October 23, 2017

VIA EMAIL: CLFS_Annual_Public_Meeting@cms.hhs.gov

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Room 314G
Washington, DC 20201

Re: Preliminary Payment Rates Based on Private-Payer Data under PAMA §216

Dear Administrator Verma:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed) and AdvaMedDx, we are writing to respond to the Centers for Medicare & Medicaid Services' (CMS') request for comments regarding the recent announcement of preliminary payment amounts for laboratory tests paid on the Clinical Laboratory Fee Schedule (CLFS).
The preliminary payments for the majority of codes on the CLFS were calculated based on data from a small number of laboratories and do not accurately represent the laboratory market as a whole. Additionally, the most common reductions in payment are between 30 and 40 percent, resulting in proposed payment rates that are much lower than even CMS predicted. In addition to questioning the accuracy of these reductions, we believe many laboratories will not be able to remain viable at these rates. This has potential implications for clinician and patient access as well as overall market concentration that could lead to higher prices and diminish any long-term savings of this regulation. As we discuss and support in detail below, we urge CMS to suspend the January 1, 2018, implementation date for these new rates and to work with stakeholders in the laboratory community to improve the accuracy and reliability of the new payment rates.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

AdvaMedDx operates as a division within AdvaMed and represents the world's leading diagnostics manufacturers by advocating for the value and power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and

abroad. AdvaMedDx member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs. Throughout this letter, AdvaMed refers to both AdvaMed and AdvaMedDx.

Section 216 of the *Protecting Access to Medicare Act (PAMA) of 2014* required CMS to develop a new process for establishing and updating payment amounts for laboratory tests on the CLFS. AdvaMed supported PAMA when it was signed into law. However, building and launching this new payment system was a complex undertaking that included a number of complicated components and revealed many issues that were neither contemplated by Congress when it enacted the law, nor anticipated by CMS in the implementation of this new system.

We recognize and appreciate that CMS has worked hard to implement the law. However, as described in greater detail below, the process has uncovered a number of concerns that should be addressed before CMS fully implements the new payment system.

For example, in many cases, commercial payers set their payment rates at a percentage of Medicare payments. Under the new system, Medicare rates will be established based solely on commercial payer rates and will not be updated for three years. If commercial payers continue to pay a percentage of Medicare rates, this will result in payment reductions for Medicare and non-Medicare laboratory payment rates alike and in continuing decreases following each subsequent data collection. This result was not anticipated, and certainly was not intended by Congress when it enacted the legislation. While this issue may not fit squarely within the scope of CMS' solicitation for comments on the preliminary payment rates, this is a significant issue for AdvaMed and the laboratory community. We, along with other stakeholders, would like to work with CMS and the Congress to address this and other issues.

After the proposed and final rules were issued, and since the issuance of the preliminary payment rates on September 22, 2017, AdvaMed has identified several significant operational and technical issues with these rates. **We recommend that CMS delay implementation of these rates by one year until these issues are addressed.**

Our comments below describe operational issues and specific areas of concern:

Operational Issues

Retroactive Data Collection Period

We are very concerned that many of the commercial rates reported to CMS by laboratories earlier this year were insufficient, or incorrect, and resulted in inaccurate preliminary payment rates as well as deep reductions from current payment amounts. Laboratories had to contend with a retroactive data collection period of January through June, 2016. Laboratories first learned about the retroactive data collection period in the CMS final rule on June 23, 2016. Most laboratories did not have existing information technology systems that were designed or equipped to retrieve the data in the manner in which CMS required it to be reported. Many laboratories encountered challenges compiling and submitting appropriate data to CMS, and

technical issues with the web portal further complicated those efforts. Ultimately, the agency had to extend the reporting period by 60 days to accommodate those laboratories. As a result of these technical and operational issues, we have significant concerns regarding the accuracy and integrity of the data submitted to CMS.

