August 31, 2017

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

Attention: CMS–1676–P

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 July 21, 2017 proposed rule to revise the Medicare physician 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 rebase CLFS fees so that they reflect private market rates. AACC is concerned that the current reporting process employed by CMS is flawed and needs to be revised if the agency is to achieve its goal -- a more accurate fee schedule.

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.

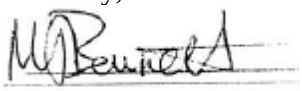
CMS's interpretation of what is an "applicable laboratory" under PAMA limits the data reporting requirements to approximately five percent of the nearly 250,000 CLIA certified laboratories.[1] It is anticipated that most of the payment information collected by the agency will come from high-volume, large commercial laboratories that generally receive lower payment rates from private insurers than physician office laboratories (POLs) and hospitals due to their discounted volume-based contracts. The Department of Health and Human Services Office of the Inspector General projected that only a small percentage of POLs, and no hospitals, were required to report payment data under the current definition.[2]

[1] Department of Health and Human Services (HHS) Office of the Inspector General (OIG), *Medicare Payments for Clinical Laboratory Tests in 2015: Year 2 of Baseline Data,* page 8.
[2] Ibid, page 8.

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 can and should be 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,* reports 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. It's likely that hospital laboratories account for a similar percentage of private sector testing.

AACC is concerned that without hospital data CMS may establish new Medicare payment rates that do not accurately reflect the broad spectrum of private sector fees. AACC urges CMS to redefine the definition of an "applicable laboratory" to ensure that hospital payment data, particularly from outreach facilities, is included in the calculation of the new CLFS rates. 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,



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