October 23, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Re: Medicare Program: CY 2018 Clinical Laboratory Fee Schedule - Preliminary Payment Rates

Dear Administrator Verma:

The Association of Community Cancer Centers (ACCC) appreciates the opportunity to comment on the preliminary payment rates developed under the Protecting Access to Medicare Act (PAMA) for the Clinical Laboratory Fee Schedule (CLFS) for calendar year (CY) 2018. ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 23,000 cancer care professionals from approximately 1,100 hospitals and more than 1,000 private practices nationwide. These include cancer program members, individual members, and members from 34 state oncology societies. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

ACCC is committed to preserving and protecting the entire continuum of quality cancer care for our patients and our communities, including broad access to appropriate cancer diagnostics and therapeutics in the most appropriate setting. Clinical laboratory tests are essential to the timely and accurate diagnosis of cancer, and to monitoring and maintaining the health of cancer patients during and after treatment. Increasingly, clinical lab tests also are the key to determining a patient's risk of disease progression, which then informs treatment choices, and to knowing which therapies will be most effective for a particular patient's cancer, often influenced by genetics or genomics. Therefore, clinical laboratory tests are not only essential to provide

diagnoses for patients and monitoring their health, but they also lead to safer and more effective treatments.

As noted below, our members are concerned about the widespread and often drastic reductions in the preliminary CLFS rates posted on September 22nd, and that this may adversely affect patients' access to clinical lab tests, including testing that is crucial to the cancer patients treated by ACCC's members. Our members report that for the testing they perform in their own labs, the margins are razor thin, and with the dramatic rate cuts being proposed by CMS, these labs may no longer be viable, which will affect whether, how and where patients receive care. We urge the Centers for Medicare & Medicaid Services (CMS) to delay implementation of the PAMA rates, and to ensure that the CLFS calculation reflects the full range of private payer rates, that labs receive better guidance on what to report and how, and that the reported data is validated.

Our members are concerned that the "private payer" data CMS used to calculate the preliminary rates for the CLFS does not accurately reflect the full range of lab payment rates. For example, while we appreciate that in the final rule implementing PAMA, CMS revised the definition of "applicable laboratory" to allow reporting of private payer rates by some hospital labs, we were disappointed that only 21 hospital labs actually reported their rates. We believe hospital labs are an important source of testing for cancer patients and that the private payer rates they receive must be included in CMS's calculation in order to accurately reflect the market-based approach Congress intended when it passed the PAMA statute. And CMS's "simulation" of the effect of having data from more hospital labs simply assumed that all those missing hospital labs were receiving the same rates as those reporting, which we believe is unlikely. In addition, many physician office labs, whose payment rates may differ from those of the large independent labs, were excluded from reporting under the low volume threshold established by CMS. Again, we urge CMS to ensure that the CLFS rates truly reflect the full range of private payer rates.

We also are concerned that the PAMA implementation process, and the complexity of this new reporting requirement, resulted in the submission of incomplete and flawed data. Because the final rule implementing PAMA was not published until near the end of the first data collection period, labs were unable to make system changes to facilitate the timely and accurate collection of the relevant data to be reported. Therefore, despite their best efforts, we believe many labs ended up reporting inaccurate and incomplete data, and we believe reporting labs interpreted the requirements in varying ways, resulting in inconsistent reporting between labs. The requirement to report every private payer rate for every test performed was an enormous new undertaking for clinical labs that were given little time and little guidance to develop and implement processes between issuance of the final rule and the first reporting period. Labs need more time to get good systems in place and the data should be validated before CMS uses it to establish CLFS rates.

As noted, we have serious concerns that the preliminary rates calculated by CMS are not accurate reflections of the private payer market rates for many tests and that the severe reductions in rates for so many lab tests will cause major disruptions in the clinical laboratory market and affect access to tests that are crucial to cancer patients, both to diagnose their disease and to monitor and guide their treatment. We urge CMS to delay implementation of PAMA until the concerns noted by ACCC and so many other stakeholders can be addressed.

Thank you for this opportunity to comment on the CY 2018 preliminary rates under the CLFS. ACCC looks forward to working with CMS in the future on its efforts to ensure all beneficiaries have prompt, appropriate, and convenient access to the full range of clinical lab tests that better diagnose their disease and tailor their treatment. Please feel free to contact Leah Ralph, Director of Health Policy, at (301) 984-5071 if you have any questions or need any additional information. Thank you again for your attention to this very important matter.

Respectfully submitted,

Mark S. Soberman, MD, MBA, FACS
President, ACCC