



August 8, 2012

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

Docket # CMS-1590-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 the July 30, 2012 *Federal Register* proposed rule modifying the physician fee schedule (PFS). This proposal requests public input regarding the assignment of the new molecular pathology diagnostic test codes, as well as the requirement that a laboratory test requisition form include the signature of the ordering provider. Our comments follow.

Assignment of Molecular Pathology Tests

AACC supports the creation of the new molecular pathology codes and the elimination of the existing stacking codes. We believe these changes will result in a more transparent payment process and make it easier for laboratories to file and payers to adjudicate claims. CMS must now decide under which payment system to place the new CPT codes -- either the PFS or clinical laboratory fee schedule (CLFS). The Agency is suggesting that all molecular pathology codes be placed on one fee schedule. AACC strongly opposes this approach if it means 'forcing' tests onto a single fee schedule simply for convenience. We believe that CMS should review and assign each molecular pathology code primarily on the basis of the level of professional expertise required to interpret a test result. The findings of this review should dictate the placement of the codes.

As part of this review, however, CMS needs to take into consideration the technology used to perform the molecular tests. Increasingly, software is being developed and incorporated into automated test systems that enable the systems to generate test results that require little or no interpretation. AACC recommends that these tests, and those that are likely to adopt such technology in the near future, remain on the CLFS since professional interpretation is not now, or will not in the future, be needed. Recent examples of such tests include quantitative analysis for viruses, such as HIV-1, HCV, and HBV, where significant past interpretation on the part of professionals has been replaced by software and automation. We anticipate that new analyses, such as copy number variation, and next generation sequencing, will follow a similar pattern with professional interpretation gradually replaced by integrated software.

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AACC also suggests that CMS consider whether there are sufficient qualified health care professionals with the expertise to clinically interpret these molecular tests if the agency places them all on the PFS. We do not believe there are currently enough properly trained physicians to handle this test volume. A blanket placement of the molecular tests on the PFS could result in: (1) laboratories being forced to provide interpretative services for free; (2) physicians signing off and laboratories billing for interpretations conducted by PhDs, which is fraud under Medicare; or (3) a delay in interpretations, which could adversely affect patient care. None of these are acceptable outcomes. We urge CMS to take this factor into consideration as it makes its determinations.

Signature on Laboratory Requisition

CMS is also proposing that the physician or qualified non-physician practitioner ordering a laboratory test document medical necessity in the beneficiary's medical record. In addition, both the medical record and the laboratory requisition would need to be signed by the physician or qualified non-physician practitioner who orders the service. AACC strongly opposes this provision for the very reasons set forth by CMS in its June 30, 2011 proposed rule retracting this policy.

As CMS stated, requiring a signed requisition form could:

- Negatively impact beneficiary access to care;
- Create unnecessary confusion among health care providers;
- Inconvenience physicians and patients alike; and
- Increase the administrative burden on many clinical laboratories.

It's our understating that CMS included this recommendation in error. We hope this is the case. AACC urges you to remove this provision.

By way of background, 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,



Greg Miller, PhD
President, AACC