



Lab Payment & Policy Outlook for 2025

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Learning Objectives

- Examine how lab sector is being impacted by key national trends
- Assess what labs can learn from latest Medicare test volume and spending data
- Discuss what's ahead for Medicare payment rates for labs and pathologists in 2025
- Identify key takeaways for labs from a series of major regulatory initiatives affecting PT, CLIA, LDTs and an FTC ban on non-competes
- Understand how a new Administration & Congress will exert influence on healthcare & lab policy going forward



Today's Agenda

- Four Important Trends Affecting Labs
- Tracking Test Volume & Spending Data Under Medicare
- Medicare Outlook in 2025 for Labs & Pathologists
- Significant Regulatory Actions Impacting Labs
- What Labs Can Expect From the New Administration & Congress



Key Trends for Labs



Key Trends to Watch

- Wave National Election Signals Political & Policy Reckoning
 - GOP trifecta ushers in era of populism in Nation's Capitol
 - Wide-ranging executive actions by new Administration
 - Shaking up healthcare: ACA, Medicare/Medicaid & regulatory reforms
- Personalized Healthcare Revolution
 - AI & automation are transforming healthcare by driving innovation
 - Moving from reactive to preventive measures to improve patient outcomes
 - Revolutionizing diagnostics by improving accuracy & efficiency



Critical Trends Impacting Labs

- People & Customer Experience As Vital Differentiators
 - Similarity of many lab services blurs customer perspective
 - Caliber of lab staff is critical in strengthening quality & driving innovation
 - Excellent customer service builds patient trust, satisfaction & drives loyalty
- Medicare Prime Target For Future Budget Cuts*
 - NHE grew 7.5% to \$4.9 trillion in 2023 and was 17.6% of GDP
 - Medicare spending grew 8.1% to \$1 billion in 2023 and is projected to double to \$2 trillion or 5.1 percent of GDP by 2033
 - Without congressional action, seniors will face an 11% cut to Medicare Part A benefits in 2036
 - One option is PAYGO sequester: automatic 4% Medicare cuts

* CBO Report on Update to Budget and Economic Outlook; 2024 TO 2034, June 18, 2024



Medicare Volume & Spending Data



Medicare Part B Spending on Lab Tests Decreased in 2023*

- In 2023, total Medicare Part B spending on lab testing dropped by 5.4% compared to 2022
- Since 2021, Medicare spending for lab tests has decreased from \$9.3 billion to \$8.0B or a drop of 15.4%
- With payment rates holding steady, changes in spending were mainly driven by test volume
- Decline is largely due to a 55% decrease in Covid-19 testing from 2022-2023

** Office of Inspector General report dated Dec 2024 (OEI-09-24)*



Trends in COVID-19 Testing

- Total Medicare spending on COVID-19 tests decreased from \$1.7 billion in 2022 to \$751 million*
- Between 2022 to 2023, COVID testing volume decreased from 23.3 million tests to 10.4M tests
- Number of Medicare beneficiaries receiving COVID tests decreased from 8.5 million in 2022 to 4.2M In 2023, dropping 55%
- COVID tests represented a smaller share (9%) of Medicare Part B spending for lab tests in 2023 compared to 20% in 2022

** Office of Inspector General report dated Dec 2024 (OEI-09-24-00350)*



Test Segments Showing Growth

- PCR-based microbiology testing (excluding COVID) is the fastest growing test segment during 5-year period from 2018-2023 with Part B claims growing by 36% per year to reach 18.3 million tests¹
- Total Medicare spending on genetic testing increased from \$1.4 billion in 2022 to \$1.8B in 2023²
- Genetic testing volume rose from 1.7 million tests in 2021 to 2.4m tests in 2022, an increase of 41%
- In 2023, spending on genetic tests was nearly a quarter of total Medicare Part B spending

¹ Source: Medicare Part B Carrier Data, 2018-2023

² Office of Inspector General report dated Dec 2024 (OEI-09-24-00350)



2025 Medicare Update for Labs



Medicare Lab Payments in 2025

- Congressional action again delays Medicare payment cuts required by PAMA¹
- The 2024 law provided a 1-year reprieve from Medicare cuts of up to for about 15% for 800 lab tests that were set to take effect Jan 1, 2025²
- Measure also delayed data reporting requirements of private payor lab rates
- Next data reporting period will be Jan 1 - Mar 31, 2026 and based on original data collection period of Jan 1 - Jun 30, 2019

¹ *Protecting Access to Medicare Act of 2014 (PAMA)*

² *Continuing Appropriations and Extension Act of 2025 (CAEA 2025)*



Congress Delays PAMA Requirements

- Following the 2026 reporting period, the data reporting cycle for lab tests will be every three years (2029, 2032, 2035, etc.)
- A zero percent payment reduction is being applied for calendar year 2025 so that lab tests under Part B CLFS may not be reduced compared to payment amount applied for calendar year 2025
- For calendar years 2026-2028, payment can't be reduced by more than 15% per year compared to amount established for a test the preceding year
- This marks 5th time Congress delayed Medicare lab cuts required by PAMA



Why Congress Keeps Delaying Lab Cuts

- Congressional Budget Office (CBO) scores *each year's delay* of PAMA (from 2020 to 2025) as saving government \$590 million over the next 10 years
- CBO found that the next private payer payment survey that would include hospital lab data would actually increase CLFS rates
- In contrast, legislation to reform PAMA called SALSA* costs the government several billion dollars, which makes it much harder to pass than each of the five consecutive one-year delays

