



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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December 31, 2020

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

RE: CMS Ruling No: CMS-2020-1-R2 – CMS Changes Medicare Payment to Support Faster COVID-19 Diagnostic Testing

Dear Administrator Verma:

The Association for Molecular Pathology (AMP) calls on the Centers for Medicare & Medicaid Services (CMS) not to implement its policy as written to reduce payment for certain COVID-19 diagnostic tests announced on October 15, 2020.

AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. Our members have played an integral role in ramping up and continuing to deliver COVID-19 diagnostic tests during the pandemic.

Since April 15, CMS has been paying \$100 for HCPCS codes U0003 and U0004 for COVID-19 tests that utilize high-throughput technologies to diagnose large number of COVID-19 cases rapidly. The agency has now reversed course: beginning January 1, 2021, CMS will pay \$75 for COVID-19 tests using these technologies and an add-on payment of \$25 for tests run these platforms if the laboratory completes the test in two calendar days or less.

AMP members adapted their laboratory testing practices quickly to respond to the COVID-19 pandemic. AMP conducted two surveys since the start of the public health emergency, the [first](#) in April and the [second](#) in August, to gain a clearer understanding of how our members have responded to the increased demand for COVID-19 testing and the accompanying challenges. According to these surveys, they have reported establishing as many as five different testing methods to provide results in a timely manner – all at their own expense. The surveys also reported that laboratories face severe and ever-changing challenges with COVID-19 testing supplies and reporting burdens.

The reimbursement of \$100 by CMS has been critical to maintain testing efforts during the public health emergency. Reducing the reimbursement for this testing performed using high-throughput technologies, and defined by CMS as performing more than 200 tests daily, does not recognize factors beyond the control of the laboratory influencing turnaround time, namely the impact of supply shortages and the time between specimen collection and delivery to the laboratory.

AMP members continue to face shortages of test kits, reagents, and other supplies necessary to perform COVID-19 testing as they continue to face ongoing supply chain issues. Without predictable access to all of these supplies, laboratories cannot turn COVID-19 tests around quickly regardless of the technology they may be utilizing. Laboratories and their staff face significant administrative burden to ensure that they have the necessary supplies on hand to conduct this testing for which they incur additional costs. To improve testing turnaround time, AMP strongly recommends that CMS work with AMP and our members to improve access to testing supplies.

Additionally, the two-day window in which a test must be completed to be eligible for the \$25 add-on payment poses an additional challenge since the period begins when the specimen is collected. This ties payment to an element that is many times outside of a laboratory's control. There are many rural and underserved areas of the country where specimens cannot be transported quickly enough to meet a two-day turnaround from the time of specimen collection. The policy as articulated by CMS penalizes these laboratories, many of which are serving underserved areas and populations; instead, AMP believes it would be more appropriate to start measuring turnaround time from receipt by the laboratory.

AMP respectfully requests CMS carefully consider these issues and revise this reimbursement policy to better support laboratories that continue to perform critical COVID-19 testing. We welcome the opportunity to work with you to develop a reimbursement policy that supports patient access to accurate and efficient testing and laboratories, which continue to operate under challenging circumstances. AMP will be closely monitoring the effects of this policy and will be following up with the Hospital and Ambulatory Policy Group to discuss it further. Please contact Tara Burke, Senior Director of Public Policy and Advocacy, at tburke@amp.org with any questions in the interim.

Sincerely,

Antonia R. Sepulveda, MD, PhD
President, Association for Molecular Pathology