Limited Data Collection

The private payer data reported to CMS does not accurately represent all segments of the clinical laboratory market, such as national and local independent, hospital outreach, and physician office laboratories. As CMS stated in its executive summary, payment rates were established using data from less than 2,000 laboratories. This figure is significantly lower than the approximate 12,000 laboratories that the Office of the Inspector General (OIG) estimated in 2016 would be the basis for new payment rates.[1] Even assuming the OIG figure is appropriate, it is worth noting that there are more than 246,000 laboratories that received Medicare payments in 2015. This small number of laboratories from which CMS collected private payer data does not accurately represent the U.S. market, counter to the original intent of the law.

No Ability to Validate Data

The data collection and reporting system lacks sufficient transparency into the rate-setting process. Additional action is necessary, in order for stakeholders to perform a meaningful review of the preliminary payment rates prior to their effective date or to request that CMS re-examine and correct rates that are potentially inaccurate–a practice that occurs in other Medicare payments systems, such the Hospital Outpatient Prospective Payment System and the Physician Fee Schedule. Even CMS, in its analysis of the data reporting, was unable to validate inaccurate or misreported data.[2]

The consequences of inaccurate payment rates and deep reductions in payment amounts will limit beneficiary access to needed laboratory tests that support patient clinical care management. In light of these inaccuracies, it is clear that CMS must address the flawed implementation that accounts for the inappropriately low payment rates.

In addition to the operational issues described above, AdvaMed has identified the following specific issues relating to the accuracy and reliability of the reported data:

Test Panels

Test panels present a number of issues, including CMS' decision to move directly to the weighted median private payer rate, rather than applying the 10 percent cap on payment reductions in 2018; data reporting, accuracy and integrity; and the resulting payment amounts based on private payer data.

[1] HHS OIG Data Brief: Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data. PAMA mandated OIG monitor Medicare payments for lab tests and the implementation and effect of the new payment system for lab tests.

[2] Summary of Data reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate Payment System, September 22, 2017, p. 5-6.

First, CPT code 80061 (lipid panel) is a high-volume test panel comprised of three component tests – 82465 (total serum cholesterol), 83718 (HDL cholesterol) and 84478 (triglycerides). CMS reported a preliminary rate for CY 2018 rate for CPT code 80061 of $11.23—a nearly 39 percent reduction in payment from the median of the locality-specific amounts paid in 2017. According to the data released with the new 2018 CLFS rates, CPT code 80061 accounts for the fourth highest amount of Medicare spending for codes on the CLFS. CMS does not list a National Limitation Amount (NLA) for CPT code 80061. However, CPT code 80061 does have locality-specific amounts. We are unclear why CMS does not list an NLA for CPT code 80061. For all intents and purposes, the functional NLA for CPT code 80061 is $18.37 (based on the median of payments across CMS' current 56 localities). By moving directly to the weighted median of $11.23, CMS will be applying a 38.9 percent reduction on a code that accounts for 6 percent of total CLFS spending.

The law states that payment amounts determined under the new methodology "shall not result in a reduction in payments (for a given test) for the year of greater than …10 percent" for each of the first three years of implementation.[3] Reducing the payment amount for CPT code 80061 by greater than 10 percent because it does not have a formal NLA listed on the CLFS is irrational and an incorrect application of the statute. AdvaMed's own analysis reveals that a reduction capped at 10 percent from the "functional" NLA described above for CPT code 80061 would reduce the overall reductions in payment for CLFS services in CY 2018 by $154 million. We recommend that CMS limit the reduction for CPT code 80061 to 10 percent as required by PAMA. That means an NLA of $18.37 should be reduced to $16.53 in 2018, rather than $11.23.

Second, we are not confident that laboratories were well-informed or understood how to report private payer prices for tests that are often paid as part of panels. On the 2017 CLFS, CMS lists 17 codes beginning with "ATP" that represent automated test panels. Each code pays a different amount depending upon how many tests are performed as part of the panel. These panel tests constitute a very high volume of services paid under the CLFS although the data on the top 25 highest expenditure codes provided by CMS with the new CLFS rates does not separately list payment for codes paid as ATPs. Despite its major significance, this issue was not addressed by CMS in its proposed rule nor was it raised by public commenters. Therefore, there is no mention in CMS' CLFS final rule of how payment would be made for tests typically paid as part of automated test panels or how private payer data would be reported.

