IDSA Headquarters
1300 Wilson Boulevard
Suite 300
Arlington, VA 22209
TEL: (703) 299-0200
FAX: (703) 299-0204
EMAIL ADDRESS:
info@idsociety.org
WEBSITE:
www.idsociety.org

IDSA
Infectious Diseases Society of America

July 10, 2019

The Honorable Scott Peters
United States House of Representatives
2338 Rayburn House Office Building
Washington, DC 20515

The Honorable Gus Bilirakis
United States House of Representatives
2227 Rayburn House Office Building
Washington, DC 20515

The Honorable Bill Pascrell
United States House of Representatives
2403 Rayburn House Office Building
Washington, DC 20515

The Honorable Kurt Schrader
United States House of Representatives
2431 Rayburn House Office Building
Washington, DC 20515

The Honorable George Holding
United States House of Representatives
1110 Longworth House Office Building
Washington, DC 20515

The Honorable Richard Hudson
United States House of Representatives
2112 Rayburn House Office Building
Washington, DC 20515

Dear Representatives,

Thank you for your leadership in introducing *The Laboratory Access for Beneficiaries (LAB) Act*, H.R. 3584. Over the past two years, significant cuts to critical clinical diagnostic tests that enable early prevention and effective treatment of infectious diseases have deterred optimal patient care. As an organization of over 11,000 infectious diseases physicians and other health care providers, scientists and public health practitioners, the Infectious Diseases Society of America (IDSA) is dedicated to promoting diagnostics innovation and protecting patient access to care. IDSA supports your legislation to delay the upcoming PAMA data reporting period, providing the necessary time to advance bipartisan reform.

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.

As part of the *Protecting Access to Medicare Act (PAMA)*, Congress directed the Centers for Medicare and Medicaid Services (CMS) to develop a market-based fee schedule for clinical laboratory services. However, the agency continues to rely on faulty, incomplete data collection that has led to an erosion of Medicare lab benefits. By basing

reimbursement on data collected from less than 1 percent of laboratories nationwide, CMS has imposed severe cuts – which for some tests will exceed 30% when fully implemented – to a range of laboratory services. Notably, cuts of this magnitude far exceed initial estimates from the Office of Management and Budget as well as the Congressional Budget Office, underscoring the failure of CMS to follow Congressional intent with the law.

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 in point-of-care (POC) testing will undermine not only individual patient care, but also essential public health infrastructure needed as the front line to detect infectious disease outbreaks.

IDSA has previously 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. We remain concerned that inaccuracies in the reporting and data collection process, as well as the cross-section of applicable laboratories surveyed, have resulted in rate determinations that will ultimately devastate ID patient care.

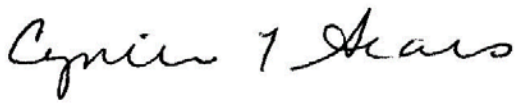
The consequences have already been severe. According to a recent IDSA member survey, over 79% of respondents will be unable to provide the full range of testing needed to rapidly diagnose infectious diseases following the PAMA cuts of 2018 and 2019. Over 32% of respondents have changed their test menu, and nearly 40% now refer more tests to another laboratory.

Your legislation is a balanced, thoughtful effort to address the unintended consequences of PAMA. HR 3584 delays the next round of data reporting by one year to ensure that all applicable laboratories required to report private payor data have the time to do so. The bill would also commission the National Academy of Medicine to assess how best to improve PAMA implementation to better reflect Congress' original intent to establish a market-based fee schedule.

Suspending data reporting in 2020 accomplishes two critical goals: it allows a more representative share of labs to report private market data; and provides valuable time for stakeholders and policymakers to determine how to reform PAMA and ensure a truly market-based system that will protect Medicare beneficiary access.

IDSA remains committed to developing a reimbursement system that promotes innovative, accessible diagnostics that improve patient care, and we look forward to working with you to advance the LAB Act.

Sincerely,



Cynthia Sears, MD, FIDSA
President, IDSA