Lab Payment & Policy Outlook for 2024

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Learning Objectives

- Assess how the end of the Public Health Emergency has influenced the policy and business climate for the lab industry
- Discuss the 2024 Medicare reimbursement outlook for labs along with the latest PAMA policy and legislative updates
- Track the status of CLIA regulatory revisions and how they would modify fees and personnel requirements
- Understand how proposed FDA and legislative initiatives would change how laboratory-developed tests (LDTs) are regulated
- Discover how FTC & DOL policy initiatives impact how labs do business

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Today’s Agenda

- Assessing the Post-Pandemic Era for Labs
- Medicare Outlook in 2024 for Labs and Pathologists
- What’s Behind the Continuing Freeze of PAMA Rates
- FDA Proposes New Regulatory Scheme for LDTs
- Latest on CLIA Fee & Personnel Changes
- Don’t Be Caught Off Guard by FTC & DOL Regulatory Moves

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Laboratories in the Post-Pandemic Era

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Post-Pandemic New Normal

- End of PHE impacts COVID-era reimbursement policies
  - Reduced high throughput testing rates
  - End of extra payment for COVID sample collection
  - More cost-sharing and prior authorization
  - Referring physician/provider requirement to test
- Pandemic fallout and consequences
- Continued growth of complex laboratory-developed tests
- Accelerated innovation and push for automation/AI

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Preparing for the Next PHE

- National Diagnostics Action Plan describes steps needed to prepare for future infectious disease emergencies and actions required
- Issued by Johns Hopkins and the American Clinical Lab Association
- Plan calls for a permanent public-private testing coordinating body to facilitate information sharing, clinical sample access and improved cooperation
- U.S. government should facilitate contracts with testing manufacturers and labs before a disease emergency, so testing can be rapidly scaled up
- Early in a disease emergency U.S. should swiftly establish billing codes, widespread coverage and national payment rates for new tests

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Medicare Payment Outlook in 2024

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Medicare Trends for Labs

- Substantial drop in COVID-19 testing impacts lab revenues
- During first 6 months of 2023, Quest's COVID testing revenue dropped 83% while LabCorp's COVID revenue was down 85% compared to first 6 months of 2022
- Analyzing Medicare Part B carrier claims, PCR-based microbiology testing (excluding COVID) dominated test volume growth, increasing by 31% per year from 2019-2022
- In contrast, Part B carrier allowed payments for genetic test codes dropped 24% to $1.6 billion in 2022
- Medicare sequestration cuts of 2% for labs and pathologists continue in 2024

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Good News From Medicare

- CMS has finalized a rule to expand Medicare coverage for diabetes screening tests to include Hemoglobin A1c (HbA1c - CPT 83036) and now allows screening tests twice every 12 months for all beneficiaries
- CMS estimates this change could raise almost $70 million in additional lab revenue per year
- Specimen collection fees for routine venipuncture (CPT 36415) have been raised to $8.83 in 2024
- In addition, Medicare rates for labs providing phlebotomy services (G0471) to a nursing home beneficiary or on behalf of a home health agency raised from $5 to $10.83 in 2024

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Medicare Payment Outlook for 2024

- President Biden signed in law a stopgap spending bill passed by Congress that delays scheduled cuts this year under PAMA to the Medicare Clinical Laboratory Fee Schedule (CLFS)
- This freezes reimbursement for nearly 800 tests on the Medicare CLFS that would have been reduced up to 15% as of Jan 1, 2024
- In addition, the next PAMA reporting period for private payor payment data is delayed one year from Jan 1 to Mar 31, 2025
- Meanwhile, Medicare global rates for high-volume surgical pathology services (CPT 88305, 88307, 88331 & G0416) will decrease 2-3% this year under the final 2024 Medicare Physician Fee Schedule

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Congress Takes Another Go At SALSA

- Bipartisan, bicameral sponsors of the Saving Access to Laboratory Services Act (SALSA) reintroduced the bill (S.1000 & H.R.2377) in the 118th Congress which runs through this year
- SALSA would protect labs from further major Medicare payment required by PAMA, limiting cuts (or increases) to maximum of 5% per year for any widely available test while modifying the frequency of data collection periods from 3 to 4 years
- Outlook for passage is decidedly negative given the added costs of SALSA, which would have to be offset by identifying other savings, plus the difficulty of getting any legislation through Congress during a presidential election year

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Will Medicare CLFS Rates Be Frozen Indefinitely?

