

August 27, 2013

Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1601-P P.O. Box 8013 Baltimore, Maryland 21244-1850

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services July 19, 2013 proposed rule regarding the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems. This proposal recommends that some outpatient laboratory tests be included in the Ambulatory Payment Classification (APC) payment categories. AACC recommends that CMS reconsider this proposal given its potential negative impact on providers and patients.

CMS states that laboratory test that are "integral, ancillary, supportive, dependent, or adjunctive to primary services provided in the hospital outpatient setting," and should be included in APCs "when they are provided on the same date of service as the primary service and when they are ordered by the same practitioner who ordered the primary service." The agency adds "the purpose of the laboratory packaging proposal is not to shift program costs onto beneficiaries, but to encourage greater efficiency by hospitals and the most economical delivery of medically necessary laboratory tests."

AACC understands that the bundling of laboratory tests and other services within APCs, in theory, should reduce CMS billing costs. However, the costs associated with performing the test (i.e. labor, reagents, quality control requirements, etc...) remain the same. We are concerned that CMS is using this proposal to further reduce laboratory payments without justification. Over the next decade, laboratory reimbursement will be reduced by more than 20 percent. This proposal adds to that amount. According to the CMS estimates, rural hospital payments will be cut by 1.3 percent, with many experiencing reductions between 1.9 and 3.5 percent. This is a significant reduction given the current environment.

CMS's proposal would also increase payments to beneficiaries. By placing laboratory tests within APCs, laboratory tests would be included as part of the APC deductibles and cost-sharing arrangements, increasing the financial burden on consumers, particularly the elderly and the young. AACC encourages CMS to reach out to these demographic groups to learn what impact these changes may have on their ability to afford health care services.

CMS August 27, 2013 Page Two

If CMS decides to move forward with this proposal, we encourage the agency to include the full laboratory fee amount in the APCs. As mentioned earlier, the costs of performing a test doesn't go down just because it is paid differently. Further, we recommend that CMS arrange for an independent audit of hospital test ordering practices to take place one year after the implementation of this provision to ensure that hospitals continue to order necessary laboratory testing vital to patient care. Specifically, the study should evaluate: whether the number of tests ordered have been reduced; has there been a decline in the quality of laboratory services; and have patient outcomes been adversely affected.

By way of background, AACC is the principal association of professional laboratorians-including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and practice 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 medicine and applications to health care. If you have any questions, please call me at (410) 328-8672, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Robert Christenson, PhD

President, AACC