CMS does address this issue in a change request dated November 10, 2016.[4] Business requirements 9837.6 and 9837.7 respectively state:

> Effective for claims with line item dates of service on and after January 1, 2018, contractors shall not bundle or roll up individually billed lab test HCPCS to a lab panel HCPCS or an ATP code, however, contractors shall continue to apply editing to ensure

[3] SSA §1834A(b)(3).
[4] Transmittal 3653, Change Request 9837, Publication 100-04 Medicare Claims Processing, "FISS Implementation of the Restructured Clinical Laboratory Fee Schedule.

> that if a lab panel HCPCS is submitted and allowed, an individual lab HCPCS that is part of the same panel is not also allowed.
>
> Effective for claims with line item dates of service on and after January 1, 2018, contractors shall discontinue specialized pricing logic for ATP multichannel tests.

This instruction is directed at CMS's Medicare Administrative Contractors, not applicable laboratories, so our expectation is that laboratories may be largely, if not completely, unaware that Medicare will no longer be paying for laboratory tests using the ATP methodology.

CMS' instructions to laboratories regarding reporting of private payer data can be found in MLN Matters Article SE1619.[5] Panel tests are not specifically referenced in this MLN Matters article but the excerpted portions of the instructions below suggest tests paid as a bundle are excluded:

> Page 8 of 12: Remittances where the payor has grouped individual HCPCS code payments into an encounter or claim level payment. When a private payor groups payments [sic] for individual HCPCS codes into a single encounter or claim-level payment that is not represented by another HCPCS code, those payments are not applicable information. In other words, if individual HCPCS codes are billed by the laboratory and the payor bundles the individual HCPCS codes into groups not represented by other HCPCS codes, the payor's bundled payment amount is not considered applicable information.
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> Page 8 of 12 and right below the above: Note: In general, if a laboratory cannot correlate a private payor payment amount and the associated volume paid at that rate to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information.

We are concerned that by not explicitly referencing tests paid as a panel, applicable laboratories may not have understood this instruction and may have reported payment amounts for tests that are infrequently paid individually and are usually paid as part of a panel. It seems highly likely that applicable laboratories would have reported private payer rates inaccurately for individual tests, particularly as they would not have known how to divide up payment for tests paid as part of a panel. For instance, if a private payer pays for a panel test by paying the full amount for the first test and an incremental amount for each additional test, then dividing the full payment for the panel by the number of tests performed and reporting that payment amount for each individual code would understate the amount that would be paid if each test were to be billed and priced individually. We see no evidence that CMS did any validation of the amounts reported by applicable laboratories to determine whether or not they reported payment amounts accurately and did not report payment when tests are paid as part of a panel. Given that panel tests represent a very high proportion of tests paid under the CLFS, the issue of how panel test prices were

[5] MLN Matters Number SE1619: Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System

reported is very significant to the accuracy of the rates Medicare will begin paying on January 1, 2018.

Recommendation 1: CMS should delay implementation of the rates by one year until it can validate that applicable laboratories did not report private payer rates paid as part of a panel and it can substantiate that applicable laboratories only reported private payer payment amounts for tests when those tests were paid individually. If CMS cannot validate accurate reporting, we recommend that CMS do additional outreach to applicable laboratories on this issue and require laboratories that reported data on test panels to resubmit the data after CMS provides clear and proper instructions indicating that payment for codes paid as part of test panels is not to be reported and payment is only reported when tests are paid for individually.

Recommendation 2: Moving directly to the weighted median of private payer data for CPT code 80061 violates the PAMA statute, which states that payment amounts for a given test shall not be reduced by more than 10 percent in the first year of implementation. If CMS does not delay implementation of the new payment rates for laboratory tests for 2018, CMS should reverse its inappropriate application of the payment reductions for panel tests, and cap its payment reduction at 10 percent of the functional NLA.

