



October 23, 2017

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016, Baltimore,
MD 21244-8013

Subj: CMS CLFS Private Payor Rate-Based Payment System

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) regarding its September 22, 2017 proposal rebasing the payment rates on the Medicare clinical laboratory fee schedule (CLFS). AACC recognizes the difficulty of the task that has been assigned to CMS. We are concerned, however, that the agency's current proposal will not achieve Congress' intent of a more rational, accurate fee schedule. Furthermore, AACC is worried that the revised CLFS, if implemented, will create new barriers to patient access to care. We recommend that CMS delay the new CLFS until the process has been revised and patient access to testing can be assured.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of progressing laboratory science. Since 1948, AACC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation.

CMS' interpretation of what is an "applicable laboratory" under PAMA limited the data reporting requirements to less than one percent of the more than 250,000 CLIA certified laboratories in the United States. According to the agency, more than 90 percent of the test payment data that was collected came from high volume, large commercial laboratories, which represent less than three percent of all laboratories. These testing facilities generally receive lower payment rates from private insurers than physician office laboratories (POLs) and hospitals due to their economies of scale and to their discounted volume-based contracts. AACC does not believe the data used by CMS in setting the revised fees properly reflects the "full spectrum of laboratories" performing testing as suggested by Congress.¹

¹ Senate Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2018, Accompanying Report Language, Page 130
<https://www.appropriations.senate.gov/imo/media/doc/FY2018%20Labor%20HHS%20Education%20Appropriations%20-%20Report%20115-150.pdf>.

AACC agrees that hospital inpatient and bundled payments should not be reported, since laboratory payments cannot be separated from overall hospital reimbursement under these payment models. However, many hospitals conduct outreach testing that should have been subjected to the reporting requirements. A 2016 study conducted by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) study, *Medicare Payments for Clinical Laboratory Tests in 2015: Year 2 of Baseline Data*, reported that hospitals account for 24 percent of all Part B laboratory payments or approximately \$1.7 billion of the \$7 billion Medicare spends annually on laboratory tests.² Yet CMS obtained information from only 21 of the 9,075 hospitals in the United States, representing **one percent** of the payment data used to set the proposed fees.

Similarly, CMS obtained reimbursement data from only 1,106 out of nearly 123,000 POLs—accounting for **7.5 percent** of the payment information used in developing the rates. The same 2016 OIG report indicated that POLs receive 20 percent of all Medicare Part B payments for laboratory services. Therefore, hospitals and POLS combined represent 44 percent of all Medicare Part B lab payments, but only account for 8.5 percent of the market data used in setting the fees. AACC believes that CMS' almost exclusive reliance on payment data from commercial laboratories undermines the validity its proposed fees and contributes to deeper cuts than Congress intended.

One unintended consequence of the proposed CLFS is that it may force many laboratories to stop or significantly curtail their testing, particularly rural hospitals, small health clinics, and POLs. CMS projects that 75 percent of all laboratory fees will be cut in 2018 with 58 percent of the tests cut so severely the reductions will be phased in over three years as required by statute. Each unnecessary cut in laboratory reimbursement, however, likely means fewer laboratories and less patient access to testing services. AACC urges CMS to redefine the definition of an “applicable laboratory” to ensure that more data from hospitals and POLs is gathered and utilized in calculating the new CLFS rates. When doing so, CMS should modify the reporting process to make it more transparent and less burdensome for laboratories.

In conjunction with revising the proposal, AACC recommends that CMS conduct and publicly release a preliminary analysis on the impact of proposed fees on the laboratory market and the provision of healthcare. Specifically, the study should address, at a minimum:

- How the new CLFS would alter the menu of testing services provided by the differing types of laboratories;
- The financial impact of the new CLFS on the differing types of laboratories; and
- Most importantly, what impact the new CLFS would have on patient access to testing, particularly geographic or population-based differences.

² Department of Health and Human Services, Office of the Inspector General, Medicare Payments for Clinical Laboratory Tests in 2015: Year 2 of Baseline Data, page 8 <https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf>.

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AACC urges CMS to delay the implementation of PAMA until these tasks are completed.

We look forward to working with you on this most important issue. If you have any questions, please email Vince Stine, PhD, AACC's Director of Government Affairs, at vstine@aacc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "MJ Bennett", written over a horizontal line.

Michael J. Bennett PhD, FRCPath, FACB, DABCC
President, AACC