ACLA
American Clinical Laboratory Association

Statement for the Record

Senate Finance Committee:
Rural Health Care in America: Challenges and Opportunities
May 24, 2018

Introduction

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to provide this statement for the record for the May 24, 2018 hearing entitled, "Rural Health Care in America: Challenges and Opportunities."

ACLA is a not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, ESRD, hospital and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion to the nation's economy.

Flawed Implementation of PAMA Section 216

Congress passed the Protecting Access to Medicare Act (PAMA) in 2014. Section 216 of PAMA dramatically changed how laboratories are reimbursed for providing clinical laboratory services to Medicare beneficiaries, moving from a static fee schedule to determining payments based on commercial payments to the broad spectrum of laboratory providers.

Congress directed the Centers for Medicare & Medicaid Services (CMS) to collect private payor payment rates and associated volumes ("applicable information") from independent laboratories, hospital laboratories, and physician office laboratories ("applicable laboratories"), and to calculate a weighted median for each test on the Clinical Laboratory Fee Schedule (CLFS) to determine a Medicare payment rate for each test.

However, CMS deliberately disregarded Congress' instructions by gathering rate and volume information from less than one percent of laboratories nationwide. This blatant omission ignores the fundamentals of a market-based system. By ignoring the data from more than 99 percent of the nation's laboratories, CMS' actions will have a chilling effect on patient care and delivery system reforms moving forward. Furthermore, per CMS' own analysis, only 36 rural laboratories in the entire United States reported data.[1] That is less than 2 percent of the total number of laboratories, although 23 percent of Medicare beneficiaries live in rural areas.[2]

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[1] *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System ("Summary"), available at https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.*

[2] *Health Care Spending and the Medicare Program, MedPAC, available at http://www.medpac.gov/docs/default-source/data-book/jun17_databookentirereport_sec.pdf.*

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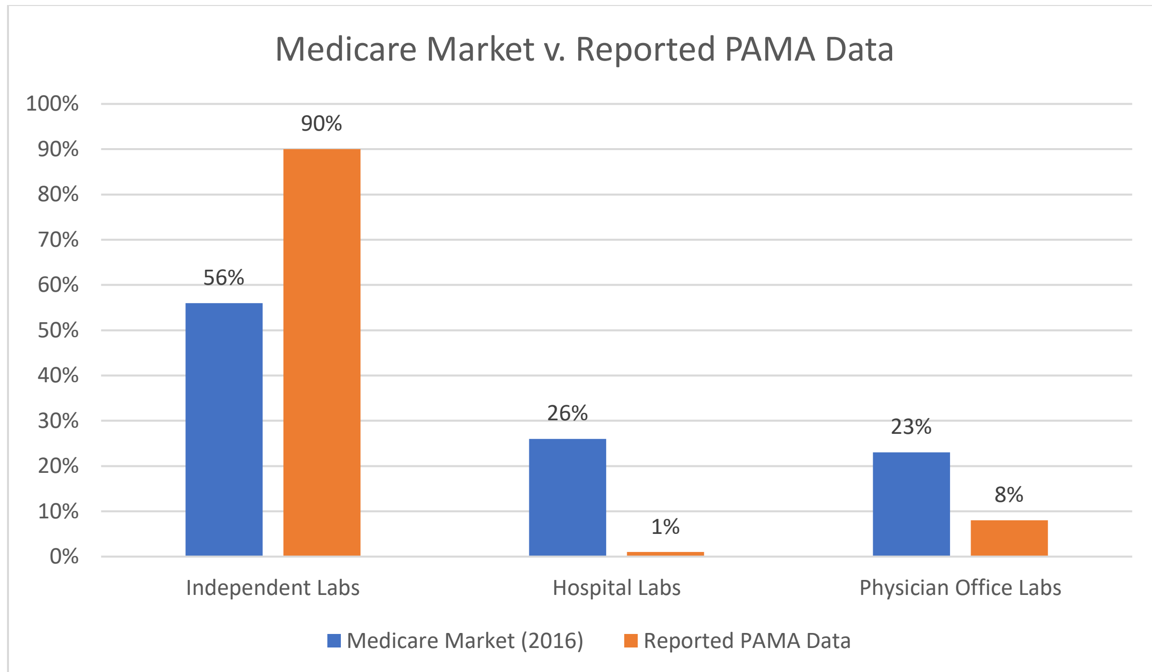
Additionally, as shown below, the volume of applicable information CMS received from independent laboratories, physician office laboratories, and hospital laboratories is far out of proportion to their respective shares of CLFS volume. [3,4]



Clearly, independent laboratories submitted a far larger proportion of applicable information than their share of CLFS volume. Hospital laboratories and physician office laboratories submitted significantly less applicable information by volume than their share of CLFS volume. Simply put, the preliminary rates cannot be characterized as "market-based" when the data does not reflect the market.

