Lab Payment & Policy Outlook for 2026

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Learning Objectives

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- Analyze how recent advancement of the “Unitary Executive Theory” has affected the decision by CDC to eliminate CLIAC and FDA’s decision to withdraw a rule to regulate laboratory-developed tests (LDTs)
- Evaluate how the One Big Beautiful Bill Act will impact Medicaid spending, pathology reimbursement and labs tied to state funding
- Find out how Congress deals with extending Affordable Care Act (ACA) premiums and whether the White House advances an alternative approach
- Identify the latest legislative and regulatory developments affecting Medicare reimbursement and policy for labs & pathologists and preview what’s ahead for payment rates in 2026
- Examine how LDTs are regulated now at the federal level

Today’s Agenda

- How the “Unitary Executive Theory” Affects Labs
- One Big Beautiful Bill Impact on Labs & Pathologists
- Update on the ACA and GOP Alternatives
- Medicare Payment Update for Labs & Pathologists
- What New PAMA Legislation Would Do & Will It Pass
- Outlook for LDT Oversight at the Federal Level

The “Unitary Executive” Impact on Health Policies & Labs

Focus on "Unitary Executive” Concept

- Unitary executive theory holds that the U.S. Constitution’s Vesting Clause gives the President sole authority over the executive branch of government
- Legal disagreements over how much power and discretion the president has
- Critics pointing to other parts of the Constitution providing for checks & balances of executive power
- Congress cedes power to the Executive Branch
- Supreme Court has embraced a strong unitary executive and held “the entire ‘executive power’ belongs to the President alone”[1]

[1] Seila Law LLC v. Consumer Financial Protection Bureau, 2020

Executive Orders Shape Health Policy

- Withdraw U.S from World Health Organization
- End COVID-19 vaccine mandates for children & schools
- Establish the Make America Healthy Again (MAHA) Commission
- Impose new constraints on executive branch regulatory agencies
- Implement “Most Favored Nation” prescription drug pricing
- Improve safety and security of biological research

Primacy of the Executive Branch

- Hire and fire any federal employee of the executive branch and authority over every federal agency including independent agencies (FTC)
- Remove or retire agency leaders including senior executives/scientists at CDC, FDA & NIH and cut HHS workforce by 20,000+
- Disband federal agencies (USAID) and slash billions of dollars of federal research grants (NIH)
- Lab impact: axing CLIAC[1] by CDC and rescinding final LDT rule by FDA

[1] Clinical Laboratory Improvement Advisory Committee (CLIAC)

One Big Beautiful Bill Act

Medicaid Takes Hit Under OBBBA

- Signature legislation containing tax and spending policies forming the core of President Trump's second-term agenda [1]
- CBO estimates OBBBA raises budget deficit over $3.4 trillion by 2034[2]
- OBBBA cuts over $1 trillion from health programs, the largest rollback in federal support for health care in U.S history[3]
- Slashes federal support of Medicaid by 911 billion (12%) over 10 years with an estimated 10M people to lose health insurance coverage
- Reduces access to health insurance coverage through the ACA marketplaces and allows a scheduled expiration of enhanced ACA tax credits at the end of 2025

1 One, Big, Beautiful Bill Act (OBBBA) , Public Law 119-21 (139, Stat. 72)

2 CB0 Estimated Budgetary Effects Public Law 119-21

3 Kaiser Family Foundation Policy Brief, July 23, 2025

OBBBA Impact on Medicare

- Provides temporary one-year 2.5% conversion factor update under the Medicare physician fee schedule for 2026
- Blocks Medicare Savings Program improvements which prevents eligible beneficiaries from making Medicare more affordable
- Prevents implementation of national nursing home standards
- Forbids Medicare from negotiating prices for orphan drugs
- OBBBA deficit increase projected to trigger automatic, across-the-board budget cuts required under the 2010 PAYGO law to mandatory spending programs including Medicare unless Congress intercedes
- Congress expected to waive mandatory cuts as it has done previously

What Lab Industry Can Expect from OBBBA

- With big Medicaid cuts, labs dependent of Medicaid funding are most hurt
- Medicaid-focused lab providers can expect the biggest impact
  - nursing homes
  - toxicology/drugs-of-abuse
  - women's health
  - prenatal and reborn screening for rare diseases
- This may give affected labs more time to prepare for the impact they face from Medicaid cuts and possibly allow Congress to delay or amend OBBBA after the 2026 mid-term congressional elections

2026 ACA Update and GOP Alternatives

Congress Debates Renewal of ACA Tax Credits

- Congressional GOP leadership and President Trump have been opposed to renewing ACA premiums which expired last year
- Using a discharge petition, House passed a 3-year extension of the ACA enhanced premium tax credits on Jan 8
- House bill goes to the Senate which previously failed to approve a similar measure and is unlikely to pass the House legislation in its current form
- Some lawmakers are hopeful the House bill will serve as a starting point for a broader compromise ACA premium measure

