Lab Industry Outlook for 2023

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Opinions expressed in this presentation are those of the speaker and do not express the views or opinions of Cardinal Health

Learning Objectives

- Examine how the federal public health emergency affects the reimbursement and policy climate for the clinical lab industry
- Track PAMA regulatory and legislative updates and learn how they change Medicare lab payment rates in 2023 and beyond
- Identify how proposed CLIA changes would modify fees and personnel requirements for labs
- Describe the shifting policy dynamics for LDTs
- Assess which lab business practices are on the OIG's fraud radar screen

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Today’s Agenda

- Labs in Era of Federal Public Health Emergency
- Medicare Payment Updates for Labs and Pathology
- Lab Legislation Would Provide PAMA Relief
- CLIA Fee and Personnel Changes Proposed
- Crosscurrents in LDT Oversight
- Tracking Lab Fraud and Abuse Enforcement

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Changing Lab Market Dynamics

- Rise of infectious diseases defines centrality of diagnostic laboratory testing
- Expansion of diagnostic testing channels
- Major operational challenges for labs
- Rethinking how CDC and FDA respond to public health emergencies
- Key payment and regulatory areas in flux
- Lab fraud enforcement moves to the forefront

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COVID Tests Drive Medicare Spending*

- Medicare Part B spent $2.0 billion on COVID-19 tests in 2021, a 29% increase from 2020
- Overall, Part B spending for lab tests rose by $1.3B in 2021, from $8.0B in 2020 to $9.3B in 2021 — a 17% hike
- Beyond COVID testing, spending in 2021 was driven by a 56% growth in high-priced genetic tests, from $1.2B in 2020 to 1.9B in 2021
- Medicare Part B spent $5.5B in 2021 on the top 25 tests, which accounted for 59% of total test spending

** HHS Office of Inspector General Data Brief, December 2022 (OEI 09 22 00400)*

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Medicare Payments in 2022 vs 2023

- Congress froze CLFS cuts of 15% under PAMA in 2022 but were set to take effect January 1, 2023
- Pathology cuts in 2022 under the Medicare Physician Fee Schedule were largely offset by a 3% hike for all physician fees but 2023 proposed MPFS set to cut most pathology codes
- Medicare sequester cuts for all providers were phased in during 2022 with full 2% starting July 1st that will continue throughput 2023
- Statutory pay-as-you-go (PAYGO) reduction of 4% defrayed by Congress in 2022 with similar cuts due again in 2023

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Congress Decides Key Lab Issues

- Final “Omnibus” spending package passed by Congress on December 23rd funded the government through September 30, 2023 plus resolved key payment and policy issues affecting labs
- Provides payment relief for Medicare providers in 2023 including labs and pathology
- Excludes lab bill making fundamental changes to PAMA
- Fails to include VALID Act which has new regulatory scheme for laboratory-developed tests (LDTs)

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Good News: Medicare 2023 Payments

- Congress extends freeze on Medicare CLFS payments under PAMA for one year through 2023 under the final omnibus spending package
- Delays PAMA reporting requirement for one year
- Reduces a scheduled 4.5% cut to the 2023 Medicare physician fee schedule by 2.5 percentage points, and staves 1.25 percentage points to the 2024 MPFS
- Statutory pay-as-you-go (PAYGO) cuts of 4% were defrayed for both 2023 and 2024

Revised PAMA Timeline

- PAMA reporting period now scheduled for January 1 - March 31, 2024 for data collected by labs in 2019
- CMS would use this data to calculate new CLFS rates for 2025-2027 period
- U.S Court of Appeals, DC District decision in favor of ACLA's long-running PAMA lawsuit against HHS does not require recalculation of past CLFS rates
- Only Congress can fundamentally modify PAMA

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Better News: Proposed PAMA Relief

- House and Senate bills (S. 4449 and H.R. 8188) introduced in last Congress would make major modifications to the 2014 Protecting Access to Medicare Act (PAMA) in determining test rates under Medicare CLFS
- Introduced mid-2022, Saving Access to Laboratory Services Act (SALSA) drew bipartisan support in both chambers
- SALSA would require a broader data collection across the lab market and imposes a cap on annual payment reductions to protect labs from deep Medicare payment cuts by instituting a gradual, phased approach

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Key Provisions of SALSA

- Require statistical valid sampling of private payor data from major lab segments for “widely available” tests
- These tests are defined as performed by more than 100 labs and whose Medicare reimbursement rate is under $1,000
- Sets limit of 5% on how much any individual CLFS rate for a widely available test could up or down from year to year and phases-in cuts
- Changes the frequency of data collection periods from 3 to 4 years

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Great News: 2023 Specimen Fees

- CMS nearly tripled the long-time $3.00 Medicare specimen collection fee for routine venipuncture (or a urine sample collected by catheterization) to $8.57 effective January 1, 2023 under the final 2023 physician payment rule
- Payment rate for labs providing phlebotomy services to a Medicare beneficiary in a nursing home on behalf of a home health agency is raised from $5 to $10.57 effective January 1st
- Starting January 1, 2024, CMS will update the specimen collection fee rate every calendar year by the percentage change in the Consumer Price Index for All Urban Consumers (CPI-U)

