



**ASSOCIATION FOR MOLECULAR PATHOLOGY**

*Education. Innovation & Improved Patient Care. Advocacy.*

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October 23, 2017

Seema Verma, CMS Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

RE: Preliminary Determinations for Calendar Year 2018 (CY2018) for New Private Payor Rate-Based CLFS Payment System

Dear Ms. Verma:

On behalf of the Association of Molecular Pathology (AMP), thank you for the opportunity to submit comments on the Clinical Lab Fee Schedule (CLFS) on preliminary determinations for calendar year 2018 (CY2018) for the new private payor rate-based CLFS payment system. AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

**PAMA Preliminary Determinations**

Laboratories and the services they provide play a vital role in healthcare with it being commonly accepted that over 70% of clinical decisions are based on laboratory test results. Over the last two decades, molecular pathology procedures, including procedures for oncology, infectious disease, and inherited conditions, have become invaluable in the clinical management and treatment plan for patients, including Medicare beneficiaries. Recent advances in molecular diagnostic technologies, including next generation sequencing (NGS), are a cornerstone of precision medicine allowing rapid and accurate testing with demonstrated marked improvements in clinical outcomes for some of the toughest diseases to treat. Laboratories play a critical role in the delivery of effective care in the Medicare population, yet they only account for 3% of Medicare spending.

After carefully reviewing the raw data and preliminary rates calculated under the new methodology established by section 216 of the Protecting Access to Medicare Act (PAMA) of 2014, AMP has serious concerns about the data used for some pricing determinations and does not believe the preliminary rates for some tests accurately reflect market based private payer reimbursement. If finalized, these rates will negatively impact patient access to timely, high quality laboratory testing for Medicare beneficiaries.

Incorporation and adoption of molecular pathology procedures into clinical practice is threatened as a result of CMS's heavy handed approach in denying coverage or reducing payment for many medically necessary services. This has created a challenging environment for innovators to translate new genomic discoveries into clinical applications. PAMA further compounds these issues as the weighted median values for some procedures grossly misrepresents actual private payer rates with the proposed values well below the actual cost to perform these procedures. This testing is critical to the rapid diagnosis and development of targeted treatments for patients, particularly those with cancer, and detecting infectious disease outbreaks. In addition to reducing patient access, the pricing reductions are also expected to accelerate market consolidation in the space, rewarding larger centralized labs while causing the closure of smaller regional and local laboratories, thereby negatively impacting jobs in multiple communities.

Molecular pathology procedures are more susceptible to potentially faulty data for a few reasons. Unlike long-established laboratory procedures, the Tier 1 and Tier 2 molecular pathology procedures were established and put on the CLFS in 2012 and underwent gapfill in 2013. In 2014, the first genomic sequencing procedures were placed on the CLFS and gapfilled in 2015. The incorporation of molecular pathology procedures onto the CLFS continues to this day, as evidenced by CLFS annual meetings being dominated by the addition of molecular pathology procedures. As new codes are added to the molecular code set, it takes laboratories time to become familiar with them and code these services correctly. Additionally, the volume for many of the codes remains relatively low compared to the more well-established tests on the CLFS. Therefore, submission of inaccurate data impacts the weighted median to a larger degree for these codes. This is further evidenced by the submission volumes, as well as the number of molecular pathology procedure codes that had 10 or less TIN submissions. Relative to other code families on the CLFS, molecular pathology procedures have a large number of codes that do not have an established NLA and thus will not be subject to any phased in-reduction.

Of the over 230 molecular tests (including oncology, inherited diseases, and infectious diseases) on the Clinical Lab Fee Schedule (CLFS), 57% will receive a decrease while 20% will receive an increase from their 2017 NLA, with ninety molecular tests (or roughly 40%) receiving a decrease of 30% or more. While we understand that when passed, the intent of PAMA was to provide savings in the Medicare spending, the decreases in reimbursement dictated by the data appear to be seriously flawed based on our analysis. In the final PAMA rule, CMS estimated that the changes would result in \$390 million in savings and that on average CLFS rates would decrease by 5.6%. The change in reimbursement represented by these preliminary rates is even more significant, with price cuts totaling \$670 million.

Furthermore, there are 48 molecular codes for which CMS never established national pricing. For these services without a NLA, the PAMA weighted median will be the first price and there is no benchmark to which we can refer to determine if the weighted median was established with accurate data. Thus, these codes for which the preliminary PAMA determination represents an extreme change in pricing will have new rates established without a phased in reduction. One example is code 81244 (FMR1 gene characterization); this is an extremely labor intensive, manual procedure that requires small batch sizes, expensive reagents and is not amenable to automation. According to labs that perform the testing, the weighted median value only represents about a quarter of the cost for the procedure and does not adequately account for the resources required and thus cannot be an accurately representation of the private payor rates.

We appreciate CMS releasing a large data set, including the raw data for many codes, for stakeholders to review. However, the data set lacks raw data for the codes in which less than 10 TINs reported prices. There are 51 molecular service codes on the list of services where fewer than 10 TINs reported data, depriving AMP of the opportunity to review the raw data for outliers or other inaccuracies that may impact pricing.

Adjustments in pricing of this magnitude **must** be based on accurate data. We recognize that our members and others in the laboratory community who reported certified the accuracy of their data. However, a careful review of the raw data reveals unequivocal significant problems with proposed pricing for some codes. We strongly believe CMS should not finalize pricing for services for which there are clearly identified issues (some examples provided below), or for codes with strong evidence that the data is not accurate, e.g., there is wide or uneven distribution of the pricing data or evidence of statistical outliers that are inappropriately skewing the final result.

### ***Examples of Potentially Flawed Data***

AMP will not be able to provide a comprehensive analysis of the data by the October 23, 2017 deadline given the short time frame and large amounts of data that must be scrutinized. The analysis below represents a preliminary review and we plan to follow up with CMS in the near future with a more comprehensive analysis on the molecular pathology, genomic sequencing, and molecular infectious disease codes.

However, we are alarmed by the outliers in the data submitted for most molecular pathology procedures commonly utilized in the Medicare population. CPT code 81207 (BCR/ABL1 [eg, chronic myelogenous leukemia] translocation analysis; minor breakpoint, qualitative or quantitative) serves as the first example we would like to highlight of a service with preliminary PAMA pricing where we have serious concerns about the accuracy of the data. BCR/ABL1 minor breakpoint testing is a critical test used to diagnose certain types of leukemia that will not be detected by other test methods. The code was reported 8,629 times with a range in prices from \$0.94 to \$1,186. The disparity between the highest and lowest prices reported leads us to believe that CMS should closely reevaluate this data. The 2017 NLA for this code was \$198.68 and under PAMA, the target NLA based on the weighted median is \$93.45.

An issue also appears to exist where a high volume of reported payments and their corresponding price amounts do not cover the cost of providing a service. CPT code 81207 also provides an example for this issue. It had a reported volume of 60 with a \$10 price amount, compared to a 2017 NLA of \$198.68. The code also had 26 submissions under \$20 in payment. When the data shows repeated instances of reported pricing that would not even cover the cost of the service, AMP believes the data should undergo further review before finalizing pricing based on the weighted median is utilized.

Another example where the price of a test does not cover the cost to perform the test is CPT code 81435 (Hereditary colon cancer disorders genomic sequencing panel), a relatively new genomic sequencing panel testing code with low volume. This code is used to test patients and their family for the presence of a syndrome that predisposes to developing cancer. The code was only reported 1,379 times by 10 or fewer TINs. In this instance, the PAMA weighted median is \$37.99 while the 2017 NLA is \$802.33. Because there were so few labs who reported data, the raw data was not released. Without an opportunity to review the raw data, we cannot accurately assess what issues may exist. However, as the dramatic reduction in pricing might suggest, a reimbursement of \$37.99 is nowhere near sufficient to cover the cost for performing the test.

One theory behind this dramatic decrease for CPT code 81435 is that many labs may not have transitioned to the new code and still reported the price per gene rather than for the entire panel. The coding for the service may not yet be uniform and the data is unreliable as a result. The weighted median of \$37.99 is extremely low and in no way could represent what any reasonable lab would accept as reimbursement for the test. If finalized, these reductions in reimbursement to labs performing the testing will most likely limit beneficiary access to care. This example highlights the unique nature of many of the codes for molecular procedures for which the agency has released preliminary pricing.

CPT code 87798 (Infectious agent detection by nucleic acid [DNA or RNA], not otherwise specified; amplified probe technique, each organism) is another example of a service where the accuracy of the data reported appears to be questionable. The code was reported 1,606,449 times, with a weighted median of \$29.83 and had a range of reported values from \$0.01 to \$10,677.62. Such disparate values being true on their face are hard to believe.

In other instances, the cost of performing the test does not even reflect the cost of the test itself. For example, the weighted median for CPT code 81341 (TRB@ [T cell antigen receptor, beta], gene rearrangement analysis) is listed at \$0.01, which is roughly the cost of a single pipette tip and does not even begin to cover the cost of performing the test. T-cell receptor beta testing is a crucial test used in the diagnostically challenging task of diagnosing certain rare and often lethal forms of leukemia. The 2017 NLA was \$68.02. In these instances, it seems clear that there was confusion on the part of the reporting entities.

### ***Flawed Data May Have Resulted from Retrospective Reporting***

We believe that one of the reasons for the flaws in the data may have been that the first round of reporting payment rates to CMS required the reporting of retrospective data. The agency's regulation was finalized at the end of the first 6 month data collection period. Applicable labs were essentially required to guess nearly six months before the final rule was published what data should be collected with reporting requirements mandating that direct payments from non-bundled payments for CLFS codes be determined in a retrospective manner.

As a result of the delay in the release of the final regulations, there were inaccuracies in the data reported as large and small laboratories struggled to submit the required data. While CMS used its enforcement discretion to extend the reporting deadline until May 30, 2017, many laboratories reported difficulty in submitting comprehensive and accurate data.

### ***Definition of Applicable Laboratories***

Given the data for analysis CMS provided with the preliminary rates, AMP does not believe that the irrational decreases resulted from inaccurate representation of the various laboratory market segments. Therefore, at this time AMP does not recommend that CMS revise the definition of applicable lab. Further, AMP is concerned that given the challenges already identified, expanding the definition of an applicable lab would likely result in further inaccuracies and reporting errors. CMS has acknowledged that hospitals do not have the capacity to report.

### ***Recommendations***

CMS must recognize that the agency's decisions are not made in a vacuum. Any changes finalized by the agency will reverberate through the private market, as private payers base their annual contracts with laboratories off the final Medicare rates. Therefore, these PAMA rates will significantly affect laboratory testing and, by extension, the quality of care and access for patients suffering from serious health concerns ranging from cancer to infectious disease. When coupled with resulting job losses and lab closures, preventing at least some rates as currently calculated from going into effect is paramount.

To ensure continued patient access to this vital testing, AMP recommends that CMS should leave the 2017 NLA in place for codes where the validity of the data is questionable until accurate data is collected. One way to accomplish this would be for the agency to partner with knowledgeable experts in statistics and laboratory medicine to identify outliers in the data received. We recommend that CMS begin this inquiry by reviewing codes where the weighted median is either 30 percent greater or lower than the existing NLA. If the highest and lowest prices do not fall within a range deemed appropriate by these experts, CMS should not finalize

pricing until a weighted median is calculated with only the statistically reliable data or new data collected. CMS should allow the pricing to proceed as planned on January 1, 2018 for sole source clinical tests and for any services where the data has been validated. Additionally, AMP requests release of the raw data for less than 10 TINS to allow proper review of a significant number of molecular pathology procedures. Recognizing the potentially sensitive nature of such data, AMP is prepared to work with CMS to ensure appropriate privacy and market protections are in place and maintained.

Thank you for the opportunity to comment on the preliminary rates. We plan to work with CMS to ensure accurate data. These comments represent a preliminary review of the extensive data released by CMS. More time is required to comprehensively and adequately analyze the molecular pathology codes. We plan to follow-up with CMS with a more extensive review of the codes in the near future.

Sincerely,

Samuel K. Caughron, MD  
Chair, Economic Affairs Committee  
Association for Molecular Pathology