- At the urging of lab interests, Congress has stepped in 5 times to delay a mandate that labs report private payor data to CMS, which was first collected during the first half of 2019
- The CBO scored a one-year delay in payment cuts, saving $590M over 10 years
- CBO believes that the next private payor payment survey which will include hospital outreach labs, leading to higher CLFS rates and thus higher Medicare spending
- Preliminary CBO score projects passing SALSA would cost $6 billion over 10 years
- Given federal budget outlook, lawmakers will likely be inclined to freeze the CLFS and keep postponing the next PAMA survey for the foreseeable future

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Changes Ahead for LDT Oversight

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Changing Landscape for Laboratory-Developed Tests (LDTs)

- LDTs are diagnostic tests designed, manufactured and used by a single lab
- As labs have run far more complex, high-risk tests for a wider range of uses during the personalized medicine era, LDTs have become a mainstay of molecular labs
- FDA estimates that there are approximately 12,000 U.S. labs performing high-complexity testing and that 10% of these are marketing LDTs
- These 1,200 labs are currently offering 80,400 LDTs with 7,776 new LDTs coming to the market each year
- FDA estimates that labs generated $28.6 billion in revenue from LDTs in 2023
- Despite their growing popularity, LDTs have escaped the bulk of federal oversight over marketing and accuracy, although they must meet CLIA requirements

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Back to the Future on LDT Regulation

- FDA first proposed a regulatory framework for LDTs in 2014 which applied a risk-based structure with a multi-year phase-in
- Proposal retracted at the end of Obama Administration in 2016
- In 2020, Trump Administration ruled that FDA could not require pre-market approval of LDTs absent formal rule-making or legislation
- This policy change put FDA oversight of LDTs in limbo, thereby creating a policy vacuum that permitted virtually all LDT COVID tests to be marketed

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Another Go at LDT Oversight

- Biden Administration revoked the policy introduced during the Trump Administration but took its time to clarify its own LDT stance, with hints by FDA that a new policy was on the horizon
- In June 2023, FDA published a notice of proposed rule-making, indicating that the agency was moving ahead with a plan to tackle LDT regulation
- FDA issued a proposed rule to regulate LDTs on Sep 29, 2023

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FDA’s Latest Plan for LDT Oversight

- FDA proposes to modify the definition of “in vitro diagnostic products” (IVDs) to expressly include laboratory-developed tests (LDTs)
- Change would require all IVDs, including LDTs, to fully comply with FDA’s medical device regulatory requirements, including applicable premarket review requirements
- FDA to phase-out its current policy of enforcement discretion for LDTs with regulatory mandates to be applied in 5 phases over 4 years
  - Phase I: 1 year after final rule labs must comply with adverse reporting requirements
  - Phase II: 2 years after final rule subject to registration/labeling requirements

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Phasing-In LDT Oversight

- Phase III: 3 years after final rule labs must comply with quality system requirements
- Phase IV: 3.5 years after final rule (but not before Oct 1, 2027) high risk LDTs subject to pre-market review
- Phase V: 4 years after final rule (but not before Apr 1, 2028) all LDTs subject to premarket review

- Proposal doesn't "grandfather" current LDTs but invited comments
- Public comments on proposed rule were due Dec 4, 2023, with FDA saying it wants a final rule out by April 2024 - may be too optimistic

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LDT Legislation Back on Capitol Hill

- Verifying Accurate Leading-edge IVCT Development Act of 2023 reintroduced in House (H.R. 2369) after failing to pass Congress in previous years
- Crafts common regulatory framework for LDTs and in-vitro diagnostics (IVDs) called in-vitro clinical tests (IVCTs) and creates a tiered, risk-based system while grandfathering in most current LDTs
- Though FDA's actions on LDTs clearly challenges Congress to accelerate the legislative process, final congressional action in 2024 remains unlikely given the political dynamics during an election year

