October 23, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via email to: CLFSAnnual Public Meeting@cms.hhs.gov

RE: Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System

Dear Administrator Verma:

The American Urological Association (AUA) is a globally-engaged organization with more than 22,000 members practicing in more than 100 countries. Our members represent the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 15,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy. The AUA welcomes the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services' (CMS) release of proposed CY 2018 Private Payor Rate-Based Payment Amounts for clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS).

The AUA supports accurate payment for laboratory tests under the Medicare program and appreciates the significant efforts CMS has made to implement Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which requires CLFS payment rates to be established based on private sector payment rates. However, we have significant concerns with the proposed 2018 payment rates posted on September 22, 2017, given lack of confidence that these rates accurately reflect private market payments for the same tests and the potential harm that insufficient rates would impose on patients and public health.

**Insufficient Rates Lead to Patient Safety Risks**

The AUA is concerned that insufficient CLFS payment rates will limit physicians’ ability to provide rapid clinical testing services for patients while they are in the office. Rapid, accurate patient testing in a physician’s office is invaluable to early diagnosis of a range of conditions, both acute and chronic, and can help to avoid the use of emergency care resulting in hospitalization. The significant proposed
physicians to provide ongoing management of chronic conditions, particularly when diagnosis and care planning require follow-up visits. These challenges will particularly affect rural patients, who already experience barriers to accessing care.

The reimbursement rates for prostate cancer detection laboratory tests (CPT Codes 84153 and G0103), have already been significantly reduced. These are prostate specific antigen tests, often performed in physician office-based laboratories, to detect malignant cells in the prostate gland. If the proposed CLFS rates are finalized, they would ultimately reduce reimbursement for these tests by 35 percent and 24 percent, respectively, subject to the 10 percent cap in annual payment reductions. Reductions of this magnitude could inadvertently prohibit the ability for physicians to sustain the cost of providing office-based laboratory tests to patients, resulting in delayed diagnosis and treatment of prostate cancer, thereby threatening patient safety. This comes at a time when the U.S. Preventive Services Task Force has issued a new draft guideline supporting shared decision making for most men with respect to prostate cancer testing.

In addition, urine cultures (CPT 87086) and sensitivity tests (CPT 87186) for positive results for urinary tract infections are also often conducted in the office setting. Reimbursement rates for both tests also would be reduced by 35 percent (subject to the annual cap) under the proposed rates. These reductions could result in the delay in treatment of a very common but serious medical condition. If patients fail to receive medical treatment in a timely manner, due to the need to travel to a separate facility for laboratory testing, they could experience further, more serious complications of the urethra and bladder. Ultimately, the impact of the proposed CLFS rates could cause patients to suffer and increase the costs of health care services. This outcome would be counterintuitive to CMS’ overarching goal to reduce health care expenditures under Medicare Part B and the CLFS.

Policy, Process, and Timing Challenges Undermine Validity of Reported Data

Misguided policies finalized in the Final Rule Implementing Section 216 of PAMA have led to significant challenges in obtaining valid payment rates that accurately reflect payments for laboratory services provided by private payors. Physician organizations strongly urged CMS to establish a data collection period at a minimum six months after the final rule was issued in 2016. This request was based on extensive experience implementing major changes to Medicare programs by physician organizations and physician practices. CMS instead mandated a complicated, detailed, confusing, and voluminous data collection requirement for a mostly retrospective data collection period that began approximately six months before the final rule was issued. This constituted an impossibility for a number, if not all, of our members to do accurately and completely. Many clinical laboratories including the largest reference laboratories that have sophisticated payments systems and that hired additional staff, struggled to collect accurate data within the specified data collection timeframe and to submit timely. All of the foregoing underscore that clinical laboratories were required to comply with a regulation that constituted an impossibility.
Recommended Actions

In order to address the above concerns, we urge CMS to modify the existing PAMA regulations through issuance of an interim final rule effective December 1, 2017, that holds the current rates in place until CMS has conducted targeted market segment surveys (reference laboratories, physician office-base laboratories, independent laboratories, and hospital outreach laboratories) to validate and adjust the final fee schedule payments calculated based on the data collection to ensure congressional intent—payment rates that accurately reflect private market payments across all market segments—is achieved.

Conclusion

The AUA appreciates the opportunity to comment on the proposed CY 2018 CLFS payment rates. If you have any questions please contact Stephanie Stinchcomb at (410) 689-3786 or sstinch@auanet.org.

Sincerely,

Chris M. Gonzalez, MD, MBA
Chair, AUA Public Policy Council