What’s Ahead for ACA & GOP Push for Changes

- Bipartisan groups of Senators working on deal to revive ACA subsidies
- Compromise would reestablish enhanced ACA tax credits for two years
- Measure would include new restrictions including minimum premium payments and income caps
- Possible option for those receiving subsidies to choose to have federal money go instead into private health savings account during second year of extension
- Final passage of ACA compromise legislation by Congress is a decidedly uphill battle with President Trump publicly indicating he may veto it
- President Trump unveils “Great Healthcare Plan” and Congress clinches a bipartisan healthcare deal that doesn’t address the ACA enhanced premium issue

Lab Payment Outlook for 2026

Medicare Lab Payments in 2026

- Spending legislation to end the government shutdown that Congress passed in Nov 2025 included a 30-day delay to scheduled lab fee cuts required by PAMA[1]
- H.R. 5271 delayed from Jan 1 to Jan 30, 2026 cuts that would have resulted in up to a 15% reduction for more than 800 tests on the Clinical Laboratory Fee Schedule[2]
- Legislation also delayed private payor data reporting by labs that now would be Feb 1 to Apr 30, 2026, and based on the original data collection period of Jan 1 to June 20, 2019
- From Jan 31, 2026 through 2028, payment may not be reduced by more than 15% per year compared to payment amount established for a test for the preceding year

[1] Protecting Access to Medicare Act (PAMA) of 2010 , P.L. 113-93

[2] Continuing Appropriations Ac of 2025 (H.R. 5371) P.l.119-37

More Medicare 2026 Updates

- Specimen collection fee for routine venipuncture during 2026 is an estimated $9.34 and $11.34 for a Medicare patient in a SNF or by a lab on behalf of HHA[1]
- Travel allowance milage fee for CY 2026 is $1.25HA[1]
- CY 2026 national minimum payment amount for pap smear is $18.54[2]
- Annual update for laboratory services made on a reasonable charge basis is 1.9%[2]
- Final 2026 Medicare Physician Fee Schedule will set a net increase of about 0.5% for pathology services based on the temporary 2.5% legislative pay bump which is offset by cuts from new "efficiency adjustments" & practice expense changes[3]
- Medicare sequestration cuts of 2% for Part B providers such as lab and pathology services are continued through 2032

1 CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 13576, Jan 8, 2026

2 MLM Matters: Clinical Lab oratory Fee Schedule: 2026 Annual Update

3 *Federal Register*, Nov 5, 2025

Some Lab Tests To Be Hit Hard Absent Hill Action

- Without congressional action to either freeze or reform PAMA cuts, some industry expert projects Medicare CLFS rates would drop an average of 8.5% in 2026 based on its analysis of the top 25 tests by Medicare Part B carrier allowed charges[1]
- Among lab tests facing the maximum 15% cut include CPT 80061 (Lipid panel), CPT 87481 (Candida by PCR) and CPT 87801 (Detect agent, multiple organisms, by PCR)[2]
- Medicare rate cuts may also influence other payers, including most commercial insurance plans that tie lab test rates to a percentage of the Medicare CLFS
- Unless Congress either continues to freeze CLFS rates or amends PAMA by the end of January, scheduled cuts will take effect Jan 31, 2026

[1] *Laboratory Economics (LE), Volume 20, No 6, June 2025, p 4*

[2] *LE, Vol. 20. No 6, June 2025, p 4*

Will Congress Again Prevent PAMA Cuts?

- Congress has frozen lab cuts mandated PAMA 5 times since 2020 based on Congressional Budget Office finding that it saved the government money
- Whether Congress does so again depend on CBO's analysis of the savings or costs of freezing lab fees
- Making any changes to PAMA in 2026 would requires a legislative vehicle
- These include possible compromise legislation to extend ACA expired enhanced tax credits and a full year 2026 appropriations bill required by Jan 30 to avoid another government shutdown
- Other vehicles are must-pass health legislation due in January include expiring FDA User Fee authority and rural health and hospital funding

CBO Error May Impact Future PAMA Rate Freeze

- For past 5 years the Congressional Budget Office has forecast that freezing PAMA rates would save the government money
- CBO's forecasting model assumed private insurance companies were adjusting the rates they pay for lab tests by annual inflation (as measured by the CPI)
- Given this assumption, CBO held that future PAMA private payer payment surveys would result in higher Medicare CLFS rates
- This led CBO to conclude that delaying PAMA implementation would save money, and this gave Congress its rationale for freezing Medicare lab rates

Revised CBO Model Makes Lab Freeze Tough

- CBO now acknowledges that private insurance companies don't typically adjust their lab test fees for inflation
- This has led to an updated CBO forecasting model minus the inflation factor for estimating Medicare CLFS payment.
- Thus a delay in implementing PAMA may not be scored as saving money, making it more difficult for Congress to freeze PAMA rates again in 2025
- Significantly, CBO scored a 30-day delay in Medicare CLFS rate cuts from Jan 1 to Jan 30 to cost the government $49 million over 10 years
- Revised CBO forecasting model raises urgency of reforming PAMA

