



Better health through  
laboratory medicine.

September 8, 2017

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Subject: CMS-1678-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 its July 20, 2017 proposed rule to revise the Hospital Outpatient Prospective Payment System. Specifically, the agency is recommending changes to the 14-day rule, which stipulates that hospitals bill for certain laboratory tests performed within two weeks of a patient's discharge—even if the hospital did not perform the test. AACC's comments follow.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of progressing laboratory science. Since 1948, AACC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation.

Currently, CMS states that if a specimen collected during a hospital encounter is utilized for testing within 14-days of a patient's discharge, the hospital is the only entity that can bill for that test. This policy has created several administrative and financial problems for hospitals and commercial laboratories, such as:

- The hospital may be required to bill for a test it did not perform nor is it involved in the patient's ongoing treatment;
- The hospital and the laboratory may be in different jurisdictions, which could result in differing coverage policies and payment rates; and
- The hospital may not allow certain specialized tests to be ordered largely, if not solely, because of the complexity of the billing arrangements and the higher costs associated with the test(s).

CMS  
September 8, 2017  
Page Two

In addition, we are concerned that patient care could be adversely affected if providers delay ordering a test until the two-week period has expired.

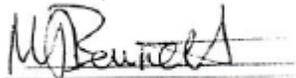
CMS is proposing to exempt molecular pathology tests and advanced diagnostic laboratory tests (ADLTs) from the 14-day restriction and permit laboratories performing those tests within that timeframe to direct bill the clinical laboratory fee schedule if certain terms are met. AACC supports this overall recommendation. We believe this change will reduce the regulatory and financial burdens on both hospitals and independent laboratories, while improving patient access to vital laboratory tests.

AACC does recommend two modifications, however:

- Criterion #1 – “the physician orders the test after the hospital discharge” should be eliminated. Although this limitation is appropriate for tests using tissue specimens, it does not reflect recent technological advances that enables some laboratories to perform the same molecular pathology test using blood or urine specimens. In these instances, the physician generally orders the test prior to the collection of the specimen (and the patient’s discharge). This criterion should be removed.
- We further recommend that the term “molecular pathology test” be broadened to include Genomic Sequencing Procedure codes (81410 – 81479), MAAA procedures (81490 – 81599) and PLA codes which involve the analysis of nucleic acid (DNA or RNA). At present only CPT codes 81161 – 81408 are included since these are the only codes specifically designated as “Molecular Pathology” procedures in the CPT. The same criteria should apply to ADLTs since any FDA approved test or panel of multiple proteins can qualify as an ADLT without being based on DNA/RNA.

We look forward to working with you on this most important issue. If you have any questions, please email Vince Stine, PhD, AACC’s Director of Government Affairs, at [vstine@aacc.org](mailto:vstine@aacc.org).

Sincerely,



Michael J. Bennett, PhD, FRCPath, FACB, DABCC  
President, AACC