

October 20, 2026

Administrator Mehmet Oz, MD
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: median data
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Median Data - Preliminary CY 2027 CLFS rates and supporting data files

Submitted electronically via CLFS_Annual_Public_Meeting@cms.hhs.gov

Dear Administrator Oz,

UnityPoint Health appreciates the opportunity to comment on the preliminary Calendar Year (CY) 2027 Medicare Clinical Laboratory Fee Schedule (CLFS) payment rates. UnityPoint Health is one of the nation's most integrated healthcare systems. Through more than 31,000 employees and our relationships with more than 420+ physician clinics, 35 hospitals in urban and rural communities, 13 home care areas of service, and 5 community mental health centers across our 8 regions, UnityPoint Health provides care throughout Iowa, central Illinois, southeast South Dakota, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health agencies provide a full range of coordinated care to patients and families through more than 8 million patient visits, including many rural and medically underserved areas.

Serving as a critical diagnostic service for the system, **UnityPoint Health laboratories provide comprehensive laboratory and pathology services to patients in our hospitals, clinics, and home health settings. Laboratory services are also provided to nursing home residents, assisted living facilities, physician offices, and other hospitals in many regions. Our laboratories perform thousands of tests daily and over 14 million tests annually.** Testing is offered in all general laboratory disciplines and some specialty services for clinical and anatomical pathology. Our team of dedicated professionals use their knowledge, expertise, skills, and abilities to provide a high-quality, full-service laboratory for our providers, patients, and families.

As a member of the American Society for Clinical Pathology (ASCP), UnityPoint Health generally supports the ASCP's comment letter to these preliminary rates. UnityPoint Health respectfully offers the following comments.

PRELIMINARY CY 2027 CLINICAL LABORATORY FEE SCHEDULE (CLFS) RATES

CMS seeks to better align the 2027 CLFS rates with private sector payment rates. Based on collection of “applicable information” from certain laboratories, CMS calculated a weighted median and attempted to control for unreliable private payer data. CMS concluded that Medicare has been paying about 16% more for laboratory services than private payors. CMS is publishing the preliminary payment rates with and without exclusions and is requesting public comment on whether this approach is appropriate for calculating the final weighted median private payor rates.

Comment: UnityPoint Health strongly opposes the magnitude of the proposed payment reductions and urges CMS to carefully evaluate whether the underlying data accurately reflect the clinical laboratory marketplace and the essential role hospital-based laboratories play in supporting patient care.

CMS' preliminary analysis indicates that 1,171 laboratory services would receive lower payment rates, while only 186 services would receive higher rates and 169 would remain unchanged. CMS further estimates that the resulting rates are approximately 16 percent lower on average than current CLFS rates and would generate approximately \$1 billion in annual Medicare savings. While program integrity and appropriate payment are important objectives, reductions of this magnitude threaten patient access, workforce stability, diagnostic innovation, and the sustainability of hospital-based laboratory services. Further, UnityPoint Health estimates the proposal will reduce annual laboratory reimbursement by \$4 million, affecting approximately \$2.2 million in hospital laboratory services and \$1.8 million in outreach testing.

Continuing Concerns Regarding Data Representativeness

CMS reports that hospital laboratory participation increased substantially during the most recent reporting cycle, growing from 21 reporting laboratories and approximately 1.1% of reporting entities in the original reporting cycle to 875 reporting laboratories and approximately 13.6% of reporting entities in the 2026 reporting cycle. **UnityPoint Health appreciates CMS' efforts to broaden participation and acknowledges that the current data set includes significantly more hospitals than prior reporting cycles. However, increased participation should not be conflated with representativeness.** CMS has demonstrated that more hospital laboratories participated in reporting, but it has not demonstrated that the reporting hospitals reflect the diversity of hospital laboratories nationwide, including rural and urban hospitals, community hospitals, integrated health systems, teaching institutions, and hospital outreach laboratories. Moreover, because CLFS payment rates are based on volume-weighted private payer data, representation by laboratory count alone does not demonstrate that hospital laboratories are proportionately represented in the underlying payment calculations. CMS has not provided information regarding the share of reported test volume attributable to hospital laboratories relative to other laboratory sectors, making it difficult to assess whether the resulting weighted median rates adequately reflect the operational realities of hospital-based laboratory services.

