



June 27, 2011

Department of Health and Human Services
Office of Documents and Regulations Management
200 Independence Avenue, SW.
Suite 639G, Washington, DC 20201

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Department of Health and Human Services' (HHS') "Preliminary Plan for Retrospective Review of Existing Rules," which implements the President's executive order directing federal agencies to review and, where possible, update and improve their regulatory policies. AACC strongly supports this initiative. We offer the following suggestions for your consideration.

Inherent Reasonableness Authority

In 2005, the Centers for Medicare and Medicaid Services (CMS) published its "inherent reasonableness (IR)" final rule, which created a mechanism for adjusting Medicare payment rates that are "grossly excessive or deficient." Under this rule, CMS has the authority to increase or decrease payments. It was envisioned that, in the cases where Medicare reimbursement was insufficient, health care providers would petition the agency for redress. This has not happened. AACC is concerned the current process may be discouraging providers from petitioning the agency. We recommend that CMS examine the IR framework and make recommendations for improving it.

Recovery Audit Contractor (RAC) program

From 2005-2008, HHS funded a pilot project, the Recovery Audit Contractor (RAC) program, to reduce fraud and abuse. This project utilized private companies to identify Medicare overpayments and underpayments to health care providers. Under this initiative, RACs are entitled to a portion of what they recover. Recently, Congress transformed this pilot project into a nationwide program, which will soon be extended to Medicaid as part of health care reform. AACC is concerned that the RACs seemed to focus almost exclusively on uncovering overpayments. During the pilot study, the RACs 'corrected' over \$1 billion in improper payments—approximately 96 percent of these funds were overpayments. Given the newly expanded role of RACs, we request that CMS evaluate whether the private contractors are adequately working to identify both 'under,' as well as 'over' payments.

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Format for New Laboratory Code Public Meeting

Every July, CMS conducts a public meeting as required by statute, to gather input on the appropriate payment amounts for new clinical laboratory diagnostic tests. AACC suggests that those companies or laboratories seeking new codes be required to submit, in advance of the public meeting, information that describes:

- the clinical use of the test and the technology employed (including a copy of the package insert for FDA cleared or approved tests);
- How the test will be utilized by the Medicare population;
- How frequently the test may be ordered (e.g., once in a lifetime; for diagnosis; ongoing monitoring)
- Where the test is likely to be performed (e.g., hospital; commercial laboratory; physician's office; nursing home, etc...)
- The costs per test, including any unique specimen collection or transportation costs; and
- The recommended cross-walk and/or payment rate.

AACC believes this information could assist CMS and the public in determining the most appropriate reimbursement amount for these new tests.

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 (314) 362-0194, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,



Ann M. Gronowski, PhD
President, AACC