September 10, 2018

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
P.O. Box 8016
Baltimore, Maryland 21244-1850

Attention: CMS-1693-P

Dear Sir/Madam,

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to comment on the July 27, 2018 proposed changes to the physician fee schedule (PFS) and other Part B revisions for calendar year 2019. 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 laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

New Clinical Laboratory Fee Schedule

Included within the document is a request for public feedback on the data collection process being utilized by the agency to gather private sector payment data from clinical laboratories. This information is to be used (as specified by the Protecting Access to Medicare Act) to update the clinical laboratory fee schedule (CLFS) so that the payment amounts reflect private market rates. AACC is concerned that the current reporting process employed by CMS is flawed and needs to be revised to ensure a more accurate and representative fee structure.

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.

AACC agrees that hospital inpatient and bundled payments should not be reported, since laboratory payments cannot be separated from overall hospital reimbursement. However, many hospitals conduct outreach testing that should be subject 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. 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 new fees.

Further, 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 of the new CLFS fees and contributes to deeper cuts than Congress intended.

AACC is pleased that CMS recognizes in the proposed rule the concerns that we, and others, have expressed regarding the limitations with the data. The agency proposes several possible changes to address this problem. Foremost, CMS is proposing to exclude Medicare Advantage (MA) Part C payments from the denominator when determining whether a laboratory meets the more than 50 percent threshold for Medicare payments received from the CLFS or PFS. Currently, a laboratory that receives less than half its Medicare payments from these two fee schedules is excluded from submitting payment data. By not counting the capitated Part C payments, the agency expects more laboratories would be required to submit payment data during the next collection period.

The agency is also suggesting that the low expenditure threshold be lowered to $6,250. Currently, a laboratory must receive at least $12,500 in CLFS revenues during the six-month data collection period to be eligible to submit payment data to CMS. Reducing the amount by 50 percent may, according to the agency, further increase the number of physician and small independent laboratories required to submit data. Although we do not believe excluding MA payments or lowering the threshold alone will achieve what is needed, we believe that the adoption of both changes would be steps in the right direction. AACC does not support increasing the threshold to $18,750, which was another option the agency suggested. We think such a change would only exacerbate the current disparity problem.

Reducing Barriers to Patient Access and Use of their Medical Records

CMS is also requesting public input "in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way."

One serious barrier to patients being able to fully utilize their electronic health information is the lack of harmonization or uniformity among laboratory test results. Currently, laboratory results may come from multiple testing facilities that use different measurement procedures. The laboratories report different numeric test values and use different reference intervals. Comparing laboratory results from non-harmonized measurement procedures may be confusing to patients, limiting their ability to take part in care decisions affecting their health.

To address this problem, Congress provided the Centers for Disease Control and Prevention (CDC) with initial funding to work towards developing uniform clinical laboratory test results. Legislators provided $2 million for this effort in fiscal year (FY) 2018 and appear likely to provide a similar amount for FY19. However, funding on a larger scale is necessary for CDC to harmonize test results in the near-term and give patients greater control over their personal health information.

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

Sincerely,

Dennis J. Dietzen, PhD, DABCC, FAACC
President, AACC