Hospital laboratories operate fundamentally differently than large commercial reference laboratories. In addition to outreach testing, hospitals maintain 24-hour laboratory operations supporting emergency departments, trauma services, inpatient care, intensive care units, labor and delivery services, oncology programs, and other critical clinical functions. Laboratories must sustain these capabilities regardless of testing volume, reimbursement levels, or profitability.

UnityPoint Health remains concerned that the current weighted median methodology does not adequately account for these operational realities. We question whether a payment methodology intended to reflect market rates accurately captures the diversity of the laboratory sector when nearly four out of every five laboratory services receiving updated payment determinations would experience reimbursement reductions under the proposal.

Historical Concerns with PAMA Implementation

The concerns raised by UnityPoint Health are not new. Since implementation of the Protecting Access to Medicare Act of 2014 (PAMA), Congress has repeatedly intervened to delay or mitigate PAMA-related payment reductions. Since 2019, Congress has enacted multiple laws¹ modifying reporting requirements and delaying scheduled CLFS cuts due to persistent concerns regarding data representativeness, payment adequacy, and patient access to laboratory services. These repeated bipartisan actions reflect a longstanding recognition that significant concerns with the current methodology remain unresolved.

Prior PAMA implementation resulted in billions of dollars in laboratory reimbursement reductions and years of financial uncertainty for laboratories across the country. Laboratories have absorbed these reductions while maintaining 24-hour testing operations, investing in new technologies, addressing workforce shortages, and meeting growing demand for molecular and precision medicine testing. **The proposed CY 2027 reductions therefore represent another round of cuts layered upon nearly a decade of reimbursement pressure.** For many laboratories, including hospital-based laboratories, the cumulative effect of these reductions poses a growing threat to diagnostic innovation, workforce sustainability, and patient access to testing services.

Impact on Patient Access and Rural Healthcare

Clinical laboratories are essential to nearly every patient care decision. Laboratory testing supports disease diagnosis, treatment selection, medication management, population health initiatives, infection prevention, emergency care, chronic disease management, and precision medicine across virtually every medical specialty. Laboratories serving hospitals, nursing homes, and rural communities were significantly affected by prior PAMA reductions despite serving some of Medicare's most vulnerable beneficiaries. These laboratories provide rapid and reliable testing that clinicians depend upon every day to triage patients, identify emerging health concerns, monitor disease progression, and make timely adjustments to treatment plans.

Continued reimbursement reductions may diminish local testing capacity. Hospitals and community-based laboratories serve as frontline diagnostic resources for hospitals, nursing homes, long-term care facilities, physician offices, and rural communities. **When local testing becomes less sustainable, laboratories may be forced to shift more testing to distant reference laboratories. This can increase turnaround times, delay diagnosis and treatment decisions, reduce opportunities for clinician consultation, and limit providers' ability to respond quickly to changing patient conditions.** For

¹ Legislative actions include the Further Consolidated Appropriations Act, 2020 (P.L. 116-94); the Consolidated Appropriations Act, 2021 (P.L. 116-260); the Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71); the Consolidated Appropriations Act, 2023 (P.L. 117-328); the Further Consolidated Appropriations Act, 2024 (P.L. 118-47); and the Consolidated Appropriations Act, 2026 (P.L. 119-75).

vulnerable Medicare beneficiaries, timely access to laboratory results is essential to diagnosis, treatment, and ongoing disease management.

Hospital-based laboratories frequently provide testing services that are not available elsewhere in their communities. This is particularly true in rural and medically underserved areas where community hospitals often serve as the primary source of diagnostic testing. Significant reimbursement reductions may force laboratories to reevaluate testing menus, staffing models, technology investments, and local testing capacity. As financial pressures increase, patients may experience longer turnaround times, greater reliance on distant reference laboratories, and reduced access to timely diagnostic information. For integrated health systems such as UnityPoint Health, laboratory services are critical healthcare infrastructure supporting emergency departments, inpatient care, oncology programs, nursing home residents, rural communities, and population health efforts. Medicare payment policies should strengthen, rather than weaken, these capabilities.

Impact on Advanced Diagnostics and Precision Medicine

UnityPoint Health is particularly concerned about the impact of the proposed reductions on advanced diagnostic testing categories. CMS reports average potential reductions of approximately 22 percent for molecular pathology testing, 23 percent for genomic sequencing procedures, and more than 19 percent for both microbiology and immunology testing categories.