PAMA Payment Amounts Not Market-Based

The flawed data reporting requirements established by CMS have resulted in Medicare payment rates that are not market-based. The Medicare payment rate cuts could be unsustainable for many laboratories furnishing services to Medicare beneficiaries and threaten access to laboratory services in some areas, particularly in rural and underserved communities. The cuts go far beyond what Congress and the Office of Management and Budget (OMB) anticipated, calling into question CMS' approach to implementing the law.

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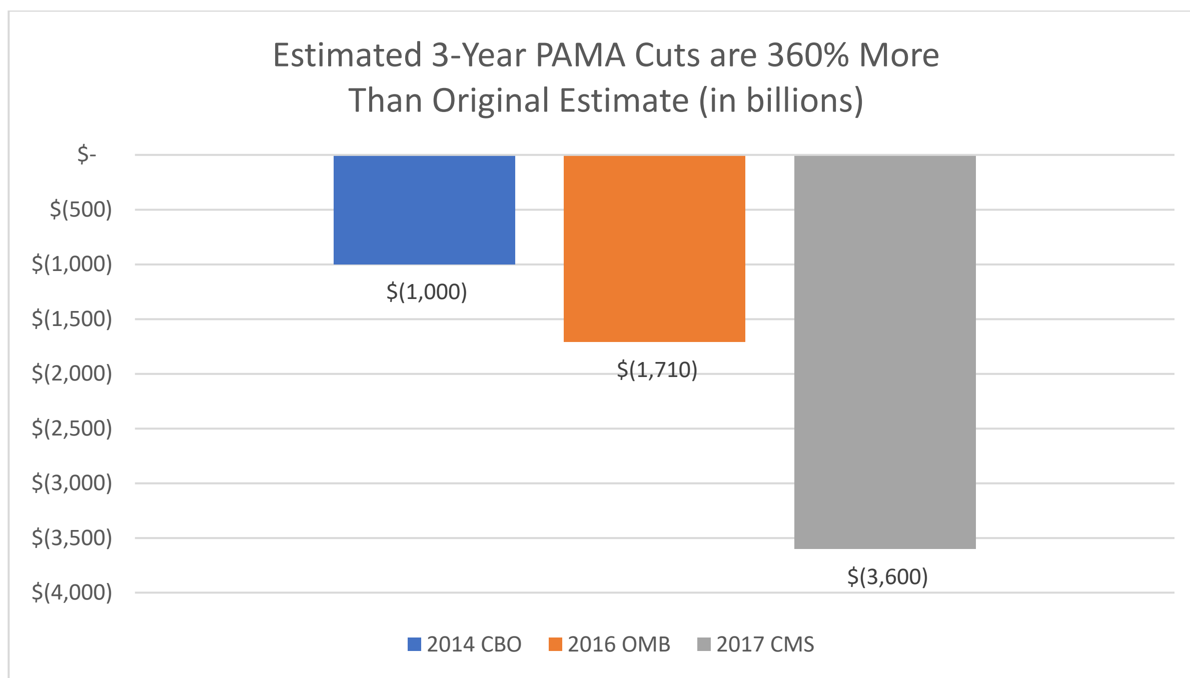
[3] *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System ("Summary"), available at https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.*

[4] *Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data, available at https://oig.hhs.gov/oei/reports/oei-09-17-00140.pdf.*

The below chart includes the increasing estimates of the PAMA cuts. The Congressional Budget Office (CBO) estimated the initial three-year transition to a market-based system at $1 billion. CMS now estimates the cuts at $3.6 billion, an increase of 360 percent.



