
November 24, 2020

Chairman Michael Chernew, PhD
Medicare Payment Advisory Commission
425 I Street, NW, Suite 701
Washington, DC 20001

Dear Dr. Chernew,

In 2019, Congress passed the *Further Consolidated Appropriations Act*, which directed the Medicare Payment Advisory Commission (MedPAC) to evaluate the methodology used by the Centers for Medicare and Medicaid Services (CMS) to set laboratory rates for the Clinical Laboratory Fee Schedule (CLFS). The advisory panel is charged with determining whether the current methodology accurately reflects the differing fees paid to segments of the laboratory community and, if necessary, make recommendations for improvement. The American Association for Clinical Chemistry (AACC) supports this reassessment of the methodology.

AACC is concerned that the current methodology is skewed towards large commercial laboratories, which offer volume discounts to their clients. Many testing facilities, such as independent regional laboratories, hospital outreach laboratories and physician office laboratories cannot achieve the same economies of scale. Private insurers recognize the value of a rapid turnaround time to patient care and are willing to pay these entities a higher fee for this service. These higher fees are not reflected in the current methodology. AACC urges MedPAC to recommend changes to the current methodology that reflect this added value to the healthcare system.

We are concerned, however, that at the September 3, 2020 MedPAC meeting the tenor shifted away from the main impetus of the congressional request for the study to other potential changes to the laboratory payment system, including competitive bidding, which legislators have already rejected. Also, many members gave the impression that any increase in Medicare spending for laboratory services is harmful to the program. AACC urges MedPAC to consider the high value and benefit accrued from laboratory testing, both to the patient and healthcare system, rather than just the costs of performing testing.

**Background**
In 2014, Congress included a provision in the Protecting Access to Medicare Act (PAMA) that barred the CMS from adjusting lab fees based on technological improvements. In its place, lawmakers directed the agency to rebase the CLFS to reflect private sector payment rates. Lawmakers wanted Medicare to get the 'best' price for testing services.

PAMA requires CMS to collect private sector data from testing facilities and use that information to set new payment rates for each laboratory test under Medicare. Under the statute, CMS can cut payments for 'overpaid' tests by up to 10 percent a year for the first three years, up to 15 percent a year for the following three years, and then by an unlimited amount moving forward—until the market-based fee for each test is achieved.

In 2017, CMS collected payment data to set the new fees, which took effect on January 1, 2018. According to CMS, fees for 75 percent of the laboratory tests on the CLFS were cut, with 58 percent incurring cuts over multiple years. Approximately 10 percent of the tests received an increase. The next collection date was scheduled for January 1, 2020 but has been rescheduled for January 1, 2022 due to the coronavirus pandemic.

**Concerns**
AACC objects to how the payment rates were determined. Of the more than 250,000 laboratories in the United States, only 1,942 were required to submit payment information—less than one percent of all testing facilities. Most of the payment data came from large, national commercial laboratories, which offer volume discounts. AACC is concerned that the payment rates are not representative of the size and scale of the broader community of laboratory test providers and this under-representation may ultimately decrease patient access to laboratory services.

On November 23, 2018, CMS published a final rule on the physician fee schedule that included changes to the PAMA requirements. The agency modified the definition of an "applicable laboratory" to include hospital outreach laboratories. The rule required these hospitals to start gathering payment information in early 2019 for reporting in early 2020 (now postponed until 2022). AACC is concerned that:

**Cuts may harm patient care** – The breadth and depth of the cuts imposed by CMS will have significant implications for the laboratory community and the patients they serve. This reduction, as outlined in MedPAC's presentation, has already reduced reimbursement for laboratory testing to hospitals by nine percent and physician offices by six percent. Over time, this trend may force these facilities to curtail or eliminate testing, particularly in rural, underserved areas, thus limiting patient access to timely care and potentially driving up healthcare costs by delaying treatment.

- **The rates are based on flawed payment data** – Only 0.7 percent of all laboratories in the United States were required to submit payment data to CMS. Most of the data came from large national commercial laboratories that are generally paid lower fees than independent, hospital, and physician office laboratories. Whereas national commercial laboratories account for 50 percent of the CLFS test volume, they accounted for 90 percent of the payment volume/data used by CMS to set the new rates. The payments rates should reflect data from a representative cross-section of the laboratory sector and ensure that the payment reductions more closely align with congressional intent.

- **Reporting process needs to be simplified** – Even large national commercial laboratories had difficulties gathering and submitting payment data to CMS, despite their relatively abundant resources. Some underserved areas do not have ready access to comparable services for collecting and submitting data. The reporting process needs to be simplified so that smaller, lower-volume testing facilities can easily and cost-effectively submit their data.

**MedPAC Discussion**

During the September meeting, the panel discussed competitive bidding for laboratory services. The objective of such a strategy would be to obtain the market rate for Medicare. It should be noted that PAMA has already set in place a process, albeit flawed, for accomplishing this goal through the collection and reporting of private sector fees. AACC recommends that MedPAC focus on correcting the problem with the current system, which is the purpose of the commission report, rather than adding another complicating factor to the payment structure.

There was also much discussion during the public session of the August 2020 Office of the Inspector General (OIG) report, *Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions*. This document described in detail a recent increase in the utilization of genetic testing and its corresponding impact on overall Medicare payments. Unfortunately, much of the discussion inferred that this was a negative development.

According to the OIG, two of the most utilized genetic tests are for cancer applications. This trend is due, in part, to recommendations from the United States Preventive Services Task Force that urge healthcare providers to use genetic tests in cancer risk assessment programs for colorectal, breast, and ovarian cancers. Further, the expansion of molecular diagnostic testing is critical to advancing personalized medicine (e.g., prenatal aneuploidy screening, tumor genomic profiling, and solid organ transplant monitoring), which has been a goal of recent administrations.

Increased testing reflects increased access, which is not [necessarily] a bad outcome. AACC urges MedPAC to take a broader view in assessing the value and cost implications of laboratory services pertaining to patient care and the financial solvency of the healthcare system.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of progressing laboratory science. Since 1948, AACC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation.

We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

David G. Grenache, PhD, D(ABCC)
President, AACC