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Proposed CLIA Changes Ahead

- CMS and CDC have issued a proposed rule that would update CLIA fee regulations
- When finalized, the change would provide sustainable funding for the CLIA program through a biennial two-part fee increase
- Rule would also amend CLIA personnel regulations to allow individuals with a nursing degree to perform high complexity testing

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Updating CLIA Fees

- Proposed rule would provide a 20% hike to existing lab user fees
- Assessing and collecting currently authorized fees that have never been previously assessed for the following activities:
    - Follow-up surveys to confirm correction of deficiencies
    - Review and approval for testing when a lab adds a new specialty or subspecialty to its services
    - Complaint surveys when the findings are substantiated
    - Desk reviews to ensure successful lab proficiency testing
    - Issuing revised or replacement certificates

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More Changes in CLIA Fees

- Collect a new, one-time $25 fee on Certificate-of-Waiver (CoW) labs to offset its administrative overhead costs of test complicity determination for waived tests by FDA
- Proposing a formula to increase user fees every 2 years to account for inflation as per the CPI-Urban Index, if needed to meet program obligations
- CMS claims that without the fee increases, the CLIA program will no longer be financially self-supporting by end of 2023

CLIA Personnel Revisions

- Proposed rule would allow individuals with a nursing degree to perform high and moderate complexity testing, placing them on the same level as clinical laboratory science, biology and chemistry degrees
- This would mean that nursing degree holders would not be required to meet any coursework or clinical training requirements under CLIA
- Proposal would not allow nursing degree holders to supervise or direct lab staff under CLIA

Lab Industry/CMS Divide

- Allowing a nursing degree holder to perform high-complexity testing has drawn strong opposition from many lab groups and AHA, among others
- Opponents successfully stopped a similar provision offered by CMS several years ago, stressing that a nursing degree typically requires a fraction of the scientific coursework and training requirements by lab testing professionals
- CMS says it sees no reason to believe that nurses would be unable to reliably perform moderate and high-complexity tests

Laboratory Director Changes

- CMS seeks to expand qualifications for a high-complexity lab director (HCLD) to include “professional doctorates” (such as a Doctorate in Clinical Laboratory Science) and individuals with "master’s equivalency" who meets certain training, experience, and certification requirements
- Currently, the HCLD position is limited to certain MDs and board-certified PhDs
- Lab professional groups divided on change, with AACC opposing and ASCLS in favor

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More Proposed CLIA Revisions

- For the first time, CMS could apply alternate sanctions including civil money penalties, a directed plan of correction and on-site monitoring to waived labs
- Removes current histocompatibility regulations that are already covered in general CLIA requirements and lab director responsibilities
- Comments on the proposal are now closed and any changes approved would become effective 30 days after publication of the final rule expected sometime later in 2023

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LDT Oversight Muddle

- Prior to 2016, FDA held that laboratory-developed tests could be regulated as medical devices and subject to CLIA requirements but applied enforcement discretion to LDTs
- Trump Administration moved to limit FDA's review of LDTs in order to increase access to SARS-CoV-2 tests
- FDA used its emergency use authorization authority (EUA) to allow labs to gain approval for COVID tests
- Biden-led HHS withdrew Trump-era policy, putting LDTs back under FDA oversight, but continued to use EUAs to get tests into the market in public health emergencies

VALID Bill Amends LDT Oversight

- Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021 was follow-up bill in prior Congress
- Crafts common regulatory framework for LDTs and in-vitro diagnostics (IVDs) called in-vitro clinical tests (IVCTs)
- This approach creates new pathways to market, post-market oversight and risk-based classification systems for these products
- Two chances to get VALID Act approved in 2022 failed; attaching bill to approved FDA user fee legislation and including it in the final 2023 spending package

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LDT Outlook Inside FDA

- For the vast majority of LDTs, FDA continues to follow its previous policy of not enforcing premarket review and other applicable requirements for in-vitro diagnostics
- Exceptions include declared public health emergencies or when a test poses a significant public health concern
- With legislation in limbo, FDA Commissioner Califf says agency would look at reforming diagnostics system with-in their current medical device framework
- Such an approach may include new rules that focus on regulatory oversight of higher-risk LDTs

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Lab Fraud and Abuse Update

- OIG issues Fraud Alert on excessive and fraudulent genetic testing (December 2021)
- July 2022 nationwide DOL enforcement action charged dozens of individuals with $1.2B in Medicare genetic testing fraud with focus on telemedicine schemes
- OIG conducts series of audits surrounding COVID-19 testing to include medically unnecessary add-on tests including $25 add-on payment for performing timely COVID testing and how the pandemic effected non-COVID testing under Medicare Part B

Feds Target Lab Abuses

- HRSA makes information requests to labs to identify over-payments and potential fraud in program that paid billions to 20,000 labs for COVID-19 tests provided to the uninsured
- Additional OIG targets include improper payments for phlebotomy travel and judgments of $126 million against urine drug testing labs and pain management clinics for illegal kickbacks to refer drug testing
- U.S. Justice Department won False Claims Act (FCA) claim against Sutter Health who agreed to settle for just over $13 million for the alleged improper billing of government health programs for urine toxicology tests done by third-party labs

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Thank you

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