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[By Electronic Submission to [CLFS Annual Public Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov)]

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: CY 2018 Clinical Laboratory Fee Schedule Test Codes Preliminary Determinations

Dear Administrator Verma:

The Infectious Diseases Society of America (IDSAs) is pleased to offer comments on The Center for Medicare & Medicaid Services (CMS) 2018 preliminary payment rate determinations for clinical diagnostic laboratory tests as required by the Protecting Access to Medicare Act of 2014 (PAMA). We recognize that CMS is committed to developing an equitable payment system that will improve patient access to diagnostic laboratory testing. We look forward to working with the agency.

Over the past several years, IDSAs has stressed the importance of diagnostic devices for the care of patients suffering from infectious diseases (ID), most notably in our 2013 report, [Better Tests, Better Care: Improved Diagnostics for Infectious Diseases](#). Improved diagnostics allow physicians to rapidly identify the pathogen infecting a patient. By prescribing the most appropriate treatment for the offending infection, there is increased likelihood of improved patient outcomes. Notably, high quality ID diagnostics protect the broader public health by providing early alerts to health officials to contain outbreaks and to prevent infection transmission.

Following the CMS 2015 proposed rule to revise the Medicare payment system for clinical diagnostic laboratory tests, IDSAs expressed [concerns](#) that the reporting of private payor reimbursement data would be overly burdensome for clinical laboratories and subsequently result in inadequate reimbursement rates for diagnostic tests. In [March](#) and [September](#) of 2017, IDSAs joined several physician groups to request an extension to the PAMA data reporting period. The letters stressed the importance of near-patient access to rapid clinical testing, citing concerns that the rates derived from the CMS-directed data collection and reporting methods would cause reimbursement for physician office-based testing services to fall below the costs of providing these services, ultimately reducing the availability of essential diagnostic tests. Although we appreciate CMS's subsequent 30-day reporting extension for applicable laboratories, we remain concerned that inaccuracies in the reporting and data collection processes, as well as the cross-

section of applicable labs surveyed, have resulted in preliminary rate determinations that will ultimately devastate ID patient care. We have highlighted specific data integrity issues that were reported by members of IDSA and other physician organizations below.

If CMS implements the proposed rates on January 1, 2018 as planned, Medicare patient access to testing will markedly decrease, thus derailing advances in rapid and near-patient diagnostics testing. Most ID diagnostic tests will get a 10% reduction in 2018, with a possibility of additional 10% reductions over the next two years (for a total 30% reduction by 2020). These rates will not reflect market-based payments as intended by Congress. IDSA would like to offer specific comments and recommendations on the methodology and impacts of the preliminary rate determinations below.

Data collection issues

IDSA has had persistent concerns that PAMA implementation was not optimal to collect accurate data; furthermore, CMS has not specified how stakeholders will be able to ascertain the accuracy of the final calculated amounts. The need to validate data in a transparent manner is essential, particularly for the first cycle of rate determinations where data integrity remains a widely shared concern. Additional data collection issues include:

- Many clinical laboratories did not learn of the requirements until well after June 2016, after the collection of accurate data became an impossibility;
- Reports have emerged that reconciling payments to tests performed was inconsistent and error-prone (particularly for paper claims), as payments such as co-pays and co-insurance were not easily reconciled to initial payments and specific tests. In some cases, payments for one test were reported as payments for different tests inadvertently;
- Even when a laboratory is paid for claims by an out of network payor, the explanation of benefits (EOB) often does not clearly state the payment rate established by the payor. Many laboratories receive different payment rates for the same test (a single CPT code) on the same date of service for patients who live in the same state. Theoretically, these claims should be paid the same amount, but often they are not. This further compounds the difficulty in discerning the payment rate established by the payor.

