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September 11, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1676–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: **CMS-1676-P — Physician Fee Schedule, Proposed Rule – Implementation of Medicare Clinical Diagnostic Laboratory Tests Payment System**

Dear Administrator Verma,

On behalf of the Coalition for 21st Century Medicine (C21), we appreciate the opportunity to comment on the CY 2018 Physician Fee Schedule Proposed Rule.[1] We are writing in response to the Centers for Medicare & Medicaid Services' (CMS') solicitation of public input on the implementation of the new private payor-rate based Medicare Clinical Diagnostic Laboratory Tests Payment System promulgated under Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA). C21 appreciates the work that CMS has performed over the past year in implementing PAMA's private payor rate-based Clinical Laboratory Fee Schedule (CLFS). We continue to support the implementation of PAMA on the schedule set out in the CLFS Final Rule,[2] which sets an effective date of January 1, 2018 for the new market-based payment rates. Additionally, we respectfully request that CMS release the application for Advanced Diagnostic Laboratory Test (ADLT) status as soon as practicable to enable qualifying tests to be designated in advance of CY 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.

[1] 82 Fed. Reg. 33950 (Jul. 21, 2017).
[2] 81 Fed. Reg. 41036 (Jun. 23, 2016).

Background on PAMA and Implementing Regulations

The CLFS Final Rule, promulgated to implement Section 216 of PAMA, requires laboratories to report private payor rates to CMS for tests furnished during a six-month data collection period. The first data collection period was January 1 through June 30, 2016, and the initial reporting period was January 1 through March 31, 2017, although the agency exercised enforcement discretion to enable laboratories to submit data until May 30, 2017.

The weighted median of the private payor rates reported for each test during this period will be the CLFS rate beginning January 1, 2018, with successive collection and reporting cycles to take place triennially for Clinical Diagnostic Laboratory Tests (CDLT), and annually for Advanced Diagnostic Laboratory Tests.[3] The agency stated in the CLFS Final Rule that it would post preliminary payment rates in September 2017, and final rates in November 2017.[4] This will allow for a public comment period on the preliminary rates in furtherance of PAMA's objective of promoting transparency in clinical laboratory payment. CMS has remained committed to implementing the new private payor rate-based CLFS on January 1, 2018 as set out in the regulations.

C21 Supports Implementation of PAMA on Schedule

C21 appreciates CMS' efforts in developing and implementing the market-based payment system under PAMA, as well as its commitment to working collaboratively with stakeholders during this process. We supported CMS' decision in the CLFS Final Rule to delay the implementation of the market-based rates by a year to January 1, 2018, due to concerns that the infrastructure for data collection and reporting would not be operational in time to set rates in advance of CY 2017 as required in the PAMA statute. Additionally, we agreed with CMS' decision to exercise enforcement discretion with respect to data reporting until May 30, 2017. That additional time was necessary for some laboratories to comply with PAMA's data collection and reporting requirements in this initial cycle. C21's member laboratories collected applicable information from the first two calendar quarters of 2016, reviewed and verified these data to ensure completeness and accuracy, and reported the applicable private payor rates by May 30, as required by the agency.

We believe that, having taken these steps, the agency should proceed with implementing PAMA effective for CY 2018. We understand that CMS has been working diligently to calculate weighted medians for CDLTs based on the data reported in early 2017. We are confident in the robustness of the data collection submitted by our members. We are concerned that any further delay in implementing the new payment system will result in confusion among laboratories and providers that have aligned their reimbursement and coding strategies with a January 1, 2018 implementation date. PAMA and its implementing regulations were intended to promote certainty, consistency, and transparency in the determination of payment rates under the CLFS. Having already been delayed by a year from its statutory timeline, any further delay of the new private payor rate-based CLFS, especially on such short notice, would disrupt the laboratory

[3] 42 CFR 414.507(a).
[4] *See* 81 Fed. Reg. 41036, 41080 (Jun. 23, 2016).

industry and be inconsistent with the Congressional objective of predictability in rate setting. For these reasons, C21 supports maintaining the current implementation schedule for PAMA, with preliminary rates released in September, final rates in November, and the new rates effective January 1, 2018.

Request Release of ADLT Application

C21 is also strongly supportive of the new ADLT payment category, through which Congress and CMS intend to provide payment at Actual List Charge to innovative diagnostic tests during an initial three calendar quarter period after they are covered under Medicare Part B. We believe the ADLT classification will apply to a small but important category of innovative tests that will improve quality of care and reduce total health care costs. To ensure that tests qualifying for New ADLT designation receive the benefit of this payment status upon the effectiveness of PAMA in 2018, we respectfully request that CMS release the ADLT application along with guidance on the designation process.

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. We are concerned that the ADLT application has not yet been released three years after the establishment of the ADLT category by PAMA and over a year after the release of the CLFS Final Rule. While we supported the delay of PAMA data collection and reporting from the initial statutory timeline, we remain concerned that the ADLT application process is not yet available for laboratories.

Comments on Initial Data Collection and Reporting Period

Finally, in the Proposed Rule, CMS requests input on specific questions related to laboratories' experience with data reporting and data collection to help inform the agency as to potential refinements to the private payor rate-based CLFS for future collection and reporting periods. In particular, CMS solicits comments on user experience with the CLFS Help Desk support services provided by the agency. Numerous laboratory members of the Coalition communicated with the Help Desk support staff, and were greatly impressed with both their knowledge and responsiveness to reporting questions. In several cases, support staff stayed on the line with laboratories for over an hour to resolve reporting issues with the CLFS Data Collection System. We greatly appreciate the assistance provided by the Help Desk and believe that this support was instrumental for laboratories to resolve questions about data reporting. We encourage the agency to continue to operate the Help Desk at the same support levels for future reporting periods.

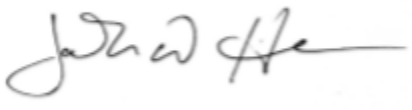
We also wish to note one suggestion that was of concern to laboratories during the initial data reporting period. During the reporting period, TIN-level entities were required to report private payor rates and volumes reported broken out by NPI number. Some laboratories' billing systems do not link payment and NPI information in a way that makes it easy to extract the information for reporting. We recommend reporting the payment rates and associated volumes for a test for an entire TIN-level entity, and not requiring the information to be identified by NPI-level entity. Such a change would provide the same information to the agency to calculate a weighted median, and would avoid unnecessary complications for laboratories.

Conclusion

C21 appreciates the opportunity to comment on the Physician Fee Schedule Proposed Rule, and thanks the agency for its efforts in implementing the private payor rate-based CLFS under PAMA. We believe that the new payment rates can be implemented January 1, 2018 as scheduled, and support doing so in line with stakeholder expectations. We also request that the agency release the ADLT application in sufficient time to allow New ADLTs to benefit from the statutorily-required payment status upon the effectiveness of PAMA.

Thank you for considering our comments and for your continued efforts to implement PAMA as scheduled and promote personalized medicine. Please contact me at (650) 243-6363 or via electronic mail to john@veracyte.com should you have any questions or if we can provide you with further information.

Sincerely,



John W. Hanna
Chair, Reimbursement Workgroup
The Coalition for 21st Century Medicine