These testing areas are among the most clinically significant and rapidly evolving sectors of laboratory medicine. Molecular diagnostics, genomic sequencing, biomarker testing, immunology, and advanced microbiology testing increasingly guide treatment decisions, support precision medicine initiatives, improve infectious disease management, and help clinicians deliver more personalized care. In oncology, biomarkers such as HER2, PD-L1, MMR, and other emerging molecular targets routinely determine patient eligibility for targeted therapies and immunotherapies. As cancer treatment continues to evolve, clinicians increasingly rely on molecular and biomarker testing to identify effective therapies, monitor disease progression, and reassess treatment options throughout the course of care. Precision medicine is no longer a future concept; it is an increasingly important component of routine patient care.

Medicare payment policies should support continued investment in advanced diagnostic capabilities.

Reductions of this magnitude risk slowing adoption of emerging technologies at a time when healthcare is increasingly dependent upon molecular diagnostics, genomic testing, biomarker-driven treatment selection, and precision medicine to improve outcomes and avoid ineffective therapies. For UnityPoint Health, the proposed reductions would affect advanced diagnostic services critical to patient care including testing categories supporting approximately \$300,000 in oncology and molecular testing.

Workforce Challenges

Like healthcare organizations nationwide, UnityPoint Health continues to face significant challenges recruiting and retaining qualified laboratory professionals. Workforce shortages remain among the most pressing operational challenges facing clinical laboratories, particularly in rural communities and specialized laboratory disciplines. To support workforce sustainability, UnityPoint Health has invested in career ladder programs, training pathways, competency development, and entry-level opportunities that help expand the pipeline of future laboratory professionals. However, these investments require financial

resources and long-term stability. Continued reimbursement reductions limit laboratories' ability to recruit, train, develop, and retain highly skilled personnel while simultaneously maintaining 24-hour operations, implementing new technologies, and meeting growing demand for increasingly complex testing services.

The impact extends beyond laboratory staffing levels alone. As reimbursement pressure increases, laboratories may be forced to defer workforce investments, delay implementation of training and career development programs, postpone technology upgrades, and reduce recruitment efforts. These pressures can limit local testing capabilities and make it more difficult to sustain specialized laboratory expertise.

Medicare payment policies should support workforce development and local employment rather than accelerating consolidation of laboratory services away from the communities they serve.

Need for Long-Term Reform

UnityPoint Health supports efforts to improve the accuracy, transparency, and representativeness of laboratory payment methodologies. Congress originally intended PAMA to establish a market-based payment system that reflected the diversity of the clinical laboratory marketplace. However, repeated congressional intervention and continued stakeholder concerns demonstrate that significant questions regarding data representativeness and payment adequacy remain unresolved. A payment system that repeatedly requires legislative relief warrants further evaluation and reform.

Future reforms should utilize market data that more accurately reflect all segments of the laboratory industry, including hospital-based laboratories, rural hospitals, integrated health systems, physician office laboratories, and independent laboratories. **A sustainable methodology should support patient access, reduce administrative burden, improve payment stability, preserve local testing capabilities, and encourage continued investment in workforce development, diagnostic innovation, and precision medicine.**

Conclusion

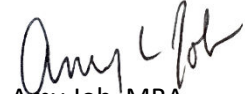
UnityPoint Health respectfully urges CMS not to finalize the preliminary CY 2027 payment rates as proposed. CMS' own analysis indicates that 1,171 laboratory services would receive lower payment rates under the proposal, including substantial reductions affecting molecular pathology, genomic sequencing, microbiology, and immunology testing. These reductions would disproportionately affect hospital-based laboratories and risk weakening patient access to timely, high-quality diagnostic services.

We remain concerned that the underlying data do not adequately represent the diversity of the laboratory marketplace or the unique role hospitals play in supporting emergency care, inpatient services, oncology programs, rural healthcare, and precision medicine. We encourage CMS to pursue a more representative and sustainable payment methodology that preserves patient access, supports workforce investments, promotes diagnostic innovation, and recognizes the essential role of hospital-based laboratories.

We are pleased to provide input on the preliminary CY 2027 CLFS rates and their impact on our clinical laboratories, patients, and communities. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Government & External Affairs at

Cathy.Simmons@unitypoint.org or 319-361-2336.

Sincerely,



Amy Job, MBA

Executive Director, Enterprise Laboratory Services



Amanda Vaske, MLS (ASCP)^{CM}

Director, Revenue Cycle - Laboratory



Cathy Simmons, JD, MPP

Executive Director, Government & External Affairs