

October 23, 2017

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the preliminary rates for the calendar year 2018 Medicare Clinical Laboratory Fee Schedule (CLFS), but do so with pronounced concern that Medicare beneficiary access to clinical testing will be negatively impacted due to the problematic manner in which the Centers for Medicare & Medicaid Services (CMS) has chosen to implement the Protecting Access to Medicare Act (PAMA). The AMA strongly urges CMS to modify the existing PAMA regulations through issuance of an interim final rule effective December 1, 2017, that holds the calendar year 2017 rates in place until CMS has conducted targeted market segment surveys (reference laboratories, physician office-base laboratories, independent laboratories, and hospital outreach laboratories) to ensure that the rates ultimately finalized by CMS are appropriate. CMS has the authority to ensure the integrity and accuracy of the data collected and must validate and adjust the preliminary rates to ensure that congressional intent is fulfilled—namely, that the rates accurately reflect private market payments.

### **Impossibility of Accurate Data Collection**

Congress intended that the Medicare CLFS rates under PAMA would accurately reflect the weighted median of private payer payments for each test. Yet, CMS chose a data collection period that was unlikely to ensure accurate data could be collected by applicable laboratories—namely a retrospective data collection period covering six months. It is not surprising that reports emerged that even the highest resourced and most prepared clinical laboratories—the large reference laboratories—struggled to gather the large volume of data and to submit it by the March deadline. CMS required the impossible of applicable laboratories and not surprisingly the preliminary rates reflect massive cuts well in excess of what Congress had intended. The cuts are so steep that 58 percent of tests will have reductions phased in over multiple years, as the preliminary rates exceed 10 percent of current rates and PAMA establishes a maximum per-year reduction. The unexpected size of the cuts—well beyond all forecasts—underscores what the AMA and other health care stakeholders reported to CMS repeatedly—it was not possible for clinical laboratories to collect the volume and complexity of the data accurately well after the time that payments were made by primary payers, secondary payers, tertiary payers, and patients. The small independent laboratories and physician office laboratories simply did not have the software and accounting methods in place to track the large volumes of data in the manner specified by CMS. (CMS

further exacerbated the difficulties by seeking six months of data when three months would have reduced the reporting burden and could have redirected resources to ensure data accuracy.)

The challenges to accurate data collection, however, will not only impact negatively payment on the Medicare CLFS, but the flawed rates could be adopted by state Medicaid programs as well as private payers once existing contracts expire. The consequences for Medicare beneficiaries are alarming as some of the most medically fragile and those in rural areas will most certainly see access deteriorate, but the impact will reverberate throughout the health care system and go well beyond the \$670 million in Medicare cuts for CY 2018. These cuts will undermine other major initiatives, such as implementation of the Medicare Merit-based Incentive Payment System and alternative payment models, as well as important public health priorities, such as the rapid detection and treatment of infectious diseases and preventing massive outbreaks.

### **Lack of Data and Rate-Setting Transparency**

Many stakeholders are identifying concerning and questionable preliminary rates that are inconsistent with the information that they have available. However, the process most stakeholders have to assess the accuracy of the data is hamstrung by the lack of transparency in the manner CMS has aggregated the submitted claims. We also find it challenging to “validate” accuracy when a large volume of data was submitted, but we believe that it was not possible to submit consistently accurate data that actually represented final and total private payer payments as defined by the statute and regulation. In short—there is every reason to believe the data submitted is wrong, but stakeholders are again asked to do the impossible: prove it. However, there is no realistic or meaningful way for stakeholders to assess the accuracy of the submissions and the final CMS aggregation based on the data that is publicly available. There is only one approach that would reasonably allow stakeholders and policymakers to have a modicum of confidence that the data is accurate—a market-based segmented survey to validate the final amounts and adjustment. CMS has numerous claims databases and sources and additional methods that would enable the Agency to conduct targeted surveys. Gathering more, massive, voluminous data from a larger pool of newly defined applicable laboratories or audits of individual laboratories is not needed or necessary.

