August 19, 2013

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P
P.O. Box 8016
Baltimore, Maryland 21244-8016

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) July 19, 2013 proposed rule, which makes "Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014." The agency is proposing to review each laboratory CPT code to determine whether technological changes have altered the costs of performing the test. If the agency determines that technological advances have reduced the cost of performing a test, it will reduce payments for that CPT code. AACC has serious concerns about the appropriateness or practicality of this proposal.

Foremost, the adoption of this proposal places clinical laboratories in double-jeopardy in regards to cutting laboratory payments for "technological changes." The Affordable Care Act of 2010 requires CMS to reduce the laboratory consumer price index (CPI) update annually by a "productivity adjustment." The agency uses the Bureau of Labor Statistics (BLS) definition for multifactor productivity to make this yearly correction. The BLS description includes factors such as "research and development (R&D), new technologies, economies of scale, managerial skill, and changes in the organization of production." Thus, laboratory reimbursement is already reduced annually for technological improvements.

CMS also needs to assess the broader impact of this proposal on patient care. These cuts, on top of the 4.95 percent already imposed on clinical laboratories this year, and more than 20 percent in payment reductions over the next decade, may put many laboratories in financial difficulty. Small physician office laboratories (POLs) and rural community-based facilities, which have higher per test costs, may be forced out of business. In addition, some hospitals may be forced to outsource much of their testing as a result of this change. AACC is concerned that the unintended consequences of CMS's action may limit patient access to testing services and delay physician access to timely test results needed to make patient care decisions.

The agency proposal also unfairly targets one element of the test pricing structure for altering reimbursement. If CMS wants to evaluate the costs associated with performing a laboratory test, it should look at the entirety of the price setting process not just technological change. There are many factors that affect the cost of a test, including labor, quality control, test reporting,

proficiency testing, information technology, administration, and regulatory requirements, just to name a few. In addition, a hospital needs to staff its laboratory all day, seven days a week to due stat tests. AACC is concerned that singling out technological changes as the only factor for evaluating the cost of testing will give a distorted view of testing costs, resulting in unfair cuts to clinical laboratories.

CMS also assumes that all laboratories adopt new technologies for conducting a test. This is not true. A laboratory with a higher test volume may select a highly automated device to perform the test, whereas other providers may use a more labor intensive method due to their low volume of testing. This is often the case in hospitals, where they need to offer certain tests that are needed urgently for diagnosis and treatment of critically ill patients, and must be available on site, even though the test volume is low. For these tests, referral to a large regional laboratory that enjoys greater economies of scale is not an alternative.

For example, chest pain is one of the most common reasons for visiting an emergency room, and the biomarker troponin is used to help distinguish between chest pain that is not related to the heart, and pain resulting from a heart attack. It is essential to make that decision rapidly so a patient experiencing a heart attack can be given appropriate treatment immediately. For smaller emergency departments, the cost per test of troponin is high since the number of troponin tests is relatively low, but sending specimens to a large regional lab where the cost per troponin result is minimized is not a practical option, and would compromise the treatment of the patient. Thus, different health care providers may employ different technologies.

CMS is suggesting that the emergence of point-of-care testing (POCT) devices has reduced testing costs, since the new technologies are often "smaller, cheaper, and more portable" and can be "performed in various institutional and community settings." AACC believes this characterization is not accurate. A POCT device may be faster and easier to use, but it's generally not less expensive. For example, the cost of POCT testing to diagnose and monitor diabetes (e.g., glucose meter; Hemoglobin A1c) is higher in POLs, Emergency Rooms, and at the patient's bedside, than if it's conducted by a core hospital laboratory or commercial laboratory using traditional testing methods. It's important to note that any savings from utilizing POCT is usually not associated with the test, but with the overall savings to the health care system as a result of earlier clinician diagnosis and faster patient treatment.

AACC appreciates CMS's desire to evaluate the role of laboratory testing in the provision of health care and the costs associated with providing these services. However, we believe the current approach outlined by CMS unjust and unfeasible. AACC suggests that CMS focus its attention on improving the proper utilization of laboratory tests. This would eliminate duplicative, unnecessary testing, while also improving patient care. CMS could utilize the Negotiate Rulemaking Process to address this concern.

If CMS continues down the path of reviewing laboratory test payments, the agency needs to create a mechanism that includes all stakeholders in the review process. This appraisal should cover all factors that affect the costs of laboratory tests, not just technology. CMS should also consider the potential impact of any adjustments on the delivery of testing services and patient care. AACC is concerned that narrowly selecting one element of the pricing structure for laboratory tests, without taking into consideration other factors, may achieve small, short-term cost-savings to CMS, but result in higher health care costs in the long-term as well as adverse patient outcomes.

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