October 23, 2017

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

Re: Biocom's Response to the Proposed 2018 Medicare Reimbursement Rates for Clinical Laboratory Tests under the Clinical Lab Fee Schedule (CLFS) pursuant to Protecting Access to Medicare Act (PAMA)

Dear Administrator Verma,

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 950 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products.

In our mission of providing feedback and communication between regulators and industry, we are writing in response to the Centers for Medicare and Medicaid Services (CMS) request for comments on data reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System and the preliminary calendar year 2018 Medicare CLFS rates.

Biocom commends the agency for its work to improve Medicare's reimbursement landscape and move toward a value-based payment system that enhances quality and delivery of care. However, we are concerned that the data collecting process used to establish the proposed 2018 CLFS rates does not adequately reflect data from all market segments and tests on the CLFS, resulting in significantly lower rates. **Therefore, we urge CMS to suspend the implementation of the new draft payment rates until the following deficiencies are addressed**:

- We believe that the payment data collected by CMS to establish the Medicare payment amount for a test on the CLFS does not accurately reflect the weighted median of the private payor rates for most tests, as required by Section 216(a) of the Protecting to Access to Medicare Act of 2014 (PAMA).

- We believe that the data collected to determine the proposed rates is not robust enough and does not fully represent the various market segments. CMS's definition of "applicable labs" excludes the majority of hospital labs which conduct half of all laboratory testing. Additionally, the criteria for the size of labs excludes many physician office laboratories. The exclusion of market price data from smaller labs creates a bias that puts smaller lab communities at a disadvantage.
- Lastly, the agency's decision to impose a retrospective data collection through rulemaking did not allow for labs to prepare to collect data accurately or in totality.

The currently proposed CLFS rates could restrict access for Medicare beneficiaries to essential and life-saving lab testing, and undercut the innovation necessary for the development of new, cutting-edge diagnostic tools. Biocom urges CMS to suspend the implementation of the proposed payment rates until the deficiencies in the data collection process, including data integrity, market representation of all segments of the laboratory market, and validation of data, are addressed. Thank you for your consideration of our comments.

Sincerely,

Joe Panetta
President and CEO
Biocom

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