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IDSA
Infectious Diseases Society of America

November 7, 2018

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

Re: PAMA implementation and CY 2019 Clinical Laboratory Fee Schedule Test Codes Determinations

Dear Administrator Verma:

The Infectious Diseases Society of America (IDSA) recognizes that CMS is committed to developing an equitable payment system that will spur innovation and improve patient access to diagnostic laboratory testing. We write to offer comments on recent reimbursement trends for clinical diagnostic laboratory tests as required by the Protecting Access to Medicare Act of 2014 (PAMA). In particular, we want to share our concerns about recent decisions by CMS and by a Medicare Administrative Contractor (MAC) that would seriously jeopardize patient access to testing. We encourage CMS to take steps to ensure appropriate reimbursement that maintains access to high-quality diagnostics for patient care and look forward to working with the agency to address this important issue.

Over the past several years, IDSA has stressed the importance of innovative 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 can allow physicians to rapidly identify the pathogen infecting a patient and prescribe the most appropriate treatment, increasing the likelihood of an improved patient outcome. Notably, high-quality ID diagnostics have a unique ability to protect the broader public health by alerting health officials of the need to trigger protocols to contain outbreaks and prevent the transmission of infections. Diagnostics also play an essential role in broader efforts to combat antimicrobial resistance, by helping to guide appropriate antibiotic use and identifying patients eligible for new antibiotic clinical trials.

Following CMS's 2015 proposed rule to revise the Medicare payment system for clinical diagnostic laboratory tests, IDSA expressed concerns that the reporting of private payor reimbursement data would be overly burdensome for clinical laboratories and would result in inadequate reimbursement rates for diagnostic tests. In March and September of 2017, our Society joined several physician groups in requesting an extension to the PAMA data reporting period and

emphasizing the importance of near-patient access to testing due to concerns that the data collection and reporting requirements could jeopardize the availability of clinical testing and patient access to services. Although we appreciated the CMS rationale document released alongside the final CY18 clinical laboratory fee schedule (CLFS) determinations, we remain concerned that inaccuracies in the reporting and data collection process, as well as the cross-section of applicable labs surveyed, have resulted in rate determinations that will ultimately devastate ID patient care.

In 2018, most ID diagnostic tests received a 10% reduction, with further 10% reductions likely over the next two years (for a 30% or greater reduction by 2020). These rates do not reflect market-based payments as intended by Congress and will derail critical advances in point-of-care (POC) testing. We are further concerned by the recent decisions made by Medicare A/B contractors to reduce or eliminate reimbursement for essential multiplex molecular diagnostics for respiratory and food-borne gastrointestinal infections for patients across the U.S. IDSA would like to offer specific comments and recommendations on the methodology and impacts of recent diagnostic test pricing trends below.

Impact of 2018-19 cuts on patient care and diagnostic test development

IDSA and others are concerned that a number of issues with the CMS approach to data collection have led to inappropriate new reimbursement rates for many tests. These reimbursement rates will reduce patient access to testing. COLA, the largest accreditor of clinical laboratories in the country, surveyed clinical laboratories nationwide to better understand the impact of in-place cuts to the Medicare Clinical Laboratory Fee Schedule as well as the potential impact of upcoming cuts. The survey found that retention of the upcoming cuts will make it more difficult for providers to offer clinical laboratory services in their practices. Participants also shared how the first 10% cut in the Medicare lab fee schedule impacted their laboratory operations as well as patient access to testing:

- 39.22% now refer more tests out to another laboratory.
- 32.84% changed their test menu.
- 31.86% will not update their equipment.
- 24.02% changed utilization.
- 16.18% laid off staff.
- 13.73% plan to shift their patient population to new testing sites over time.

Over half of respondents also agreed that they would not be able to absorb an additional 10% cut in the Medicare laboratory fee schedule for 2019 and may stop offering testing services as a result. Now, nearly 40% of respondents send clinical specimens to outside commercial reference laboratories for testing more frequently as a result of recent payment cuts. This outsourcing significantly increases the turnaround time required to get the results to physicians and directly hinders patient care. 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 outcomes. Public health responses also require rapid identification of an emerging health risk, and any delay in activation of important public health protocols allows dangerous infections to spread.

Delays incurred by sending specimens to reference laboratories may significantly impact the detection of outbreaks of infectious diseases. The high numbers of clinical laboratories that changed their test menus or utilization as a result of reimbursement cuts are also worrisome, as these behaviors indicate a likely reduction in testing options available to patients. 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.