PAMA Changes Under RESULTS Act

Failure of Previous PAMA Bills

- Prior PAMA reform measures - Lab Act (2019) and SALSA[1] (2022)[1] failed primarily because of their estimated costs
- CBO scored SALSA to cost $6 billion over a 10-year span
- SALSA limited how much lab fees could rise or be cut annually and ensured that all labs (especially hospital labs) were fairly represented in future surveys used to formulate CLFS fee
- Key barrier to passage was CBO score which requires legislators to identify savings to offset PAMA reform costs[2]

1 Saving Access to Laboratory Service Act
2 Pay-As-You-Go (PAYGO) budget law of 2010, P.L. 111-39

New PAMA-Fix Bill Pending in Congress

- New legislation to fix PAMA - the Reforming and Enhancing Sustainable Updates to Laboratory Testing Services (RESULTS) Act - was introduced Sep 10, 2025 in both the House & Senate
- The bill has gained significant bi-partisan support with some four dozen co-sponsors in the House
- House Commerce & Energy health subcommittee held hearing on Jan 8
- Legislation has not yet been scored by CBO
- Goal of lab lobby groups (ALCA, NILA, etc.) is to attach the RESULTS Act to a broader healthcare package being considered by Congress

1 H.R. 5269/2761 in 119th Congress

Summary of RESULTS Act Provisions

- Freeze Medicare CLFS rates at current levels form 2026-2028
- Medicare lab payments for 2029 would be based on weighted median private payer rates from Jan 1 to June 30, 2027
- Labs would no longer be required to report their private-payer payment data
- Data would be supplied to CMS from a claims data base (including at leas 50 billion claims from more than 50 private payers) from an independent non-profit entity (e.g., the FAIR Health Database[1])
- Rate deductions would be limited to 5% with no cap on rate increase

[1] https://www.fairhealthconsumer.org

RESULTS Act Summary

- Private-payer payment data would be collected and analyzed every four years (instead of current three years)
- Special reporting rules would apply to non-widely available lab tests codes (100 or fewer labs perform) and Advanced Diagnostic Laboratory Tests (ADLTs)
- Most important changes: removes the reporting burden from labs and decreases the yearly limits of cutting rates while removing the cap on rate increases

RESULTS Act Faces Key Hurdles

- Possibility of another government shutdown, fierce partisan divide & fast-approaching 2026 mid-term election cycle creates unstable political climate for advancing legislation on Capitol Hill
- Limited time this year to advance RESULTS Act before scheduled PAMA cuts take effect on Jan 31, 2026
- Biggest obstacle in getting PAMA reform bill through Congress is CBO score of bill which is likely to tally billions given 3-year freeze proposed for Medicare CLFS fees
- Finding offsetting savings remains crucial barrier to passage

Outlook for LDT Oversight

Legal Demise of the LDT Rule

- In May 2024, FDA issued a final rule to regulate laboratory-developed tests (LDTs) by phasing out its decades-long policy of enforcement discretion across five stages[1]
- Rule required most LDTs to comply with the same regulatory framework as medical devices & other IVDs & seek premarket clearance or approval before use
- In case filed by ACLA opposing the LDT rule, the U.S. District Court for the Eastern District of Texas struck down the FDA rule entirely in March 2025[2,3]
- The Court ruled that the agency exceeded its statutory authority and that LDTs (services performed within a single laboratory) are not ”devices” under the Food Drug & Cosmetic Act

1 *Federal Register* (89 FR 37296), May 6, 2024

2 American Clinical Laboratory Association et alv. U.S. Food & Drug Administration et al (Filing 93)), May 29, 2024

3 U.S. District Court Eastern Of Texas Sherman Division Memorandum Opinion and Order,, (Document 93), March 31, 2025

FDA Rescinds LDT Rule

- Final May 2025, FDA declined to appeal a federal court ruling that invalidated its final LDT rule following a 60-day appeal window[1]
- FDA Office of Regulatory Affairs published notice in August 2025 announcing that the agency had officially rescinded the LDT rule previously vacated by a U.S. District Court[2]
- FDA issued a new final rule reverting the text of its applicable device. regulations to the version in effect prior to May 2025 final rule
- The practical effect of FDA's new LDT rule is to maintain the status quo, exercising enforcement discretion for LDTs and permitting the use of LDTs. without clearance or approval by the agency

1 *Federal Register*,(FDA) Vol 90, No. 150, August 21, 2025

2 *Federal Register (HHS/FDA) Vol 80, No, 180, September 19, 2025*

Outlook for LDT Federal Oversight

- Absent FDA enforcement, labs offering LDTs must still comply with CLIA requirements and standards set by private accrediting bodies plus possibly scrutiny by payers & state regulator
- FDA continues to maintain authority to intervene when LDTs present safety concerns, are improperly promoted, or otherwise fall outside the parameters of CLIA oversight
- Though further changes in LDT regulation is not likely under the Trump White House though future Administration may craft a narrower rule
- Another possible alternative is enacting new legislation (similar to the VALID Act[1]) to affirm FDA's authority over LDT's

1 Verifying Accurate Leading-edge IVCT Development (VALID) Act OF 2025, H.R. 3694

Thank you

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