What to Expect Under FDA's LDT Rule

- When FDA releases a final LDT rule it is likely to trigger litigation from various stakeholders
- Lawsuits are expected to contend that the Food, Drug & Cosmetic Act does not grant FDA the authority to regulate LDTs
- FDA'S regulation of LDTs may well force many labs to stop offering certain moderate and high-risk LDTs due to the increased costs involved in going through the agency's premarket approval process
- Particularly vulnerable would be low-volume LDTs that could become unaffordable in most lab settings

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CLIA Fees & Personnel Update

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Key CLIA Changes Effective This Month

- CMS and CDC published a final CLIA rule at the end of 2023 which becomes effective Jan. 27, 2024 for most provisions
- Increases CLIA user fees and clarifies CLIA fee regulations
- Makes several changes to CLIA personnel requirements affecting both testing personnel and laboratory directors
- Allows for the imposition of alternative sanctions on Certificate-of-Waiver (CoW) labs in lieu of only imposing principal sanctions
- Removes histocompatibility-specific requirements from that are already addressed by the general QC requirements under CLIA

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Overhaul of CLIA Fees in 2024

- Increases CLIA user fees by 18%
- Institutes a formula to increase user fees every 2 years
- Starts to collect authorized fees never been previously assessed
  —follow-up surveys to confirm correction of deficiencies
  —review & approval for testing when adding a specialty or subspecialty
  —performing a substantiated complaint survey
  —performing desk review of unsuccessful PT performance
  —Issuing a revised or replacement certificate
- Collects a new one-time $25 fee on CoW labs

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Rule Revises Testing Nurses May Do

- Changes proposed rule that defined a nursing degree as equivalent to a biological science degree thus permitting nurses to perform moderate and high complexity testing
- Creates a separate pathway & educational requirements for those with nursing degrees to become moderate complexity testing personnel
- This means nurses may no longer perform high complexity testing which changes previous CMS policy
- Strengthens and clarifies requirements & documentation for training and experience for moderate and high complexity testing personnel

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Lab Director Changes Finalized

- Expands qualifications for a high-complexity laboratory director (HCLD) to include “professional doctorates” including a Doctorate in Clinical Laboratory Science
- Qualifies individuals with “master’s equivalency“ who meets certain training, experience & certifications requirements
- Requires laboratory directors to be on-site at the lab at least once every 6 months with at least a 4-month interval between the two on-site visits
- Closes loophole that would potential allow holder of Batchelor’s degree in nursing to serve as laboratory director

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FTC Policy Surprises

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FTC Moves Against Genetic Testing Company

- Federal Trade Commission takes enforcement action against a genetic testing company which underscores the agency's focus on protecting sensitive data
- Recent first-of-its-kind agency action serves as a warning to all labs concerning their privacy and security practices related to genetic data
- Case involves a company that analyzes consumer-provided DNA samples and uses the results of that analysis to generate personalized reports and other tailored products

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FTC Takes On Genetic & DNA Labs

- FTC said company left sensitive genetic and health data unsecured, deceived consumers about their ability to get their data deleted and changed its privacy policy retroactively without notifying and obtaining consent from consumers whose data had already been collected
- As part of settlement the company must pay $75,000 which the FTC intends to use for consumer refunds
- FTC most recently went after DNA test company for misrepresentations to consumers which resulted in a $700,000 penalty plus agreement to give clients the right to delete biometric information

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FTC Wants to Restrict Non-Competes

- FTC proposed rule would ban employers from imposing non-competes on their employees
- Agency says the practice suppresses wages, hampers innovation, and blocks the starting of new businesses
- Commission has received more than 27,000 comments on its proposal and is expected to vote in April 2024 on the final version of its proposed ban
- Entities are exempt if they do not carry on business for their own profit or that of its members — i.e., non-profit hospitals

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DOL Independent Contractor Rule

- Department of Labor rule would revise its interpretation of when a worker may be considered an independent contractor
- Final rule adopts a six-factor, “totality of the circumstances” framework for analyzing worker-employer relationships
- This change expands the reach of federal law that requires employers to extend benefits and protections to workers classified as employees
- Effective March 11, 2024, the rule is expected to draw strong pushback including legal challenges by various employer-affiliated groups

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Thank you

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