



Submitted via e-mail

October 5, 2017

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Implementation of CLFS Private Payor Rate-Based Payment Amounts for CY 2018

Dear Administrator Verma:

On behalf of the Coalition for 21st Century Medicine (C21), we write in support of the implementation of the private payor rate-based payment amounts for CY 2018 under the Clinical Laboratory Fee Schedule (CLFS). We commend the agency on its efforts to implement the provisions of Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) and the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CLFS Final Rule)¹. C21 supports the on-schedule implementation of private payor rate-based payment amounts for CY 2018 effective January 1, 2018, and believes that maintaining this effective date is critical to fulfill PAMA's goals of improving the transparency and predictability of the CLFS rate-setting process. In addition to implementing the market-based rates effective January 1, we also respectfully request that the agency immediately release the application for Advanced Diagnostic Laboratory Test (ADLT) classification and a streamlined designation process to ensure that appropriate tests can be designated as new ADLTs effective January 1, 2018.

C21 comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. C21's mission is to improve the quality of healthcare by encouraging research, development, and commercialization of innovative diagnostic technologies that will personalize patient care, improve patient outcomes, and substantially reduce healthcare costs. C21 supported the enactment of Section 216 of PAMA to provide transparency, predictability and market based pricing for innovative laboratory tests.

¹ 81 Fed. Reg. 41036 (Jun. 23, 2016).

Support Implementation of PAMA on Schedule

C21 appreciates CMS' diligent work to develop and implement the market-based payment system under PAMA, and its consideration of stakeholder input throughout this process. Along with many stakeholders, C21 supported the agency's decision in the CLFS Final Rule to delay the implementation of the private payor rate-based payment amounts by one year from the statutory required date of January 1, 2017. We also supported CMS' exercise of enforcement discretion with respect to the reporting of private payor rates between the original deadline of March 31, 2017 and May 30, 2017. We believe that these steps were important measures to ensure that stakeholders had the time to develop infrastructure for data collection and reporting and to navigate the new data collection and reporting policies for the first time. The C21 member laboratories reported private payor rates prior to May 30, 2017.

We believe that the agency provided additional notice and safeguards by posting the preliminary rates on September 22, 2017, including "raw" data files, and providing a 30-day public comment period,² even though these steps are not required by statute. Our members have reviewed these preliminary payment amounts and have confirmed that they accurately reflect the data submitted earlier this year. We commend CMS for its efforts in calculating and releasing these payment amounts on schedule, and strongly support the finalization of the private payor rate-based payment amounts in November and the implementation of the market-based system on January 1, 2018.

C21 believes that the implementation of the private payor rate-based payment amounts on schedule in 2018 is important to the achievement of PAMA's objectives. We are concerned that any such delay would undercut Congress and the agency's objectives of improving transparency and predictability in the setting of rates for clinical diagnostic laboratory tests. The effect of a delay would be especially disruptive to laboratories relying on the implementation of Section 216 of PAMA as it would come only weeks before the private payor rate-based payment amounts are to take effect.

Release ADLT Application and Start Designation Process

In addition, C21 supports the new ADLT payment category, through which innovative diagnostic tests will be paid based upon private payor rates reported after six months and then annually rather than undergoing initial crosswalk or gapfill and triennial reporting to establish rates. We believe that this classification will apply to a small number of tests but will serve as a catalyst for innovative advanced diagnostics that benefit patients by personalizing treatment decisions. C21 has provided detailed input to CMS on the development of the ADLT application and on the importance of coordinating the ADLT designation process, the assignment of specific HCPCS codes for New ADLTs, and the beginning of payment at Actual List Charge.

² See Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule, Fact Sheet, *available at* <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-17.html>; *see also* 81 Fed. Reg. 41036, 41080 (Jun. 23, 2016).

We are concerned, however, that three years after PAMA established the ADLT category and a year after the CLFS Final Rule further refined it, the application for ADLT designation has not yet been released. This is particularly problematic because the New ADLT payment status is scheduled to go into effect with the rest of the new market-based payment system on January 1, 2018, and many laboratories expected their tests to apply for and receive this classification as of that date.

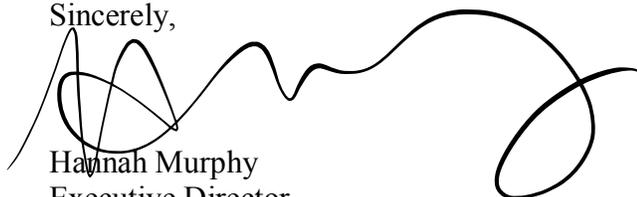
We respectfully request that CMS work to ensure that qualifying tests are able to be designated as New ADLTs in time for separate payment status to take effect January 1 as scheduled. We believe that CMS can accomplish this by releasing the application for ADLT status immediately, and establishing a streamlined designation process for the fourth quarter of 2017 that will enable tests to be designated as New ADLTs prior to January 1.

Conclusion

C21 appreciates the opportunity to comment on the preliminary CLFS private payor rate-based payment amounts for CY 2018, and we thank CMS for its efforts in implementing the new market-based payment system. We believe that the new payment amounts can and should be implemented on January 1, 2018, as scheduled, and that the agency should release the ADLT application to enable those provisions of PAMA to take effect as scheduled as well.

Thank you for considering our comments and for your continued efforts to implement PAMA as scheduled and to promote personalized medicine. Please contact me at Hannah Murphy at hmurphy@c21cm.org should you have any questions or if we can provide you with further information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Hannah Murphy', with a large, stylized flourish extending to the right.

Hannah Murphy
Executive Director
Coalition for 21st Century Medicine