



November 6, 2020

Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Subject: Amended CMS-2020-1-R2

Dear Administrator Verma,

The American Association for Clinical Chemistry (AACCC) opposes the Centers for Medicare and Medicaid Services (CMS) October 15, 2020 decision to reduce Medicare payments for molecular pathology high throughput COVID-19 diagnostic tests that are not completed within two days of the specimen being collected. Starting January 1, 2021, the agency will pay laboratories that fail to meet this requirement \$75 per test rather than the current fee of \$100.

AACCC agrees that timely testing is vital to diagnosing, isolating, and treating patients with the coronavirus and performing much needed contact tracing. Clinical laboratories are committed to providing high quality, timely, accurate tests. Many laboratories are completing their testing within the timeframe specified by CMS. For those laboratories not meeting this timeframe, it is often for reasons outside of their control.

For example, many testing facilities cannot obtain the supplies, particularly the test kits and reagents, needed to continue to rapidly perform the high volume of COVID-19 tests that they receive. Another reason is that staffing is increasingly becoming an issue as the volume of testing continues to rise and the number of highly trained laboratory professionals needed to perform these tests is limited. Finally, laboratories sometimes receive COVID-19 samples days after they were collected making it impossible for them to achieve a two-day turn-around time.

AACCC does not think that cutting payments to laboratories, which are already incurring significant costs to perform these tests (e.g., purchasing new equipment, using additional personal protective equipment, and meeting new data reporting requirements) will improve the testing situation. In fact, we are concerned that reducing payments may force some laboratories to outsource COVID-19 tests, which will most certainly delay the reporting of timely, actionable results.

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If CMS decides to proceed with this change, AACC recommends that you make several modifications to the current document. Currently, it is unclear when the two-day timeframe begins--when the specimen is first collected or when the laboratory receives it. We recommend:


- The 48-hour clock begin once the laboratory receives the specimen and the completed paperwork. Sometimes couriers are delayed in getting the sample to the laboratory and occasionally the test requisition is incomplete requiring the laboratory to seek the missing information that is mandatory to have before testing can begin.
- The test should be considered completed when the test results are posted in the electronic medical record. At that point, the information is available to the ordering physician to diagnose and treat the patient.

CMS also stipulates that a clinical laboratory conducting high throughput COVID-19 tests must also complete 51% of those tests within the two-day timeframe during a calendar month to be eligible for the higher payment. AACC suggests that certain specimens be excluded from this calculation, such as those: collected at-home; used for clinical research; provided without a collection date; or collected under a contractual agreement with a specific turnaround time.

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 laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

We look forward to working with you on this important issue. If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,



David G. Grenache, PhD, D(ABCC)
President, AACC