



December 20, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1525-FC
P.O. Box 8013
Baltimore, Maryland 21244-1850

Subject: CMS-1525-FC

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the November 30, 2011 Hospital Outpatient Prospective Payment final rule, which details forthcoming Medicare changes to the Hospital Outpatient Quality Reporting Program (OQR). Included among these changes are 23 new quality indicators for measuring hospital performance. Under OQR, hospital payment updates are based on their compliance with specified quality measures.

Although we generally support the OQR program, AACC has some specific concerns about one of the new indicators, "OP-16: Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain patients (with Probable Cardiac Chest Pain) Received Within 60 minutes of Arrival." AACC agrees that using the turnaround time for a troponin measurement that is performed for the diagnosis/management of an individual suspected of having an acute myocardial infarction (AMI) is a valid quality measure. We are concerned, however, with using turnaround time as the sole means of assessing the value of this test. Rather than focusing on time, we think the emphasis should be on assuring that the troponin value is used effectively for timely decision-making.

The final rule states that the troponin test must be conducted and results reported "within 60 minutes of arrival," which for most institutions will require that the test be performed at the point of care (POC) by the health care professional at the bedside, who is generally less proficient in conducting such testing than laboratory professionals. In addition, the sensitivity of the current generation of POC assays is much lower than those devices available in the central laboratory, thus resulting in a greater risk of misdiagnosing the patient and doing more harm than good.

If CMS is going to use turnaround time as a measure, it should identify the evidence for selecting 60 minutes. We are not aware of any evidence to support the use of the timeframe suggested in this rule as the cutoff point for evaluating whether the use of the troponin assay results in an improvement in patient outcomes. If the agency decides to move forward with this new measure, it should use the indicator as a means of gathering the data needed for making such an assessment and not link it to Medicare payments.

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Further, if CMS chooses to move forward with this measure, as is, AACC recommends that the agency more clearly define turnaround time. If it means when the patient first walks in the door and into the waiting room, many Emergency Departments will not be able to meet a 60 minute turnaround time, even with point-of-care testing. It would make more sense to define the time as the time of triage (i.e., when it is first known to care givers that the patient has chest pain).

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,

A handwritten signature in cursive script that reads "Ann M. Gronowski". The signature is written in black ink and is positioned below the word "Sincerely,".

Ann M. Gronowski, PhD
President, AACC