The current CMS approach to PAMA implementation does not make any provision for the improved access that rapid, accurate near-patient clinical testing provides. The PAMA weighted median provides a single rate which is depressed by the high volume of large laboratories and will not cover the costs of clinical testing in a physician office laboratory. More patients will require care in emergency departments when a diagnosis cannot be made, and treatment cannot be initiated in a physician's office (or other locations where near-patient testing occurs).

The U.S. Department of Health & Human Services Office of the Inspector General recently issued a report concluding that increasing the reporting from more clinical laboratories (such as hospital, community, and physician office-based laboratories) would not materially or meaningfully affect the 2018 payment rates calculated under PAMA. This is due to the flawed weighted median methodology of PAMA which reflects the high volume, low cost rates of large laboratories and does not account for the varied costs of performing tests in other sites of service that have lower volume, such as tests performed in a physician's offices as part of the patient's medical visit. This is particularly concerning given that PAMA requires data to be collected and calculated using a weighted median every three years, thus indicating that the rates will continue to be cut regardless of the actual costs associated with offering POC testing. We are disappointed that while the CY 2019 Physician Fee Schedule (PFS) Final Rule expands the definition of "applicable laboratory" to encompass hospital laboratories and others that serve beneficiaries enrolled in Medicare Part C, it does not adjust the methodology of using a weighted median to a weighted mean.

IDSA urges CMS to consider revised 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.

Medicare Administrative Contractor reimbursement determinations

In 2017, Medicare Administrative Contractor (MAC) Palmetto GBA released draft local coverage determinations (dLCD) for multiplex nucleic acid tests for respiratory viruses and foodborne gastrointestinal (GI) panels. Both dLCDs proposed reduced or eliminated reimbursement for critical infectious diseases diagnostics. IDSA worked with other concerned stakeholders to draft comments for both the GI and respiratory panel dLCDs outlining our joint concerns and recommendations. In 2018, following the release of similar draft proposals by

additional contractors, IDSA members submitted comment letters in each MAC jurisdiction where their patients would be negatively impacted by the proposed determinations.

While the recent release of the final Palmetto LCDs for both sets of panels incorporates additional targets for reimbursement in partial accordance with the IDSA recommendations, several issues remain unaddressed. We are concerned by the limitation of respiratory panel reimbursement to a maximum of 5 targets, the dearth of ICD-10 codes covered in the GI panels, and by the failure of Palmetto to address our remaining comments in their public response. Further, we disagree with their assertion that testing for viral etiologies is not "reasonable and necessary" under Medicare standards when the ability to confirm a viral diagnosis could reduce empiric antibiotic use, which in turn could reduce the risk of *C. difficile* infection and the development of antibiotic resistance. As additional MACs weigh final determinations for reimbursement rates that will affect patients across the country, we urge CMS to conduct appropriate oversight of contractors like Palmetto to ensure adequate reimbursement for diagnostic tests to protect patient access to testing.

Recommendations

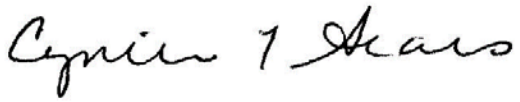
IDSA is concerned that the methodology being used to implement PAMA will devastate recent progress in ID patient care. In the long run, it's likely that the brunt of the cuts will impact small labs that lack scale, allowing large reference laboratories to monopolize the industry. The public health consequences that result from a significant reduction of POC testing (including physician office-based and regional clinical laboratories) will undermine essential public health infrastructure needed as the front line to detect infectious disease outbreaks. A significant decrease in patient access to clinical testing options will have a negative impact on patient care and efforts to drive 21st Century Cures Act priorities.

As an organization that represents physicians and scientists who develop and use these tests, we strongly urge CMS to:

- **Freeze upcoming PAMA cuts for two years while stakeholders work with CMS and Congress to develop a comprehensive solution to ensure that Medicare reimbursement truly reflects the market;**
- **Address the flawed methodology for calculating fees on the Medicare CLFS, as the current method will, in particular, reduce patient access to appropriate care in rural and underserved areas and, overall, to rapid, accurate clinical testing;**
- **Utilize existing program integrity and program administration authorities to remedy data accuracy through a statistical survey method that is least burdensome on providers and reflects the full range of health care sites and their associated services and relative costs;**
- **Expand Medicare's determination of "medically necessary" services to include multiplex tests that are essential to rapid diagnosis for infectious diseases patient care. This will ultimately reduce test turnaround time, hospital stay length, disease transmission, and healthcare costs while enhancing the appropriate use of antibiotics that reduce antimicrobial resistance**.

IDSA remains committed to developing a reimbursement system that promotes innovative diagnostics and improves patient access and care, and 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,



Cynthia Sears, MD, FIDSA
President, IDSA