



July 12, 2012

Mr. Glenn McGuirk
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

Docket # CMS-1441-N

Dear Mr. McGuirk:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) regarding the newly created 2013 molecular pathology codes. We support CMS's decision to adopt more specific codes, which would more accurately inform the agency of the tests being performed and would assist it in determining appropriate payment levels.

Currently, Medicare reimburses for molecular pathology tests using 'stacking codes,' which allow providers to bill for each procedure they perform. Payers have complained that the current system is susceptible to fraud and abuse. To address this problem, the American Medical Association (AMA) drafted and approved a new series of CPT codes specifically for molecular pathology tests. This new code set is comprised of Tier 1, which includes the most commonly performed tests, and Tier 2, which includes the more complex tests. On January 1, 2013, the stacking codes are expected to be eliminated in favor of the new molecular codes.

AACC supports the elimination of the 'stacking codes.' We agree that greater transparency is needed in the payment process to eliminate potential false billing claims, which could defraud the government. AACC further supports the adoption of the AMA's new CPT codes that would make it easier for testing facilities to file and payers to adjudicate claims. CMS is currently seeking input on where these new molecular codes should be placed—either the physician fee schedule (PFS) or clinical laboratory fee schedule (CLFS). The Agency recently stated in the PFS proposed rule that it believes all the molecular pathology codes should be placed on one fee schedule. AACC strongly opposes this approach.

AACC recommends that CMS review and assign the molecular pathology codes based on the level of professional interpretation required, not simplicity of implementation and oversight. The agency acknowledges in the PFS proposal that it received differing feedback from medical and laboratory groups on the placement of these tests. We believe that CMS should build upon that input, and the information gleaned from the laboratory public session, to work with stakeholders to find common ground. AACC is concerned that a 'blanket' assignment of these tests based on convenience, rather than established criteria, may result in the incorrect placement of tests that could have unintended consequences for patient care and laboratory reimbursement. We will

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provide our specific recommendations regarding the placement of the new molecular codes when we respond to CMS's PFS proposed rule.

AACC is also concerned that the culmination of this molecular coding process may unintentionally create a shortage of qualified personnel needed to interpret these procedures. Doctoral Scientists currently interpret and report results for molecular tests on the CLFS using stacking code CPT 83912. This code will be eliminated at the end of this year. If the molecular tests are placed on the PFS, Doctoral Scientists will not be able to provide interpretive services, since they are not on the list of providers able to bill on that fee schedule.

AACC recommends that CMS develop a regulatory plan to ensure patients have access to qualified personnel, such as Doctoral Scientists, to interpret molecular tests regardless of how they are billed. If the Agency determines that this issue requires a legislative correction, we urge it to contact the appropriate congressional committees, in a timely manner, and impress upon them the need for action. AACC stands ready to work with you on this most important issue.

AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (804) 828-0375, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in blue ink, appearing to read "G Miller", enclosed in a thin black rectangular border.

Greg Miller, PhD
President, AACC