AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
U.S. Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to discuss important regulatory steps that can be taken to relieve the administrative burdens faced by physicians that negatively impact their ability to provide patient care. As noted by AMA staff in our recent discussion, we urge the Centers for Medicare & Medicaid Services (CMS) to implement a number of measures to ensure that the payment rates calculated based on the Protecting Access to Medicare Act of 2014 (PAMA) methodology are accurate. Among a number of pressing concerns, most immediately it has become clear that the integrity of the data for calculating payment is not assured since the data collection process has been hamstrung by the Obama Administration's decision to impose a retrospective data collection period. In addition, the regulation issued did not provide a clear and transparent mechanism for aggregation of each clinical test payment data and a means for stakeholders to validate the accuracy of the final payment amount. As the rates will be effective on January 1, 2018, there is very limited time for CMS to address deepening concern that the payment rate will not actually reflect the weighted median of private payer payments as Congress intended. The consequences for our patients will be pronounced.

Physician practices and clinical laboratories have reported that the decision to establish a retrospective reporting period for data collection has hindered their ability to capture or reconstruct the actual final payment for applicable clinical tests. The AMA has previously recommended that the data collection period should be prospective in order to provide physician practices and clinical laboratories an adequate amount of time to work with their vendors to prepare their systems to collect the required information. Instead, the final regulation provided for a retrospective data collection period. Not surprisingly, there are reports that partial payments have, in some instances, been reported as a total payment, particularly for paper transactions where co-pays, co-insurance, and primary/secondary payer payments could not be reconciled to generate an accurate total payment amount. We have learned of other difficulties that even large clinical laboratories have encountered.

In addition, given the difficulties with the Agency's beta test for submission of data prior to the actual data submission period, there is concern that the process for aggregating reported data for each clinical test and calculating the weighted median could be error prone and CMS has not specified steps that will be taken to provide transparency or validation. By way of comparison, the first year that the Open Payments Program was implemented there were significant irregularities and difficulties where CMS was

responsible for separating manufacturer payment amounts for attribution to individual physicians and teaching hospitals. The amount of data reported for the PAMA reporting exercise involves a tremendous amount of data and that there is no ability to assess whether the final payment amount actually reflects the data submitted.

Based on the lack of data integrity, we anticipate that patients will experience reduced access across the board to clinical laboratory testing and patient access to in-office testing will be particularly hard hit. Given the direction of the current policy, many clinical laboratories will close. Laboratory testing furnished at the point-of-care, such as in a physician's office, enhances patient centered care and outcomes while also decreasing the costs of care coordination and administrative processes to the health care system. Patients are often able to undergo the tests and receive the results during the course of a routine office visit, avoiding additional appointments and providing timely information on the patient's clinical needs. In-office testing can be used to diagnose illnesses like HIV and monitor chronic conditions like diabetes and high cholesterol. Some of the most clinically fragile patients, including patients with cancer undergoing chemotherapy, typically require in-office testing prior to treatment. It is critically important that CMS determine accurate payment rates. Otherwise, clinical laboratories as well as physicians will find it increasingly impractical to offer in-office testing.

Because the PAMA regulation was not promulgated to reasonably effect congressional intent—namely, obtain accurate data in order to establish the correct weighted median for each test on the Medicare clinical laboratory fee schedule—we urge you to implement a number of steps. We recommend that CMS issue an Interim Final Rule with comment in order to:

- Expand the definition of "applicable laboratory" to include hospital outreach laboratories as this is necessary to accurately reflect the private payer payment which is required under PAMA.
- Conduct market segment surveys (reference laboratories, physician office–based laboratories, independent laboratories, and hospital laboratories) to validate and adjust the final amount calculated based on the data collection to ensure it accurately reflects private payer payments—which CMS has the authority to do under a general grant of authority in the Social Security Act to administer the Medicare program.
- Allow pricing for tests performed at a single clinical laboratory to proceed as planned since the data can be expected to be accurate and the final amount calculated easily validated by the clinical laboratory.

At a time when relief from overly burdensome regulation has become a top priority of the Trump Administration, we urge CMS to ensure that implementation of PAMA results in as little administrative burden and disruption as possible. We look forward to ongoing communication and dialogue with CMS as implementation continues to ensure that Medicare beneficiaries have access to medically necessary clinical testing.

Sincerely,

James L. Madara, MD