

March 30, 2017

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

DELIVERED BY ELECTRONIC MAIL

Dear Administrator Verma:

On behalf of the undersigned organizations that represent physicians who provide medical care directly to patients and other laboratory clinicians, we are writing concerning the implementation of the Medicare Clinical Laboratory Fee Schedule (CLFS) reform as enacted by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA). While we appreciate that the Centers for Medicare & Medicaid Services (CMS) has attempted to address varied concerns through thoughtful engagement, we strongly urge that you extend the PAMA data reporting period deadline to March 30, 2018. The clinical laboratories that are on the front lines of providing services directly to their patients, physician office-based laboratories (POLs), are not able to meet the reporting deadline, in part due to the difficulties created by the fact that most of the data collection period started prior to the issuance of the final regulation specifying the data collection reporting requirements and collection period. In addition, we have strong concerns that the current data collection and reporting requirements, as well as the method for pricing applicable tests on the Medicare CLFS, will jeopardize the availability of clinical testing and patient access to these services in the setting where patients receive most of their medical care.

In brief, the decision to establish these new reporting requirements and reporting period before the final rule was issued added to the complexity, complications, and difficulty of collecting, synthesizing, and transmitting the required private payer payment rates. With the final rule being published on June 23, 2016, including the reporting period defined as January 1 – June 30, 2016, the final rule has the effect of requiring clinical laboratories to comply with new Medicare reporting requirements retroactively. Prior to the data collection period, POLs were not in a position to seek the needed adjustments to their administrative claims software and vendors to capture the information. Physician practices typically need six months to a year advance notice that they will need to comply with a significant payment or delivery reform in order to understand the new requirements, implement the needed modifications to their practice and IT capabilities, and to complete training while continuing to provide for patient medical care. Furthermore, the significant other payment and delivery changes that POLs are preparing for that are occurring simultaneous with PAMA implementation, namely preparation and implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), have imposed an unprecedented number of challenges on these practices. Finally, though the number of POLs that have to report the data is relatively small, the number of POLs that have to collect and

analyze the data is a larger number because POLs need to collect data in order to assess whether they are subject to the reporting obligation.

In light of the above challenges, we are also very concerned that POLs have not had sufficient time to ensure the completeness and correctness of the data, which exposes them to potential penalties and undermines the accuracy of the overall private payer rates. Furthermore, we are concerned that CMS' data collection system is not yet functioning at adequate capacity as reportedly many operational problems from the 2016 test phase appear unresolved and are hampering laboratory data submissions. Additional time would allow POLs, other stakeholders, and the Agency the time needed to address data collection concerns, collect, and ensure accurate submission of all applicable data as this will impact the final CLFS under PAMA.

Finally, POLs provide essential, rapid point-of-care testing to their patients. The foregoing is consistent with the focus of payment delivery reform to center medical services around the patient to enhance coordination and to optimize compliance and improved health outcomes. If clinical testing at the point-of-care is no longer available, it undermines this overarching effort. In addition, there are a number of point-of-care clinical tests that provide accurate and rapid results that are important to address important public health goals, such as antibiotic stewardship, by ensuring appropriate and judicious prescribing of antibiotics. Requiring elderly and medically fragile Medicare beneficiaries to wait additional time for testing results or to seek clinical testing outside of their physician's office, particularly those in geographically remote or underserved areas, imposes additional burdens on this vulnerable patient population and their caregivers.

We appreciate the consideration that CMS has given to the administrative impact of data collection and reporting requirements to date, and look forward to working collaboratively with you to address these other broader patient access and improved health outcome goals.

Sincerely,

American Academy of Family Physicians
American College of Physicians
American Medical Association
American Osteopathic Association
COLA
Infectious Diseases Society of America
Medical Group Management Association