



October 23, 2017

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: Medicare Clinical Laboratory Fee Schedule Rates for 2018
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Preliminary Calendar Year 2018 Medicare Clinical Laboratory Fee Schedule Rates

Dear Administrator Verma:

On behalf of the American College of Physicians (ACP), I am writing to share our comments on the preliminary rates for tests in the Medicare Clinical Laboratory Fee Schedule (CLFS) for calendar year (CY) 2018, as announced on September 22, 2017. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 152,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The Protecting Access to Medicare Act (PAMA) of 2014 included a provision in section 216 that revises the methodology for determining payment rates for many tests paid under the Medicare CLFS. Under the revised methodology, payment amounts will be set based on the weighted median of private payer rates for the test, which will be determined based on information reported to CMS during a data collection period. Rate reductions cannot be more than 10 percent each year for the first three years of implementation (2018 – 2020). Under the preliminary rates for CY 2018, 75 percent of tests will receive a rate reduction, with nearly 60 percent of tests with a cut so large that it will have to be phased in over multiple years.

ACP is concerned that deficiencies in the data collection methodology resulted in inaccurate payment rates for Medicare CLFS tests. CMS issued a final rule on June 23, 2016, that specified the data collection period of January 1 – June 30, 2016, which required retrospective collection of data. This is despite ACP and other physician organizations strongly urging CMS to establish a data collection period that would begin a minimum of six months after the issuance of the final

rule in 2016. This request was based on extensive experience implementing major changes to the Medicare program by physician organizations and physician practices. CMS instead mandated a complicated, detailed, confusing, and voluminous data collection process for a mostly retrospective data collection period that began approximately six months before the final rule was issued. This made it extremely challenging for a large number, if not all, of our members to comply accurately and completely. Many clinical laboratories, even including the largest reference laboratories that have sophisticated payment systems and hired additional staff, struggled to collect and submit accurate data within the specified data collection timeframe.

ACP urges 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-based laboratories (POLs), 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.

In a survey of ACP member laboratories, respondents voiced concern that the cuts PAMA would impose on Medicare reimbursements would have a “high impact” on the laboratory services offered to patients, which would lead to POLs “decreasing or stopping” those crucial services at the time of a patient’s appointment. Point-of-care testing (near-patient testing) is critical to many patients, especially those who are being treated for an infection, have uncontrollable diabetes, or are receiving chemotherapy, etc., or live in a rural area.

For example, as several POL employees stated, “patients on chemotherapy need CBC, CMP results ASAP, otherwise, they have to return for treatment” and “chemotherapy cannot be administered until lab testing is completed.” Most importantly, “patients should be able to come in one day and have most services provided. Cancer patients need one stop visits.” Many independent physician offices currently maintain POLs on-site, allowing patients to get the necessary CBC testing done in the office prior to starting the treatment. If POLs are forced to close due to payment rate reductions, these patients will be forced to go to the nearest reference lab, wait for the CBC results and then be required to return to the physician’s office to receive treatment. This presents an even greater challenge in rural areas, where the closest reference lab may be more than 100 miles away.

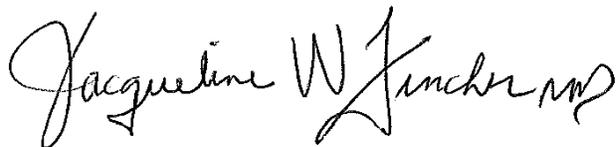
Patients throughout the United States will be facing similar scenarios if the most basic of lab tests can no longer be offered in the physician’s office. With the looming cuts to reimbursements, ACP members are facing the hard choice of whether to provide on-site care to patients when it will result in their losing money on each test performed. As one internal medicine office reported, “our profit running our lab at this time is minimal – less than \$50 per day on average for two internists. There are even some months when we lose money on our lab. If Medicare reduces the reimbursement for office based labs at all, we will have no choice

but to close our lab.” Another states “my reimbursement is down and with PAMA, [I] may end up closing the door!”

If the Medicare CLFS payment rate reductions are implemented as proposed and POLs and small, independent laboratories in rural areas are forced to close, it will result in issues accessing point-of-care testing not only for Medicare patients but also for those with Medicaid or commercial insurance. In the event of a public health crisis such as an infectious disease outbreak, these labs are also critical to managing the spread of disease due to their ability to rapidly rule diseases in or out while the patient is on-site. ACP urges CMS to halt implementation of the preliminary Medicare CLFS rates for 2018 until market segment surveys can be completed and final payment amounts can be adjusted accordingly in order to minimize the negative impact that these revised rates will have on patient access to testing in POLs.

Thank you for considering our comments. Please contact Brian Outland, ACP’s Director of Regulatory Affairs, by phone at (202) 261-4544 or e-mail at boutland@acponline.org if you have questions or need additional information.

Sincerely,

A handwritten signature in black ink that reads "Jacqueline W. Fincher MD". The signature is written in a cursive, flowing style.

Jacqueline W. Fincher, MD, MACP
Chair, Medical Practice and Quality Committee
American College of Physicians