IDSA is very concerned that CMS's market-based reporting approach, in which only laboratories that receive 50% of their Medicare revenues and over \$50,000 annually for services billed under the Clinical Lab Fee Schedule (CLFS) or Physician Fee Schedule (PFS) were eligible to report reimbursement rates and volumes, has excluded hospital-based laboratories to their detriment. The effects of excluding such large parts of the laboratory market appears to have been exacerbated by issues of data accuracy and integrity, and the retroactive data reporting period caused many laboratories to cite issues with the data they submitted. The proposed cuts to Medicare clinical tests, including those performed in physician offices, could force most physicians' offices and hospital-based laboratories to stop offering many (if not all) tests performed near to patients. The rationale for these cuts is based on incomplete and inaccurate data.

IDSA urges CMS to consider additional weighting that reflects the broad scope of the market, and the value of local, rapid laboratory services that are critical in ID patient care. For example, CMS could seek data from private insurers on the rates paid to hospital laboratories and physician offices for diagnostic tests.

Impact on patients and diagnostics development

IDSA and others are concerned that the many issues with the CMS approach to data collection will lead to inappropriate new reimbursement rates for many tests that will subsequently serve to reduce patient access to testing.

In the face of insufficient reimbursement levels, our Society believes that many clinical microbiology laboratories, especially in leading U.S. medical centers that provide advanced specialized care to highly complex patients, will be forced to send clinical specimens to outside commercial reference laboratories for testing. This will significantly increase the turnaround time required to get the results to physicians. Rapid diagnostics that facilitate early initiation of life-saving treatment are critical in ID patient care, where even a few hours' delay can significantly impact patient outcomes¹. Public health responses also require rapid identification of an emerging health risk, and any delay in activating critical public health protocols allows dangerous infections to spread. Access to rapid diagnostics have been cornerstones of the successful identification of the 2001 anthrax attacks, the 2003 global SARS outbreak, the 2014-16 Ebola outbreaks, and the 2017 measles outbreak in Minnesota. Delays incurred by sending specimens to reference laboratories may significantly impact the detection of future infectious disease outbreaks.

Finally, inadequate reimbursement rates could create a major disincentive for diagnostic test development in the United States, where the cost of trials may be too expensive for manufacturers to pursue licensure. This chilling impact on innovation could leave U.S. patients without access to the newest, state-of-the-art diagnostic tests.

Recommendations

IDSA strongly urges CMS to modify 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-based laboratories, independent laboratories, and hospital outreach laboratories). CMS has the authority to ensure the integrity and the accuracy of the data collected. CMS must validate and adjust the preliminary rates to ensure congressional intent is fulfilled—namely, that the rates accurately reflect private market payments across all market segments.

IDSA is concerned that the present issues with the CMS approach to data collection has resulted in inappropriate reimbursement rates for many diagnostic tests that will subsequently serve to reduce patient access to testing. The public health consequences that result from a significant

¹ Institute of Medicine (US) Forum on Microbial Threats. Global Infectious Disease Surveillance and Detection: Assessing the Challenges—Finding Solutions, Workshop Summary. Washington (DC): National Academies Press (US); 2007. 3, Detection and Diagnostics.

reduction of near-patient testing (including physician office, hospital-based and regional clinical laboratories) will undermine essential public health infrastructure needed as the front line to detect infectious disease outbreaks. A substantial decrease in patient access to clinical testing options (including point-of-care testing) will have a negative impact on patient care and efforts to drive 21st Century Cures Act priorities.

IDSA remains committed to developing a reimbursement system that promotes innovative diagnostics and improves patient access. We hope these comments are useful to CMS as the agency moves forward in their efforts to reform clinical laboratory diagnostic reimbursement. Should you have any questions or concerns about these comments, please feel free to contact Jaclyn Levy, IDSA Senior Program Officer for Science and Research Policy, at jlevy@idsociety.org or 703-299-1216.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul G. Auwaerter". The signature is fluid and cursive, with a prominent initial "P" and "A".

Paul G. Auwaerter, MD, MBA, FIDSA
President, IDSA