COLLEGE of AMERICAN PATHOLOGISTS

January 8, 2021

Carol Blackford
Director, Hospital and Ambulatory Policy Group
And
Ryan Howe, PhD
Acting Deputy Director, Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Mail Stops C4-03-06 and C5-07-22
7500 Security Boulevard
Baltimore, MD 21244-1850

RE. SARS-CoV-2 Test Pricing Issues – Follow up from January 4, 2021 CAP CMS/HHS meeting

Dear Ms. Blackford:

The College of American Pathologists (CAP) appreciates CMS and HHS participation in the conference call on Monday, January 4, 2021 regarding concerns and confusion our members are having with CMS SARS-CoV2 test pricing and policies (CMS-2020-1-R and CMS-2020-2-R2).

As discussed on our conference call, we want to clarify our understanding of the agency's response to our question about the data collection requirements of CMS-2020-2-R2 to qualify to bill U0005, where "the majority of a laboratory's CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 for all patients (including non-Medicare patients) in the previous calendar month have to be completed in 2 calendar days or less from the date the specimen was collected." The CAP understands from our conversation that the purpose of the turn around time (TAT) measure is to determine the payment for U0005, and since U0005 is by definition applied to those services coded as U0003 or as U0004, then the services for which this TAT must be measured are those coded U0003 and U0004 for Medicare patients plus, for all other patients, those services that would be coded U0003 or U0004 if they were Medicare patients. **If this is not accurate, please let us know as we will be advising our membership on this issue.**

The CAP also reiterates our concerns with CMS-2020-1-R2, the payment rates and HCPCS coding for SARS-CoV-2 nucleic acid tests. Roughly one million COVID-19 tests are being provided every day, and laboratories are processing tests efficiently and quickly in most instances, however there are factors outside of our control that lead to delays. These factors include delivery times for off-site collected specimen and the availability of supplies needed to run tests. In fact, most providers have been forced by supply limitations to diversify and develop more than one (and often multiple) nucleic acid test (NAT) methods and are now managing various combinations of analytical platforms, to address the unprecedented shortages and urgent demands for expanded immediate availability of SARS-CoV-2 testing in their communities. Provider laboratories cannot sustain inadequate payment in this setting of overall increased costs and complexity of testing during the national public health emergency.

The CMS' new pricing scheme with CMS-2020-1-R2 (including U0005 requirements and 2021 gapfill methodology for the other SARS-CoV2 codes) does nothing to solve these problems but penalizes laboratories and creates a new administrative demand on laboratory resources. This is an effective cut in payment despite the current fees being already inadequate in many parts of the country, where prompt testing already requires laboratories to use every available platform.

As the pandemic has evolved, the increasing need for testing has been exacerbated by the need to decrease the time from specimen procurement to test result notification (a.k.a., turnaround time), so that patients can be quickly identified, quarantined, and begun on an appropriate treatment regimen. Often, the only way to accomplish this is by bringing the testing back from remote, national/regional commercial laboratories which can provide exclusively high-throughput testing, to local hospital and clinic laboratories, where the patients actually are. Thus time-sensitive testing for diagnosis and management of symptomatic individuals with COVID-19—as well as minimizing asymptomatic SARS-CoV-2 infection/exposure risks in the delivery of other health care (e.g., surgery, invasive procedures)—at these sites cannot always be "high throughput" and will typically have a higher (not a lower) cost per test.

We believe the Medicare CLFS payment rates established for SARS-CoV-2 nucleic acid testing have been improperly valued, and that the established processes for determining these clinical laboratory test prices were not appropriately followed. The prices established by the MACs failed to account for costs and resources necessary to bring testing online during the national public health crisis for laboratories of all sizes and localities.

The current HCPCS nucleic acid test coding paradigm does not adequately recognize these important issues and the full cost burden of providing testing across the continuum of all laboratory settings. At a minimum, all SARS-CoV-2 NAT Medicare CLFS payment rates should have a national payment rate equivalent to the current (2020) rate for high-throughput tests (HCPCS codes U0003 and U0004). We also believe CMS should make the updated increased price for CPT code 87635 retroactive to the date that this CPT code was created and implemented (March 16, 2020). The CAP also requests that the CMS withdraw HCPCS codes U0001, U0002, U0003, U0004, U0005, and establish a new price for CPT code 87635 at a national payment rate equivalent to the current (2020) rate for high-throughput tests (HCPCS codes U0003 and U0004) to ensure laboratories are reimbursed appropriately for the resources needed to perform the tests**.**

In summary, the CAP recommends:

- **Cease implementation of CMS amended policy CMS-2020-1-R2 as it is highly burdensome and counterproductive**
- **At a minimum, all SARS-CoV-2 NAT Medicare CLFS payment rates should have a national payment rate equivalent to the current (2020) rate for high-throughput tests (HCPCS codes U0003 and U0004). We also believe CMS should make the updated increased price for CPT code 87635 retroactive to the date that this CPT code was created and implemented (March 16, 2020). Special ruling is needed to increase SARS-CoV-2 nucleic acid test CLFS payment rates at the national level.**
- **The CAP requests that the CMS withdraw HCPCS codes U0001, U0002, U0003, U0004, U0005, and establish a new price for CPT code 87635 at a national payment rate equivalent to the current (2020) rate for high-throughput tests (HCPCS codes U0003 and U0004) to ensure laboratories are reimbursed appropriately for the resources needed to perform the tests.**

The College of American Pathologists appreciates your consideration of these comments. Please direct questions to Pam Wright at pawrigh@cap.org, Todd Klemp at tklemp@cap.org, or Ayanna Wooding at awoodin@cap.org

Sincerely,

Stephen Black-Shaffer, MD, FCAP
College of American Pathologists
Chair, CAP Economic Affairs Committee