Drugs of Abuse Testing

Coding changes in the last several years have affected Medicare payment for drugs of abuse testing. In 2015, CMS replaced some deleted CPT codes for drug testing with new G-codes. Providers were instructed to use the G-codes in the same manner in which they had used the corresponding CPT codes that were deleted. However, for some drug testing codes the code instructions and descriptors were revised for 2015 in lieu of deletion. Medicare also replaced analyte-specific codes with new G-codes codes that bundled multiple drug tests into drug class(es), including metabolites, per day (e.g. less than 7, 8-14, 15-22, and greater than 22). Subsequently, Medicare considered and/or reconsidered decisions regarding drug testing codes, and ultimately, for 2016 and 2017, approved and priced four G-codes (G0480-G0483) describing definitive drug testing. For presumptive testing, CMS created three G codes (G0477-G0479) that were in use during the 2016 data collection period from January 1, 2016 through June 30, 2017 that were later replaced by CPT codes 80305-80307 beginning in 2017.

Private payers have not adopted these Medicare changes across the board, and as a result, a dual coding system has emerged in which some commercial payers require use of the G-codes while others continue to require use of the CPT codes. Without clear instructions from CMS regarding the process for collecting and reporting this data, for purposes of PAMA, it is very likely that laboratories inaccurately reported their private payer data for these drug testing codes. While some laboratories were able to report the data for these tests correctly in cases where commercial payers were using the comparable G-codes, other laboratories may have reported data for the CPT codes, which would not be applicable to the drug tests described by the CMS-established G-codes. AdvaMed is concerned that this bifurcated coding system that now exists between Medicare and private payers for drugs of abuse tests has resulted in inaccuracies in the reported data and resulting payment rates. We are concerned that the resulting payment rates for drugs of

abuse tests are significantly skewed. The weighted medians for the G-codes for definitive drug tests (G0480-G0483) represent reductions of 23-59 percent.

The G-codes for the presumptive drug tests (G0477-G0479) that were in effect during the 2016 data collection period have been replaced CPT codes (80305-80307). As the presumptive drug tests G codes were in effect during the data collection period and the CPT codes for these same services were not, CMS has private payer data reported for the G-codes but no data reported for the CPT codes. However, the CPT codes are one-to-one replacements for the G-codes and CMS established NLAs for the CPT codes of $14.96 (80305), $19.95 (80306) and $79.81 (80307) beginning in 2017. While our recommendation is to continue to use the established NLAs for drugs of abuse testing, if CMS does not adopt our recommendation, the Agency must, at a minimum, compare the private payer rates reported for G0477-G0479 to the NLAs reported for CPT codes 80305-80307 and apply the transitional 10 percent limit on payment reductions accordingly consistent with the statute as referenced above.

CMS' preliminary rates show payment amounts for 2018 through 2020 for G0477–G0479 even though these codes are no longer in effect. CMS does not show payment amounts for CPT codes 80305-80307 for 2018 through 2020 even though these codes will be in effect during this period. As 80305-80307 are one-to-one replacements for G0477-G0479, if CMS does not adopt our recommendation to continue the current payment amounts for presumptive and definitive drug testing, the transition payments reflecting the 10 percent cap on payment reductions for presumptive drug testing would be:

Presumptive Testing CPT Code	2017 NLA	Analogous G-Code	G-Code Weighted Median	2018 Payment CPT Code with 10% Reduction Cap
80305	$14.96	G0477	$12.60	$13.46
80306	$19.95	G0478	$17.14	$17.55
80307	$79.81	G0479	$62.14	$71.81

Recommendation: For 2018, CMS should continue to use the payment amounts established for these drug testing codes through the agency's current process for setting payment amounts for new tests. Historically, drugs of abuse testing codes were cross-walked to existing codes, and were subject to discussion at CLFS public meetings as well as public comment periods. Based on the significant changes over the last five years with respect to these codes, and the lack of clear instruction to laboratories regarding data collection and data reporting for these codes, the probability for errors in the rate-setting data is great. CMS did its due diligence and established payment amounts for these G-codes with considerable input from the public, including the PAMA-mandated Advisory Panel, in the very recent past. CMS should therefore retain the payment amounts it established for these drugs of abuse codes for 2018 and work with stakeholders to determine how best to determine private payer rates in a future data collection and reporting period. Alternatively, if CMS reduces the payment amounts for these G-codes, it should limit any reduction to 10 percent of the amount CMS established for these codes in 2017 per the statute.

