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IDSA
Infectious Diseases Society of America

July 8, 2019

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

[By Electronic Submission to CLFS_Annual_Public_Meeting@cms.hhs.gov]

Re: June 24 CMS Clinical Laboratory Fee Schedule Annual Public Meeting

Dear Administrator Verma:

The Infectious Diseases Society of America (IDSA) recognizes that the Centers for Medicare & Medicaid Services (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). We appreciated the time devoted to discussion of automated chemistry test panels at the June 24 CMS Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting and want to share our concerns about creating new payment codes for tests without evidence of unbundling or improper billing. 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 identify patients eligible for new antibiotic clinical trials. We should incentivize the development of better, more rapid, cost-effective diagnostic devices that have the potential to improve antimicrobial

therapy and thereby improve clinical outcomes significantly. The available newer methods have already been shown to be associated with reduced mortality of certain infections.

Following the CMS 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 2017 and 2018, our Society joined several laboratory and 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 and 2019, most ID diagnostic tests received successive 10% reductions, with a further 10% reduction likely in 2020 (for a 30% or greater reduction overall). These rates do not reflect market-based payments as intended by Congress and will derail critical advances in point-of-care (POC) testing. Specifically, high quality, POC testing provides crucial support in patient care by spurring appropriate antibiotic use (or withholding antibiotics if a viral infection is diagnosed) and further assists in limiting the development of antibiotic resistance. Based on the June 24 CLFS meeting discussion about automated chemistry test panels and payment implications under PAMA, IDSA would like to offer specific comments and recommendations on the November 2018 U.S. Government Accountability Office (GAO) report on the implementation of new rates and subsequent CMS recommendations.

GAO analysis and CMS recommendations

On November 30, 2018, the GAO released a report on CMS implementation of new laboratory payment rates under PAMA. As part of its report, the agency was tasked with analyzing 2016 Medicare claims data and assessing the future financial impact of the implementation of PAMA. The report claims that Medicare costs could increase by as much as $10.3 billion by 2020 due to the unbundling of certain laboratory panel tests. This conclusion, however, is based on a fundamental misunderstanding of how laboratories bill and are reimbursed for panel testing and suggests that labs are receiving “excess payments” by no longer charging Medicare reduced rates for bundled tests – a claim that is inaccurate and unfounded.

According to standard industry practices, clinical laboratories are required to bill Medicare for panel tests according to guidelines outlined by the American Medical Association (AMA) Current Procedural Terminology (CPT) codes. Recent survey data of more than 20 million claims for the comprehensive metabolic panel found that labs consistently billed panel tests as required. However, rather than acknowledge the practices currently carried out by the vast majority of labs across the country, the GAO report concocted a hypothetical scenario that suggests labs are unbundling certain panel tests and receiving larger reimbursements for individual tests. This assumption is not only grossly inaccurate and runs counter to standard,

demonstrated industry practice, but also leads to the inflammatory and false claim that Medicare is overpaying clinical laboratories for panel tests on a scale of billions of dollars. In the process, the report neglects the dangers that CMS' continued cuts pose to the clinical laboratory industry and the patients they serve.

At the June 24 CLFS annual public meeting, CMS proposed setting payment for automated multi-channel chemistry (AMCC) panels and single-test CPT codes using data gathered under PAMA and creating G codes based on the number of analytes performed for any additional analytes billed beyond the CPT panel. To address anticipated cost differences based on the GAO report, CMS has also proposed potential options including creating separate U codes for combinations of 2-23 chemistry tests ordered or creating five tiers of U codes for ranges of combinations of chemistry tests ordered.

IDSA agrees with clinical laboratory and diagnostics organizations that the GAO report erroneously claims inappropriate billing for panel test codes, and we recommend that CMS proceed very cautiously with creating any new payment codes for tests. A survey of clinical laboratories conducted under attorney-client privilege by counsel on behalf of the American Clinical Laboratory Association (ACLA) found virtually no change in laboratory billing practices between 2017 (pre-PAMA) and 2018 (Year 1 of PAMA) for the test panels at issue. Out of tens of millions of claims, laboratories billed for individual codes in a panel, rather than the panel code, in less than one-tenth of one percent of claims. The percentages before PAMA rates were implemented and after are comparable. It is also critical to remember the congressional intent of moving to a market-based system under PAMA. We are in the early years of the Act's implementation, and fully weighted medians are expected to go into effect in 2020. Nearly all AMCC tests are billed in panels which are experiencing some of the most severe reductions under PAMA (e.g., comprehensive metabolic panel facing a 31% cut by 2020). Over time, the aggregate spending for these tests will go down.

Conclusion

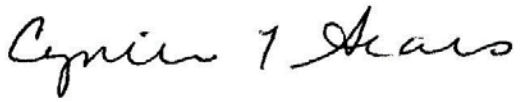
There is no proof that laboratories are working in a way to necessitate CMS action, and any efforts the agency takes to impact reimbursement should be undertaken with the utmost transparency and with full stakeholder input. If CMS is concerned about program vulnerability, it should perform data analysis on more than one year of data and implement targeted, corrective actions that do not penalize the laboratory industry currently following CPT guidelines. Implementing a group code would render moot any data collected during the first half of this year and reported to CMS in early 2020. Terminating these codes in favor of new codes would prevent CMS from setting market-based payment rates until at least 2024, and there is no guarantee these new codes would be recognized by payers at all.

IDSA is concerned that the methodology being used to implement PAMA will reverse recent progress in ID patient care. In the long run, the brunt of the cuts will likely 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 not only individual patient care but

essential public health infrastructure needed as the front line to detect infectious disease outbreaks.

Our Society remains committed to developing a reimbursement system that promotes innovative, accessible diagnostics that improve patient 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 Director for Science and Research Policy, at jlevy@idsociety.org or 703-299-1216.

Sincerely,



Cynthia Sears, MD, FIDSA
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