September 7, 2020

Ms. Carol Blackford
Director
Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

RE: CLFS Crosswalk Recommendation for SARS-CoV-2 Amplified Probe Testing under code 87635

Dear Ms. Blackford:

On behalf of the organizations listed below, which represent the major clinical laboratory stakeholders involved with testing for SARS-CoV-2, we are writing to **support a recommendation for crosswalk of new code 87635** "*Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique*" **to code 87502** "*Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or subtypes*" (CY 2020 CLFS rate = $95.80) as best reflecting the resources required to develop and furnish critical COVID-19 diagnostic testing reported under code 87635.

The organizations listed below as well as all commenters at the June 26th CLFS Annual Public Meeting recommended to crosswalk new code 87635 to code 87502 or to code U0003 ("*Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R).*"[a] At the July 29th Meeting of the Advisory Panel for Clinical Diagnostic Laboratory Testing, the subcommittee that considered code 87635 indicated that they initially were supportive of the crosswalk to code 87502 consistent with public commenters' recommendations, but they then deferred to one of the panel members who suggested that code 87501 "*Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, includes reverse transcription, when performed, and amplified probe technique, each type or subtype*" (CY 2020 CLFS rate = $51.31) was a more appropriate crosswalk since SARS-CoV-2 testing is seeking to detect a single virus, like tests under 87501 seek to detect a single type of influenza. The CDLT Panel then supported the crosswalk to code 87501 by a vote of 9 to 2 votes for gapfill and 1 abstention.

We respectfully disagree with the crosswalk to code 87501 as this crosswalk fails to cover the substantial resources required to develop and furnish amplified probe testing for SARS-CoV-2 in the context of the COVID-19 public health emergency.

Clinical laboratories and manufacturers rose to meet the needs of the healthcare community by investing substantial resources rapidly to develop tests for SARS-CoV-2. The development of these tests involved substantial costs, including:

[a] It is unclear if code U0003 is a valid code for crosswalk since its rate of $100 was not established through standard CLFS processes, and the rate for this code is also under consideration this year. We believe the $100 rate currently applicable for code U0003 would be an appropriate crosswalk for code 87635 ***IF*** code U0003 is acceptable for crosswalk.

- Development and ramping up production capabilities under the EUA program requires many test developers to stall other projects which is associated with a significant opportunity cost.
- Changeover costs in test development are significant. While some testing resources can be redirected from one product to another, there are significant changeover costs. Usually changeover costs can be planned so that the fewest possible changeovers are needed to achieve a steady test supply. However, under the public health emergency, production had to be rapidly ramped up to meet the demand. We anticipate that when the public health emergency is over, the demand for tests may drop significantly, and test developers will experience changeover costs again.
- The FDA has not announced any pathways to permit SARS-CoV-2 tests on the market under an EUA to continue to be marketed following the end of the PHE. As such, it appears that manufacturers will have to take current SARS-CoV-2 tests through FDA premarket review processes following the conclusion of the PHE.
- Accelerated development timelines require test developers to pursue numerous avenues of development that they would not normally pursue if they had more time.

Several of the stakeholders listed below previously submitted proprietary cost information to CMS and the MACs to quantify some of the costs associated with the factors above in order to support the differential costs of COVID-19 testing compared to other microbiology tests that otherwise may seem methodologically similar but which do not involve these extraordinary costs incurred due to the public health emergency.

In addition to the substantial development costs, ongoing operational costs for SARS-CoV-2 molecular testing include the following:

- Technicians need additional PPE because of the high transmissibility of SARS-CoV-2.
- Reagent costs are several times what they were prior to the pandemic.
- Patient service centers need additional shifts/expanded hours, resulting in higher labor costs.
    - Demand for testing continues to be high.
    - Waiting rooms cannot be crowded with individuals who may be infectious.
    - Appointments must be spread further apart to allow for social distancing and collection station sterilization.
- The entire cost of the specimen collection – already higher than normal – will be attributed to the SARS CoV-2 test alone.
    - Oftentimes the cost of specimen collection is spread among several tests for which specimens are collected at once (*e.g.*, CBC, cholesterol, HbA_{1C}).
    - In most cases a specimen will be collected only for the SARS CoV-2 test.
- Laboratories need to repurpose equipment that otherwise would be used for different testing in order to accommodate higher demand for SARS-CoV-2 testing, in some cases even developing multiple kinds of tests to meet test demand in the presence of supply chain shortages.[b]
- Laboratories have far greater public health reporting demands now than with typical microbiology tests.
    - Laboratories are reporting different information to multiple public health agencies in different states and different levels of government.
    - There are additional labor costs for IT specialists to extract data from the laboratory information system and interface with multiple public health agency reporting systems, including to provide real time reporting.

[b] See Association of Molecular Pathology Survey: https://www.amp.org/advocacy/sars-cov-2-survey/

- Laboratories incur additional costs associated with prioritization of specimens to ensure only the proper patients are tested in the right order, in accordance with public health guidance, including IT costs and costs associated with disruption of the normal workflow.
- Widespread availability of SARS-CoV-2 testing requires the involvement of all kinds of laboratories.
    - Small laboratories and those in rural areas tend to have higher cost structures.
    - Many laboratories will not do this testing if they cannot cover their costs, and testing will not be widely available enough for it to be a useful public health tool.

In conclusion, test developers invested significant resources and set aside important projects to assist to develop SARS-CoV-2 amplified probe testing in response to the COVD-19 pandemic. Clinical laboratories performing these tests continue to incur extraordinary costs in furnishing these tests—costs that are substantially in excess of costs incurred when performing amplified probe testing for a single type or subtype of influenza. These test developers have been acting under the hope that CMS would establish appropriate and fair reimbursement for this testing. **Therefore, we strongly urge CMS to establish a rate for 87635 by crosswalk to code 87502 as recommended by stakeholders and consistent with the extraordinary resources required to develop these tests and required to continue to offer these tests to Medicare beneficiaries**. We also ask that CMS consider the precedent of its decision for future public health emergencies when test developers must act with uncertainty regarding future payment.

In addition to making our recommendation for the crosswalk determination for 87635, we also raise concern about Medicare coverage for molecular respiratory viral panel tests that include SARS-CoV-2. As a critical component of triage protocols, these tests are critical for ruling in/ruling out COVID-19 patients with other viral respiratory conditions, and helping to guide immediate appropriate treatment during the PHE. There has been shifting Medicare coverage without notice and comment for these tests, and as a result, some laboratories are currently absorbing the cost of performing these tests, which can be critical to preventing transmission and speeding recovery during this national emergency.. As laboratories are attempting to provide SARS-CoV-2 testing during the PHE using appropriate, available, SARS-CoV-2 test kits, including some which include other relevant respiratory viral pathogens, Medicare coverage should be predictable and consistent.

We welcome an opportunity to meet with you and your colleagues prior to the publication of the Preliminary Determinations to discuss this recommendation.

Sincerely,

AdvaMedDx
American Association for Clinical Chemistry
American Clinical Laboratory Association
American Society for Clinical Pathology
Association for Molecular Pathology
College of American Pathologists
Point of Care Testing Association