

November 24, 2015

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS-2015-0109

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) October 1, 2015 proposed rule to revise the Medicare payment system for clinical diagnostic laboratory tests. Although AACC appreciates the complexity of implementing the laboratory provisions outlined in the Protection Access to Medicare Act (PAMA), we are concerned that the proposed payment revisions will adversely affect the ability of many laboratories to continue testing or force them to significantly scale back their test menu.

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.

Scope of Cuts

Clinical laboratories are a critical component of the healthcare system. These testing facilities provide clinicians and other healthcare professionals with cost-effective, objective data for diagnosing, treating and monitoring patient care. Some estimate that approximately 70 percent of all medical decisions utilize laboratory results even though laboratory testing only accounts for three percent of Medicare expenditures. Unfortunately, the PAMA legislation authorizes additional cuts in laboratory payments, which may adversely affect patient access to care, particularly in underserved communities.

CMS projects that the proposed rule will cut laboratory payments by \$2.94 billion over five years and \$5.14 billion over ten years. This projection far exceeds the estimates of the Congressional Budget Office (CBO), which estimated the cost savings associated with the PAMA laboratory provisions to be approximately \$2.5 billion over ten years—less than half of what the agency now proposes. AACC is concerned that CMS is making steeper cuts than Congress intended

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and that these unwarranted reductions may cause less precise health care and produce wasteful increases in overall health care spending with no benefit to the health of our nation's citizens. We strongly advise CMS to reduce the size of the proposed cuts.

Applicable Laboratories

PAMA states that an "applicable laboratory" is a laboratory that receives a majority of its Medicare revenues under the clinical laboratory or physician fee schedules or section 1833(h) of the Social Security Act. Laboratories meeting this definition must report to CMS their private sector test fees during a time period established by CMS. This information will be used to set the new Medicare rates for the clinical laboratory fee schedule (CLFS). The Agency states that "the statute intends to limit reporting primarily to independent laboratories and physician offices." AACC is concerned that CMS' interpretation of this provision, which excludes hospital laboratories from those reporting data, will set up a system wherein testing will be undervalued.

We agree 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 subject to the reporting requirements. In the Office of the Inspector General September 2015 *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data* report, the agency 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.

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. A 2013 study conducted by Avalere Health indicates that private sector insurers generally pay more to hospitals than to commercial laboratories for testing services, since hospitals generally do not perform a sufficient number of these tests to offer volume discounts. By excluding hospital data, CMS may set artificially lower payment rates that will adversely affect all testing facilities, including those not subject to the reporting requirements. AACC urges CMS to include hospital laboratories within the data reporting requirements.

Advanced Diagnostic Laboratory Tests

PAMA established a new payment category for Advanced Diagnostic Laboratory Tests (ADLTs). According to Congress, these tests are "a clinical diagnostic laboratory test...that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than The original developing laboratory (or a successor owner) and meets one of the following criteria:

- (A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield single patient-specific results.
- (B) The test is cleared or approved by the Food and Drug Administration.
- (C) The test meets other similar criteria established by the Secretary."

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CMS proposes to eliminate “proteins” from the first criterion, limiting payment to molecular pathology analysis of multiple biomarkers of DNA or RNA. AACC strongly disagrees with this change. Many proteins are well established biomarkers that, when used in combination with other parameters, including other proteins, DNA and/or RNA gene expression markers, can yield unique and valuable clinical information. CMS should re-insert “proteins” in the definition.

The agency also added a new criterion not included in the statutory definition that would require ADLTs to “provide new clinical diagnostic information that cannot be derived from any other test or combination of tests.” AACC does not agree with this recommendation. The CMS language may limit test innovation by excluding tests that may provide the same data as another test, but can identify a condition more quickly and/or accurately. These test improvements can be equally vital to advancing and improving patient care. We join with the PAMA Advisory Panel on Clinical Diagnostic Laboratory Tests in urging CMS to delete this criterion.

Implementation

To meet the implementation deadline of January 1, 2017, the proposed rule would have applicable laboratories reporting their private payer billing data starting January 1, 2016, to be finished by March 31, 2016. AACC believes that this timeframe is unrealistic given the agency’s delay in finalizing a process for collecting and reporting payment data. We recommend that CMS delay the final implementation of the new payment rates from January 1, 2017 to January 1, 2018. The reporting period should also be delayed, providing the agency time to finalize the rule and educate laboratories about the requirements. Such a delay would also allow laboratories to develop a process for gathering, evaluating and reporting the data and would give CMS time to publish the weighted median payment rates. The proposed changes to the CLFS need to be implemented in a thoughtful, prudent manner to avoid confusion and the creation of unnecessary, far-reaching problems for patients, clinical laboratories and CMS.

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

Sincerely,



David D. Koch, PhD, DABCC
President, AACC