Tests Performed in Physician Office Laboratories (POLs)
The final rule implementing the new CDLT payment system under PAMA, excluded significant portions of the market, particularly physician office laboratories. While the final rule allowed a small number of hospital outreach laboratories to report commercial payer data, ultimately only 21 hospital laboratories actually reported data. AdvaMed previously has recommended that CMS should evaluate tests that are offered and furnished in different settings by different types of laboratories and establish a mechanism to improve the data reporting for those providers and tests to ensure more accurate market representation, recognizing the goal of balancing the demand for sufficient private sector data with the burden of data collection and reporting.

Physician office laboratory reimbursement, when compared to average payment amounts received by larger independent reference laboratories for the same tests, will often reflect differences in the cost structure of performing tests in the physician office setting as opposed to the reference laboratory setting. The tests that are performed in physician office laboratories are often "point-of-care" tests that provide immediate results, and allow the physician to treat based on those results. Physician office laboratories may perform the majority of these tests although these same physician offices may not have been required to report private payer rates because they were exempt under the low-expenditure threshold. This means that the weighted median would reflect the lower prices of the large independent reference laboratories that perform the same tests even though those laboratories represent a minority of those tests performed at the point of care. CMS' data would appear to support this conclusion. CMS noted that the private payer data reported to the agency by physician office laboratories represented only 7.5 percent of the laboratory data reported to CMS. The majority of test volume was reported by independent laboratories, including large reference laboratories, skewing the volume-weighted medians toward those large laboratories.

While the law requires CMS to calculate the volume-weighted median private payer rate and to use that data to establish new payment rates for 2018 and beyond, the application of the law, combined with the exclusion of the majority of physician office laboratories from reporting and the lower volume performed in those laboratories (relative to large reference laboratories) will result in significant reductions in payment for tests performed in physician office laboratories because the weighted median is unrepresentative of the physician office laboratories that actually perform the tests. In many cases, the new payment rates will be insufficient to cover the cost of providing those tests in the physician office laboratory, and could ultimately impact patient access to important and critical diagnostic tests. As these tests are performed at the point of care, sending them to independent laboratories to be performed will result in delays in providing care to patients.

Recommendation: CMS should modify the PAMA regulation to address data integrity concerns and market exclusions through a statistically valid process that is least burdensome on providers.

In summary, AdvaMed is concerned about the accuracy and reliability of the preliminary payment amounts that were announced by CMS in September. The rates represent substantial

payment reductions for many laboratory tests and the potential impact of those reductions for laboratories, clinicians, patients and other stakeholders is significant.

Again, we urge CMS to suspend the January 1, 2018, implementation date for these new payment rates and to work with stakeholders in the laboratory community to improve the accuracy of the rates. Once the new payment amounts become effective, they will remain in effect for three years and will not be updated based on inflation, or otherwise revised, until the next data collection and reporting period in or around 2020. The proposed rates have the potential to drastically distort the laboratory marketplace over the course of three years. Therefore, it is critical that the Agency take the necessary actions to get it right.

We appreciate the opportunity to provide these comments to CMS and are happy to respond to any questions you may have. If you have any questions about these comments, please contact me or Chandra Branham, JD, Vice President for Payment and Healthcare Delivery Policy at cbranham@advamed.org or (202) 434-7219.

Sincerely,

Donald L. May
Executive Vice President, Payment & Health Care Delivery Policy
AdvaMed