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Centers for Medicare & Medicaid Services

Clinical Laboratory Fee Schedule (CLFS) Team

RE: Comments on Preliminary CY 2027 Clinical Laboratory Fee Schedule Payment Rates and Supporting Data

Dear CMS CLFS Team:

Thank you for the opportunity to comment on the preliminary Calendar Year 2027 Clinical Laboratory Fee Schedule (CLFS) payment rates and supporting data.

I have spent more than three decades working across clinical diagnostics, molecular diagnostics, and genomics, including the development, commercialization, reimbursement, and market access of diagnostic technologies. Today, as Founder and Managing Partner of The Deerborne Group, I advise Fortune 500 diagnostic companies, clinical laboratories, venture capital and private equity investors, and other stakeholders navigating many of these same issues.

I support the underlying principle of market-based reimbursement: Medicare payment for clinical laboratory services should appropriately reflect the commercial market. The effectiveness of such a system, however, depends on the quality, breadth, and representativeness of the commercial data used to establish those rates.

After reviewing CMS's preliminary CY 2027 results and supporting information, I believe several aspects of this reporting cycle warrant further consideration before the rates are finalized.

The 2026 reporting cycle represents a substantially broader market sample

CMS has made meaningful progress in expanding participation since the first PAMA reporting cycle. The number of laboratories submitting data increased from 1,942 in 2017 to 6,411 in 2026, an increase of approximately 230%.

The composition of the reporting population has also changed materially. Hospital laboratory participation increased from 21 laboratories in 2017 to 875 in 2026, while physician office laboratories increased from 1,106 to 3,262. CMS notes that regulatory changes made in 2019 were intended, in part, to facilitate greater hospital outreach laboratory participation and believes those revisions contributed to increased hospital reporting in 2026.

Broadening the dataset is an important development. At the same time, the magnitude of the change in both the size and composition of the reporting population raises an analytical question that I believe is important to understanding the preliminary CY 2027 results:

To what extent are changes in the weighted median private-payor rates attributable to changes in commercial reimbursement, and to what extent are they attributable to changes in the composition and volume distribution of the laboratories now represented in the dataset?

Understanding that distinction would provide useful context for laboratories, diagnostic developers, investors, and other stakeholders evaluating the resulting rates.

The magnitude and distribution of the preliminary changes deserve closer examination

CMS reports that the preliminary private-payor data would produce an average potential reduction of approximately 16% relative to CY 2026 CLFS rates before application of the statutory phase-in provisions.

The results are not uniform across laboratory medicine.

CMS reports potential weighted-rate changes of approximately:

- 22% lower for Molecular Pathology;
- 23% lower for Genomic Sequencing;
- 19.3% lower for Microbiology;
- 19.3% lower for Immunology; and
- 2.4% lower for Proprietary Laboratory Analyses (PLA).

The difference between the results for Molecular Pathology and Genomic Sequencing and those for PLA codes is particularly noteworthy.

There may be multiple explanations for this divergence. PLA codes are test-specific and may differ from conventional molecular pathology and genomic sequencing codes in utilization, laboratory concentration, market maturity, commercial contracting, test mix, and other characteristics. The aggregate data alone does not establish causation. Nevertheless, a difference of this magnitude warrants examination.

It raises a broader question about whether different coding structures and market characteristics are capturing commercial reimbursement in materially different ways—and, if so, what those differences tell us about the market signal being used to establish Medicare payment rates.

The underlying distribution matters as much as the aggregate result

CMS reports that 1,528 HCPCS codes received a weighted median from private-payor data. Of those with comparable CY 2026 rates, 1,171 have a lower weighted median, 186 have a higher weighted median, and 169 are unchanged.

CMS has also taken steps to improve data quality by removing exact duplicate records and payment-rate observations exceeding 100 times the CY 2026 CLFS payment rate. Publishing calculations both before and after these exclusions is helpful and provides stakeholders greater visibility into the methodology.

Given the breadth of the resulting payment changes, additional analysis of the underlying distributions could further strengthen confidence in the final rates. It would be useful to understand the degree to which the preliminary changes within major test categories are driven by:

- changes in the mix of reporting laboratory types;

- concentration of testing volume among reporting laboratories;
- changes in private-payor rate distributions since the previous reporting cycle; and
- differences in the characteristics of tests represented by conventional CPT and PLA coding structures.

This information would help distinguish broad changes in commercial reimbursement from changes arising from the composition of the market sample itself.

Broader policy context

These questions arise at a time when Congress is separately considering potential changes to the private-payor-based CLFS framework through the bipartisan Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act.

CMS, of course, must administer the CLFS under current law. I mention the legislation not to suggest otherwise, but because the broader policy discussion underscores the importance of accurate and representative commercial-market information in establishing Medicare laboratory payment rates.

The preliminary CY 2027 data provide an important opportunity to evaluate how the current methodology is functioning with a substantially larger and more diverse reporting population than was available during the first PAMA reporting cycle.

Conclusion

CMS should be commended for making the preliminary rates and supporting data available for public review and for substantially expanding participation in the private-payor reporting process.

The broader dataset represents meaningful progress. At the same time, the magnitude of the preliminary changes—particularly within Molecular Pathology and Genomic Sequencing—and the substantial divergence between those categories and Proprietary Laboratory Analyses raise questions that merit careful examination before the CY 2027 rates are finalized.

A sustainable, market-based laboratory payment system does not require preserving every existing reimbursement rate. It does require confidence that the market information underlying those rates accurately and appropriately represents the diagnostic services being reimbursed.

Thank you for the opportunity to provide these comments and for your consideration.

Respectfully,



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