**Saving Access to Laboratory Services Act (SALSA)*



More Medicare 2025 Updates

- Specimen collection fee for routine venipuncture is \$9.09 with additional \$2 for a Medicare patient in a SNF or by a lab on behalf of HHA¹
- CY 2025 national minimum payment amount for pap smear is \$18.19²
- Final 2025 Medicare Physician Fee Schedule results in an average cut of 2.5% for pathology PC and average of 2.7% TC services³
- In year-end budget bill Congress failed to restore the lion's share of 2025 physician cuts as it did in previous years
- Medicare sequestration cuts of 2% for Part B providers including lab and pathology services are continued through 2032

¹ CMS Pub 100-04-Medicare Claims Processing, Transmittal 13037, dated Jan 10, 2025

² MLM Matters: Clinical Laboratory Fee Schedule: 2025 Annual Update

³ Federal Register, Dec 9, 2024



Top Regulatory Initiatives



CLIA Proficiency Testing Update*

- Final rule is first update of PT requirements since 1988
- Requires PT for 86 analytes, adding 29 new analyses while deleting 5
- Grading criteria for PT more stringent than before
- Labs performing moderate & high complexity testing & voluntarily participate in PT for waived tests must comply
- Total of 7 CMS-approved proficiency testing programs
- Effective July 11, 2024 except new analytes which are effective Jan 1, 2025
- *Reminder:* Labs should review what tests they have started and stopped & re-enroll required analytes in PT program plus enroll any new analytes

* *Federal Register, July 11, 2022*



Revised CLIA Requirements*

- Final rule revises methodology for assessing CLIA fees & allows CMS to impose alternate sanctions of CoW labs
- Deletes CMS proposal to allow nurses with bachelor's degree to perform high complexity testing
- Recognizes the clinical doctorate in clinical lab science as a qualifying degree for high complexity lab directors
- Allows individuals with associate degrees plus four years of clinical training/experience to qualify as technical consultant for moderate complexity testing
- Revised fee provisions effective Jan 27, 2024 & revised personnel rule valid Dec 28, 2024

** Federal Register, Dec 28, 2023*



Ban on Non-Compete Agreements*

- Final FTC rule prohibits employers from enforcing new non-compete agreements or existing ones with workers, effective Sep 4, 2024
- Exception applies to existing non-competes for “senior executives” earning more than \$151,164 who are in a “policy-making position”
- Allows non-competes between buyer and seller of a business
- Texas federal court on Aug 20 issued a national injunction blocking the rule but this doesn’t prohibit FTC from addressing noncompetes via a case-by-case basis
- New FTC leadership may not appeal to the Fifth Circuit

**Federal Register, Apr 23, 2024*



Final Rule on Laboratory-Developed Tests*

- Final FDA rule amends the regulatory definition of “IVD Products” to include LDTs
- Phases Out Enforcement Discretion for LDTs:
 - Stage 1: LDTs are subject to Medical Device Reporting (“MDR”) as well as adverse event reporting, one year after the final rule’s publication date (May 6, 2025)
 - Stage 2: LDTs are subject to registration/listing, labeling, and investigational use requirements two years after the final rule’s publication date (May 6, 2026)
 - Stage 3: LDTs are subject to Quality System regulations three years after the final rule’s publication date (May 6, 2027)
 - Stage 4: High-risk LDTs are subject to premarket review three-and-a-half years after the final rule’s publication date (Nov. 6, 2027)
 - Stage 5: Mid-and low-risk LDTs are subject to premarket review four years after the final rule’s publication date (May 6, 2028)

* *Federal Register, Apr 29, 2024*



Final FDA Rule on LDTs

- Five Important Exceptions
 - Currently-marketed LDTs
 - LDTs Designed for Rare, Unmet, or Specific Needs
 - LDTs Reviewed by Other Government Agencies
 - Pre-1976 LDTs
 - Forensic Use LDTs
- Pending litigation by ACLA/AMP and Trump Administration may well impact implementation of rule



What's Ahead for Labs in the Nation's Capitol



New Washington Political Dynamics

- Republicans win White House, gain 3 Senate seats & lose 1 House seat
- GOP controls House with historically slim majority
- Trump White House promises major government shakeup with strong executive actions plus utilizing budget reconciliation to get tough spending and immigration bills through Congress in first 100 days
- In budget deal, House GOP agree to raise the borrowing limit \$1.5 trillion by Mar 2025 in exchange for \$2.5T in mandatory spending cuts
- Picks for top health posts including HHS, CMS, FDA, CDC & NIH include some controversial choices which may draw congressional pushback



Trump 2nd Term Health Agenda

- Promote access to healthcare via market competition & transparency
- Focus on deregulation by reversing or modifying Biden-era policies
- Enhance flexibility and choice in healthcare to states & consumers
- Boost private insurance involvement in Medicare via Medicare Advantage
- Make changes in ACA Marketplace & consumer assistance programs
- Cut Medicaid coverage & spending plus approve waivers to include work requirements



Trump White House Impact on Labs

- Look for more stringent policy on issuing new healthcare regulations and far fewer challenges of court rulings blocking new federal rules
- Continued legislative discussions around PAMA reform very likely under new Congress and Administration but CBO score/cost may be significant barrier
- District court ruling overturning FTC ban on non-compete agreements highly unlikely to be appealed by new FTC and Justice Department leadership
- Final FDA rule on laboratory-developed tests (LDTs) faces strong headwinds during the emerging political environment in 2025



Will Final LDT Rule Be Overturned?

- Trump Administration can't rescind final regulation by executive order, but other means exist to end FDA's rule to regulate LDTs
- Administration has option to go through notice-and-comment rule-making process to propose a new rule that rescinds the LDT final rule
- Court challenge against LDT rule by ACLA/AMP likely to go against FDA doing first quarter of 2025 with government seen unlikely to appeal
- On Capitol Hill, look for new "lab-friendly" legislation (i.e., VALID Act) to regulate LDTs to be introduced and possibly passed by GOP-led Congress





Thank you

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