficiency, and reliability of laboratory testing on which Medicare beneficiaries and their health care providers rely. Laboratories continually invest resources to improve turn-around times and the efficiency of their laboratory processes and to develop innovative tests, and inadequate reimbursement makes these investments impossible.

Our ongoing experience with COVID-19 testing illustrates the importance of adequate reimbursement for laboratories and a variety of laboratories operating in the marketplace. During the COVID-19 pandemic, clinical laboratories have been a major part of the nation's response. ACLA member laboratories have performed about half of all COVID-19 diagnostic testing in the United States to date. Clinical laboratories have been critical innovators during this crisis. They have been able to develop a wide range of COVID-19 tests tailored to different testing platforms using different types of specimens. One of the most striking lessons from the pandemic is that not all laboratories and tests are created equal – this is apparent from the variety of laboratories and tests that have received Emergency Use Authorization from the Food and Drug Administration. In April 2020, Medicare reimbursement for COVID-19 molecular testing was increased to a price that is adequate to cover the cost of performing the tests, which drew far more laboratories and laboratory testing options into the marketplace. If COVID-19 testing were to be subject to competitive bidding or another pricing methodology aimed primarily at lowering the price as far as possible, few clinical laboratories would have had the incentive to enter the market, and the country would have far fewer COVID-19 tests and testing options than it does today.

Ideas like competitive bidding have been considered for clinical laboratory services in the past, yet these kinds of plans have been rejected as an inappropriate rate-setting method for laboratory services. Such schemes cannot take into account important factors that go beyond the price of the service. Proposals that aim for the lowest price fail to account for the complex inputs that enable laboratories to maintain quality and innovation in their services.

The 2003-2008 demonstration project for laboratory competitive bidding turned out to be a failure. It was stopped by a federal court injunction, and ultimately, by Congress. Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub.L. 108-173) required CMS to conduct a demonstration project on competitive acquisition of clinical laboratory services that would otherwise be paid under the Medicare Part B fee schedule. The objective of the demonstration was to determine whether competitive bidding can be used to provide Part B clinical laboratory services at fees below current Medicare payment rates while maintaining quality and access to care.

In April 2008, a federal district court in San Diego issued a preliminary injunction halting the competitive bidding demonstration slated to begin in San Diego on July 1, 2008. The District judge cited the potential for "irreparable harm" to Medicare beneficiaries and the laboratories that

serve them. On July 15, 2008, Congress removed CMS's authority to conduct the Medicare Laboratory Competitive Bidding Demonstration project in Section 145 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) (Pub.L. 110-275).

There are many reasons why the 2003-2008 competitive bidding demonstration experiment failed and should never be tried again. The laboratory sector is extremely segmented and specialized. No one laboratory performs all of the tests, and no one laboratory serves all geographies or all beneficiaries. While many laboratories may perform routine tests, they often send complex tests to a reference lab, and some innovative genetic testing laboratories perform a very limited menu of esoteric tests, but never perform a routine blood test.

Access could suffer by emphasizing price over quality. By its very nature, competitive bidding places an emphasis on obtaining the best price and neglects quality and access concerns. Competitive bidding could result in a reduction in the widespread and ready access to laboratory services that Medicare beneficiaries rely on, because fewer laboratories will remain in the market to provide these services.

Medicare does not reimburse providers of other medical services using competitive bidding. Neither hospital services, nor physician services, nor skilled nursing services under Medicare are competitively bid. These services are too specialized, localized, diversified, and complex to pick a very limited number of "winners" who would bid a very low price. Congress would not ask these service providers to bid to "win" Medicare's business, because such a plan would never work. The same is true for clinical laboratory services.

E. Molecular Pathology Test Services are Improving Patient Care

During the September 3rd MedPAC meeting, MedPAC staff and commissioners noted and discussed growing utilization of molecular pathology test services and whether MedPAC should pursue recommendations to curtail such utilization, mentioning patient cost-sharing and prior authorization as potential policies. ACLA believes such policies could roll back recent improvements to patient care and, further, as mentioned by some MedPAC Commissioners, controlling utilization is outside the scope of the study mandated by Congress.

Molecular pathology test services are a powerful and comparatively new class of health care services which, in the past ten to fifteen years, have been on the leading edge of realizing the promise of personalized medicine. The goal of personalized medicine has been to assess and take advantage of distinct traits between patients and/or diseases to choose more effective treatment and prevention protocols, or to rule out those protocols which may be ineffective or even harmful. Molecular pathology test services are the tools which help to identify these distinct traits and differences, and also aid in measuring the actual outcomes. In oncology alone, such tests have advanced care and survivability in breast cancer, lung cancer and colon cancer, with progress moving beyond oncology into mental health and heart disease. By empowering earlier diagnoses and interventions, and measuring outcomes, these services not only improve care, but reduce health care costs.

Given that these services are new – representing entirely new opportunities for patient care, MedPAC staff's finding of utilization growth is not surprising. These are services and tools that did not previously exist and providers and patients are increasingly learning of their value. For this reason, ACLA believe it is unwise to rush and consider policies which would erect barriers to patient access for molecular pathology tests. Barriers that would delay earlier cancer detection and earlier avoidance of ineffective drug treatments, reversing the recent improvements to patient care. ACLA further agrees with MedPAC Commissioner comments that examination of such utilization policies is outside the scope of the current study. As previously discussed, the study before the Commission should remain focused on less burdensome and more representative private market data which will result in a more stable and sustainable Medicare CLFS.

F. Conclusion

In conclusion, ACLA supports the intent of PAMA to create a CLFS that reflects broad scope of market rates for clinical laboratory services. It is critical that MedPAC give careful consideration in its recommendation to Congress on how to establish national CLFS rates in a way that is not overly burdensome and that truly reflects the entire market for laboratory services. Thank you again for the opportunity to provide comments on this important issue. We look forward to working with you to help you develop recommendations.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association

CC: James Mathews, Ph.D.