### **The Critical Need for a Strong Clinical Testing Ecosystem**

It is essential that congressional intent is fulfilled as a general rule, but this is the most significant change to payment of the Medicare CLFS in decades, and we are concerned that the cuts will eliminate small, independent laboratories in rural communities as well as clinical testing for patients in their physician’s office-based laboratory (POL). The implications for clinical care and public health are sobering given the critical role clinical testing plays generally, but particularly rapid, near patient testing in POLs. Such testing ensures the U.S. health system has a strong and comprehensive network of clinical laboratories (including POLs, independent, reference, and hospital community outreach labs) to provide the first line of detection and defense against an infectious disease outbreak or pandemic in the interest of public health. POL testing advances patient-centered care as part of 21<sup>st</sup> Century medicine initiatives to leverage innovations in order to ensure care is delivered near to patients (particularly important for Medicare beneficiaries who may have more comorbidities, may be more medically fragile, and may face more barriers (cost and geographic, for example) to accessing clinical care). Point-of-care testing is an important component of such efforts. POL testing improves patient care continuity and optimizes care

coordination and efficient communication to minimize patient burdens associated with fragmented care by facilitating and advancing new payment and delivery models as required under the Medicare Access and CHIP Reauthorization Act of 2015.

### **Serious, Negative Impact on Vulnerable Patient Populations and Public Health**

Real accounts from around this country put a face on this issue and underscore the serious threat of these preliminary rates to individual patient health outcomes and public health. According to an oncologist from Michigan, “[t]o have testing on the day of treatment, before we start, is very important.”<sup>1</sup> Laboratory testing at the time of a cancer patient’s treatment visit is often necessary to determine treatment dosages and to assess side effects resulting from chemotherapy medications and any combination of other medications the patient may be taking. Sending such testing to large reference laboratories in remote and rural communities is challenging logistically and a hardship for already medically fragile patients. This oncologist shared that one of his patients was “complaining of low-grade fever and weakness,” and the POL testing indicated that the patient was suffering from neutropenia and low hemoglobin levels, which are quite common in patients undergoing chemotherapy.<sup>2</sup> As a result of having laboratory testing information immediately available, the oncologist planned for a blood transfusion and growth factor treatments.<sup>3</sup> This improved the patient’s health status while saving the health system the cost of a hospital visit. Another family physician in Oklahoma shared that the closest independent laboratory is “300 miles away.”<sup>4</sup> If his three physician practice no longer provided laboratory services “it would be devastating to our community,”<sup>5</sup> and his patients would bear the brunt of the burden and negative impact on their clinical care. Instead of decreasing the number of emergency department visits, the lack of POL testing will mean more Medicare beneficiaries will need to receive care in more costly sites of care because their treating physician is not able to offer rapid testing in-office and the patient’s health status worsens.

It is not only in rural communities that such cuts will impact health and well-being. Physicians and public health professionals must have quick, near real-time access to clinical test results to identify, mitigate, and contain infectious disease outbreaks. We certainly need large reference laboratories, independent laboratories, and hospital laboratories for that purpose, but patients often first show-up in their physician’s office. Physicians are able to rule out other potential common infections fast in their own laboratory while the patient waits. If the infection is not identifiable, the physician can quickly refer the specimen to a reference laboratory or directly to the public health laboratory. The foregoing is an essential line of defense to address the constant threat of infectious disease outbreaks.

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<sup>1</sup> COLA. (2017). Value of Near Patient Testing, April 2017. Near Patient Testing Matters Portal. Retrieved from: <http://www.nearpatienttestingmatters.org/> COLA conducted a survey of randomly selected physicians providing clinical laboratory services within their medical practice to participate in a study of near patient testing in counties that make up some of the most rural counties in the nation. The interviews were semi-structured and conducted in a confidential manner. The semi-structured format enabled COLA researchers to capture specific data, while at the same time, allowing free space for the physicians to identify their key concerns. In addition to the in-depth interviews, COLA designed a national practice survey to gather additional quantitative and qualitative data relating to the impact of near patient testing on patient care.

<sup>2</sup> Id.

<sup>3</sup> Id.

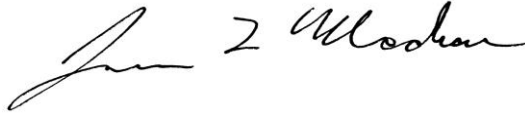
<sup>4</sup> Id.

<sup>5</sup> Id.

## **Conclusion**

The collection of inaccurate and wrong data due to impossible collection conditions should not be the basis for Medicare's 2018 cost year rates—and yet it is. The consequences will be borne first by the most vulnerable and medically fragile as well as those who already face significant access challenges to their overall care. These present sufficient concerns for CMS to take the immediate action that the AMA has urged since July of this year. The cascade across the broader health care system, including Medicaid beneficiaries and those who are privately ensured, must surely prompt immediate action to take a measured and prudent set of steps to assess the accuracy of the data utilizing transparent and reliable additional data sources. Thank you for the opportunity to comment. If you have questions, please contact Shannon Curtis, Assistant Director of Federal Affairs, at [shannon.curtis@ama-assn.org](mailto:shannon.curtis@ama-assn.org) or 202-789-8510.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD