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U.S. Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

DELIVERED VIA EMAIL TO [CLFS\\_Annual\\_Public\\_Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov)

The American Society for Clinical Laboratory Science (ASCLS) is writing in response to the request for comments on the preliminary determination of payment rates for the 2018 Clinical Laboratory Fee Schedule.

ASCLS is the nation's oldest and largest non-registry professional association representing clinical laboratory professionals. The Society's mission includes vigorously promoting high standards in all aspects of clinical laboratory science practice, education and management to ensure professional competence, and ultimately to ensure excellent, safe, accessible, efficient, and effective laboratory services for consumers of healthcare. Our 9,000 members include clinical laboratory directors, managers, administrators, supervisors, and staff at all levels of practice and specialty.

As a professional society focused on assuring the efficacious delivery of the clinical data that underpins the entire healthcare system in the United States, ASCLS objects to the careless implementation of these proposed rates. If implemented, the loss of access to services will cause increased morbidity and mortality across the healthcare system, felt most acutely in elderly populations and those who live in rural areas.

The Proposed 2018 Clinical Laboratory Fee Schedule was engineered to circumvent Congressional intent, built on data collected almost exclusively from a small, narrowly-defined and homogenous subset of laboratories, and analyzed employing questionable methodologies.

Reductions to HCPCS Codes Without National Limitation Amounts (NLA)

The proposed fees for some HCPCS codes are as much as a 64 percent lower than what was reimbursed in many states in 2017. This ignores the intent of Congress, which sought to limit reductions to allow the market to adjust and minimize disruption to beneficiaries.

*(3)(A) "Payment Amounts determined under this subsection for a clinical diagnostic laboratory test... shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year greater than the applicable percentage..."*

For those HCPCS codes without a NLA, CMS failed to set a reasonable benchmark for current laboratory reimbursement, and instead, proposes implementing the weighted median in the first year. Some notable examples are:

| Test (Code)                 | State Median 2017 | Weighted Median | % Change |
|-----------------------------|-------------------|-----------------|----------|
| Lipid Panel (80061)         | \$18.37           | \$11.23         | -38.8%   |
| Acute Hep Panel (80074)     | \$64.35           | \$38.79         | -39.7%   |
| Estradiol Rsp Panel (80415) | \$76.66           | \$40.60         | -47.0%   |
| Gluc Tol Panel (80424)      | \$69.27           | \$34.69         | -49.9%   |
| Metyrapone Panel (80436)    | \$125.05          | \$69.35         | -44.5%   |
| Trh Stim Panel (80439)      | \$92.20           | \$33.07         | -64.1%   |

Where there is no NLA, CMS should **set the benchmark at the median of all the local coverage determinations for that code**. To do otherwise would force almost all laboratories to accept a larger than 10 percent decrease, which is forbidden under the law.

Data Collection Was Skewed and Resulted in Artificially Low Weighted Medians

The manipulation of the “applicable laboratory” definition by CMS intentionally skewed the data collection and artificially lowered the weighted median of payment rates.

After defining “applicable laboratory” in the narrowest possible terms, the Agency collected 90 percent of reported data from independent laboratories. Hospitals and physician office laboratories, which provide 44 percent of laboratory services under Medicare, represented just 8.5 percent of the reporting entities. Less than one percent of hospitals and physician office laboratories reported data. CMS admits that just 1.85 percent of data was collected from laboratories serving rural areas.

Hospital laboratories represent 24 percent of the laboratory billing from the CLFS, but data was collected from just 21 of the 6,994 hospital laboratories. Physician office laboratories represent 20 percent of the laboratory billing for Medicare, but only 1,106 out of approximately 236,000 POLs reported. (OEI-09-16-00040)

By comparison, independent laboratories represented 33.9 percent of the reporting entities and more than 90 percent of the reported data. Independent laboratories provide a valuable service, but function under different business models and serve fundamentally different roles in the healthcare system.

Smaller, local, independent, physician office and hospital laboratories, functioning closest to the patient and clinician, provide services for nursing home residents, patients requiring frequent testing for management of chronic conditions like diabetes and hypothyroidism, same day information for

oncologists to treat their patients undergoing chemotherapy or those suffering from infections that require rapid detection and identification for proper monitoring and treatment.

To serve the needs of their patients, local laboratories provide more rapid results drawn from more specialized test menus without economies of scale. The methods used by CMS to collect and interpret an incomplete dataset without validation excluded the possibility of measuring those differences.

#### Data Lacks Validation and Contains Significant Numbers of Errors

A basic review shows the reported data set provided by CMS to be riddled with unsupported outliers and clear errors.

One egregious example is 2,412,474 tests reported with a payment rate of zero, which represents ten percent of the reported test volume. Putting aside the legal issue of collecting “payment” data on tests for which a laboratory received no payment, this points to a lack of basic verification as well as confusion around what should and should not be reported on the part of laboratories.

The agency compounds the problem of “garbage in, garbage out” by using the data to create specious assumptions and feeding them into “simulations” to divine if broader reporting of data would have changed the outcome. Based on those “simulations,” CMS claims that additional reporting would not have made a “significant impact.”

However, this exercise deliberately ignores the fact that unreported data would likely be at higher payment rates, making the outputs entirely useless as a predictor of the actual market. In the analysis, CMS appears to consider the unreported and unobserved pricing as a null set and assumes that the missing data occurred randomly and the data set was of sufficient size and diversity that the law of large numbers would cause a natural return to the mean.

The uncollected data is likely to look very different than what was collected from a small homogeneous group in the data set. Data reported by hospitals and physician office laboratories would likely be at the 75<sup>th</sup> and 90<sup>th</sup> percentiles, not the mean assumed in the simulations.

We echo the now prescient concerns of the Department’s Office of Inspector General in 2016 that reported the lack of data validation.

*"Absent processes to verify whether applicable labs report their data or to verify the quality of data that labs report, CMS may set inaccurate Medicare payment rates for lab tests. PAMA required CMS to set Medicare payments rates for lab tests by using a market-based approach... If CMS does not have appropriate safeguards to ensure that all*

*applicable labs report complete and accurate data, it may result in new Medicare payment rates that are inaccurate.” (OEI-09-16-00100)*

#### A Deeply-Flawed Process Reducing Access to Care

The laboratory community has warned CMS and Congress during this entire process that the implementation of PAMA was improperly managed. The agency’s own analysis shows significant numbers of reporting entities don’t appear to meet the definition of applicable laboratories, and many more who should have reported didn’t. The analysis also shows that entities submitted inaccurate data. CMS exhibited a pattern excluding data that would have increased the weighted median, but included questionable data that lowered the weighted median.

In its 2016 report, the OIG estimated that 3,500 laboratories would report, but actual reporting entities number barely half that. Paired with the fact that the proposed fee cuts exceed the Congressional Budget Office estimated savings from PAMA by more than 300 percent, it is clear this implementation fails to maintain alignment with Congressional intent.

The wide-ranging impact these cuts will have on the entire healthcare system are too concerning to base on incomplete and unverified data, poorly analyzed. The implementation of these regulations is hopelessly broken and, if allowed to move forward, will cause a deterioration in the diagnostic and treatment capacity of clinicians, resulting in patient harm and deaths.

We urge the Department of Health and Human Services to **postpone implementation** until it can work with stakeholders to properly collect data that accurately reflects the market and demonstrate its ability to appropriately analyze that data.

We are happy to discuss our concerns in greater detail if you will find it helpful

Sincerely,



Debra Rodahl, MBA, MLS(ASCP)<sup>CM</sup>  
ASCLS President

cc: James Flanigan, CAE, Executive Vice President