Under PAMA Sec. 216, nine of the top 10 laboratory tests (by CLFS spending) will be cut by more than 30 percent when fully phased-in. Moreover, 18 of the top 25 lab tests (by CLFS spending) will be cut by more than 30 percent, and another three of the top 25 tests will be cut by between 20 and 30 percent. For example:

- Comprehensive metabolic panel will be cut by 37 percent (41.6 million tests performed in 2016)

- Complete blood count will be cut by 35 percent (42 million tests performed in 2016)

- Vitamin D test will be cut by 35 percent (9 million tests performed in 2016)

- Glycosylated hemoglobin A1c test will be cut by 36 percent (19.3 million tests performed in 2016)

- Thyroid stimulating hormone test will be cut by 35 percent (21.5 million tests performed in 2016)

Collectively, laboratories performed more than 133 million of the foregoing five tests for Medicare beneficiaries in 2016. The top 25 tests by CLFS spending represented fully 63 percent of all Medicare payments for lab tests in 2016, or $4.3 billion.[5] But the deep cuts are in no way

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[5] *Medicare Payments for Lab Tests in 2016: Year 3 of Baseline Data (OEI-09-17-00140) at 3.*

limited to the highest volume test codes. The majority of test codes will be cut by more than 10 percent when they are fully phased-in.[6]

Cuts of this magnitude could be unsustainable for many laboratories serving beneficiaries in rural areas, physician office labs in many locations, and nursing homes, and they could threaten beneficiary access to even basic laboratory testing. The costs of providing laboratory testing to Medicare beneficiaries in these areas is higher than in urban areas. It is likely that the cost could exceed the return for some routine tests, meaning some rural labs may shutter and some physician offices no longer will offer routine lab testing to their patients to inform treatment and enable diagnosis at the time of a patient's visit. It is unlikely other laboratories will rush in to fill the void once these laboratories stop operating.

This misguided approach to PAMA implementation will directly harm millions of beneficiaries, and beneficiaries in rural areas will be most severely impacted. Over the next three years, ACLA has estimated that laboratories in an urban area like Washington, DC will experience a 15 percent cut, while some laboratories in rural areas, for instance rural hospital laboratories, will experience a 28.5 percent cut.[7] By drastically cutting rates, particularly for the top-25 most performed lab tests, CMS is severely affecting beneficiaries managing diabetes, heart disease, liver disease, kidney disease, prostate and colon cancers, anemia, infections, opioid dependency and countless other common diseases and conditions. Reducing access to clinical lab services will ultimately drive up the cost of care for beneficiaries and taxpayers and result in delays in care as well as adverse outcomes.

The harm from these cuts only increases for beneficiaries who are frail or reside in medically underserved communities, such as rural areas. These communities and patients rely on a shrinking number of smaller, local laboratories: laboratories that will face the brunt of these cuts. These cuts will force laboratories serving the most vulnerable and homebound to either shut down operations, reduce services, eliminate tests, or lay off employees. Ultimately, patients will have fewer options to receive the lab test services that will keep them healthy and out of the hospital, particularly patients who are less mobile or would have to travel unreasonable distances to receive laboratory services.

Cuts to Medicaid Payments for Labs Further Threaten Rural Patient Access

In addition to the direct cuts to Medicare laboratory rates, we have seen additional cuts in state Medicaid reimbursement rates. More than one-third of all states have pegged their Medicaid rates for laboratory services to the Medicare CLFS. Those state that base their Medicaid reimbursement on then-current Medicare CLFS rates experienced a cut in Medicaid reimbursement, in addition to Medicare reimbursement, as the new PAMA rates went into effect on January 1, 2018. Since the new CLFS rates went into effect, some states have reduced Medicaid reimbursement for laboratory services even further, beyond the already deep PAMA

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[6] *Summary at 6. CMS itself said that "about 58 percent of HCPCS codes will receive a phased-in payment reduction in CYs 2018, 2019, and 2020, rather than a full private payor rate-based payment amount in CY 2018 because the total payment decrease" will exceed 10 percent.*

[7] *CMS Final 2018 Clinical Lab Fee Schedule Rates, 2016 100% Outpatient Standard Analytic File, 2016 Physician/Supplier Procedure Summary File*

cuts. The application of an even lower percentage of Medicare rates by state Medicaid programs imposes even greater reductions than anticipated for Medicaid beneficiaries particularly in rural and underserved areas where there are relatively few providers. These Medicaid cuts, in addition to the Medicare cuts, may leave providers no choice but to discontinue laboratory services for Medicaid patients as the rates will be less than what they cost to provide the services.

Conclusion

ACLA thanks the Committee for consideration of our comments. We look forward to working with the Senate Finance Committee and stakeholders on advancing legislation to address the flawed implementation of Section 216 of the Protecting Access to Medicare Act, protecting access to laboratory services for Medicare beneficiaries.