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[By Electronic Submission to www.regulations.gov]

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

Re: Comments on Docket No. CMS-1621-P; Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System;

Dear Sir/Madam:

The Infectious Diseases Society of America (IDSociety) is pleased to offer comments on The Center for Medicare & Medicaid Services (CMS)'s proposed rule to revise the Medicare payment system 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, and look forward to working with the agency.

Over the past several years, IDSociety 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 a positive 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.

In our report, IDSociety identifies inadequate Medicare reimbursement as a barrier to the clinical integration of new diagnostic technologies. If these tests are more expensive than older counterparts, they often do not receive reimbursement levels via gap-filling or cross-walking that covers the cost of the test until a new procedural code has been assigned. As a result, hospitals and physicians are frequently unable to offer new tests to patients until a new procedural code is assigned to allow for appropriate billing. Such delays impede patient access to newer tests that may offer faster, more precise results that can reduce unnecessary treatments, speed access to appropriate treatment, improve patient outcomes and reduce healthcare costs. Even when new codes are assigned, they still often do not adequately reimburse the full cost of testing, further limiting patient access to innovative tests.

IDSA agrees that a reexamination of diagnostic laboratory test reimbursement will help improve timely patient access to testing, and applauds CMS's efforts to implement a market-based payment system to set reimbursement levels for testing. However, we also urge caution from CMS as it undertakes the most comprehensive revision of laboratory reimbursement in 30 years. Specifically, CMS must design and advance an approach that will provide the agency with the diverse data it needs to set appropriate payment rates while not overburdening the private entities tasked with providing the necessary data. IDSA would like to offer specific comments and recommendations to the proposed rule below.

Applicable Laboratories for reporting market reimbursement rates

IDSA is very concerned that the market-based reporting approach, as currently proposed by CMS, could impede patient access to local and rapid diagnostic testing. CMS proposes that 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) will be eligible to report reimbursement rates and volumes on which the weighted median reimbursement level for a test will be calculated. CMS itself has indicated that almost all hospital based laboratories will be excluded, leaving most of the reporting to larger commercial laboratories. IDSA appreciates CMS's intention to minimize the prohibitive administrative burden of reporting to hospital laboratories. However, we are extremely concerned that the reporting commercial laboratories receive lower reimbursement levels given their larger volume of testing compared to hospital laboratories. While the market-based reporting will include a weighted median to account for high volume, lower cost testing, in the absence of any hospital laboratory reimbursement data, IDSA is extremely concern that reimbursement levels may nevertheless be set too low to sustain the routine use of ID diagnostics by hospital laboratories and physician practices.

In the face of insufficient reimbursement levels, our Society believes that many clinical microbiology laboratories, especially in leading US medical centers that provide high quality 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 outcomes. Public health responses also require rapid identification of an emerging health risk, and any delay in activation of important public health protocol allows dangerous infections to spread. Delays incurred by sending specimens to reference laboratories may significantly impact detection of outbreaks of infectious diseases. 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 US patients without any access to the newest, state of the art diagnostic tests.

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. If that is not possible, we

recommend CMS consider a mechanism that allows hospital laboratories and physician offices to submit their information voluntarily. In such an instance, CMS must work closely with hospital laboratories to design a simple mechanism that imposes minimal burden on hospital laboratories, as these facilities lack the administrative capabilities to comply with the reporting as currently proposed.

Reporting information on reimbursement cost and volume

CMS reports that eligible laboratories should only report the reimbursement level paid by each payer for a given test, and the volume of such tests for each payer. Given the Affordable Care Act's mandate to incorporate quality into patient care, IDSA is concerned that this proposed rule does not account for how higher cost diagnostic technologies may result in significant advances in the quality of patient care. For example, newer tests that can provide more rapid results with greater specificity and sensitivity can reduce unnecessary treatments (as well as their associated costs and adverse events) and allow for faster initiation of appropriate treatment, significantly improving patient outcomes. **IDSA recommends that CMS examine whether its market-based reimbursement system can link to ongoing quality of care efforts.**

Furthermore, while reimbursement payments can be useful, unfortunately in many cases, the current reimbursement payment does not cover the actual cost of running a test. This is particularly true for newer tests that would often provide the greatest benefits for patients. We remain concerned that the new market-based system will be unable to account for tests that are regularly under-reimbursed for the cost of their actual testing, potentially resulting in the loss of patient access to these tests. **IDSA urges CMS to consider how it can capture this information, so it can be instructive in further refining its proposed market-based payment system. In addition to its advanced diagnostic laboratory test provisions, we recommend CMS consider utilizing existing mechanisms, including the New Technology add-on payment (NTAP), and Ambulatory Payment Classification, to ensure adequate reimbursement for diagnostic tests.**

Implementation Timeline of data collection and reporting

In its proposed rule, CMS intends to issue its final rule by the PAMA-mandated deadline of January 1, 2016. IDSA believes that this deadline does not give CMS adequate time to thoughtfully consider recommendations by stakeholders and, if necessary, develop modifications to the rule. IDSA also believes that laboratories subject to reporting may not have adequate time to prepare for reporting compliance, especially in the absence of the regulatory guidance CMS intends to release at a later date. **IDSA urges CMS to consider extending the timeline for implementing its data collection and reporting system so both the agency and eligible laboratories can better prepare for implementation.**

IDSA remains committed to developing a reimbursement system that promotes innovative diagnostics and improves patient access, and we hope these comments are useful to the 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

Greg Frank, PhD, IDSA Program Officer for Science and Research Policy, at gfrank@idsociety.org or 703-299-1216.

Sincerely,

A handwritten signature in black ink that reads "Johan S. Bakken MD, PhD". The signature is written in a cursive, slightly slanted style.

Johan S. Bakken MD, PhD, FIDSA
IDSA President

About IDSA

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as *Acinetobacter baumannii*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*, emerging infections such as Middle East respiratory syndrome coronavirus (MERS-CoV), Enterovirus D68, and Ebola, and bacteria containing novel resistance mechanisms such as the New Delhi metallo-beta-lactamase (NDM) enzymes and others that make them resistant to a broad range of antibacterial drugs, including one of our most powerful classes of antibiotics, the carbapenems (carbapenem-resistant Enterobacteriaceae, or CRE).