2022 Outlook for the Clinical Laboratory Industry

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Learning objectives

- Describe key impacts the COVID pandemic is having on the clinical laboratory industry
- Examine the latest PAMA policy developments and how they will affect laboratory payment this year and going forward
- Understand federal payment and private payor policies for clinical laboratories and anatomic pathology services
- Explain what labs can expect from regulatory mandates for LDTs, ERKA, OSHA Surprise Billing & Hospital Price Transparency

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Today’s agenda

- Lab industry impact in COVID era
- Key PAMA updates
- Lab and AP payment alerts
- Key regulatory issues to watch

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How COVID has affected the lab industry

- Affirms critical role of diagnostic testing
- Reveals testing infrastructure vulnerabilities
- Breakdown of supply chain
- Test volumes zig zag
- Decline of routine diagnostic screening testing

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Major COVID impacts on labs

- Spur development **and** adoption of new technologies
- Major federal support for rapid diagnostic tests
- Boom in CLIA labs
- Escalation of chronic personnel shortages
- Rise of emergency payment policies and regulatory flexibilities

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Latest on PAMA

- A little history first
- Reporting and payment cut deadlines delayed
- MedPAC suggests modified surveys
- Update on legal challenges
- What's ahead in 2022 and beyond

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Brief history of PAMA

- Congress passes Protecting Access to Medicare Act of 2014 which ties Medicare payment to private payor rates
- With data provided by selective labs, CMS sets market-based prices under the Medicare Part B Clinical Lab Fee Schedule (MLFS)
- Allows Medicare to cut lab payments up to 10% in 2018-2020 and by 15% in 2021-2023
- After industry push, CMS amends PAMA regulations in 2018 requiring more hospital labs to collect and report data

Three laws delay PAMA cuts & deadlines

- Laboratory Access for Beneficiaries (LAB) Act of 2019 delays the lab reporting requirement one year until 2021 and mandates a MedPAC study to improve PAMA data reporting
- CARES Act (enacted March 2020) freezes CLFS payments under PAMA for one year through 2021 and delays lab reporting for one more year to 2022
- The Protecting Medicare and American Farmers from Sequester Act (signed December 10, 2021) freezes the Medicare CLFS in 2022 and delays lab data reporting under PAMA for one year until 2023

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Summary of PAMA changes for 2022 & beyond

2022 PAMA provisions

- Medicare Clinical Laboratory Fee Schedule is frozen, following a similar freeze that took place in 2021
- One-year delay of second round of private-payor payment data reporting, following similar delays in 2020 and 2021
- Data was collected January 1 - June 30, 2019 by independent and hospital labs and POLs

PAMA in 2023 & beyond

- Effective Jan 1, 2023, 15% fee cuts for some 600 mostly high-volume lab test codes on Medicare CLFS
- PAMA payment reporting period scheduled for January 1 - March 31, 2023
- CMS will use this data to calculate new CLFS rates for 2024-26 period

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MedPAC examines PAMA payments

- LAB Act mandated the Medicare Physician Advisory Commission to analyze less burdensome ways for PAMA to collect private payor payment data in a representative sample of all lab segments
- MedPAC found PAMA payments skewed with the methodology reflecting fully 85% of Medicare payments made to independent labs but only 22% of payments made to hospitals and POLs
- MedPAC found when PAMA is fully implemented in 2025, lab fees will have been cut in the aggregate by 24%

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MedPAC reports to Congress

- In its semi-annual report to Congress this past June, the panel leans toward a simplified payment survey focused on the most efficient (i.e., lower cost) independent, hospital outreach labs and POLs
- Panel concedes that a routine survey of the three lab segments would result in an increase in Medicare spending for lab testing ranging from 15-24%
- MedPAC report advisory only; Congress has final word on making any future PAMA changes

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PAMA court challenges

- ACLA files lawsuit in December 2017 claiming that HHS wrongly excluded hospital outreach labs from the first private payor survey used to determine the Medicare CLFS rates under PAMA
- U.S. District Court for the District of Columbia dismissed the case in September 2018 on grounds that the ruling on establishing PAMA payment amounts was barred by the statute

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Legal challenges fizzle

- In 2019, the U.S. Court of Appeals for the D.C. Circuit overturned that dismissal, sending it back to the lower court
- Lower court again dismissed the case as moot in late March 2021
- ACLA files notice of appeal this past May while acknowledging it is critical for Congress to take legislative action to reform PAMA

Good news: More provider cuts averted

- Protecting Medicare and American Farmers from Sequester Act also suspended a 4% cut to all Medicare providers including labs starting January 1, 2022 under the PAYGO Act of 2010, which was triggered by emergency pandemic spending
- In addition, law includes a 3-month extension to the 2% sequester relief applied during 2021 to all Medicare payments through March 31, 2022, followed by 3 months of a 1% sequester relief through June 30, 2022
- A full 2% sequester cut is effective July 1 - December 31, 2022 (sequester now extended through 2030)

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More good news: Path cuts reduced in 2022

- Both Medicare PC and TC rates for many pathology services were cut by about 4% under the final 2022 Medicare Physician Fee Schedule
- Cuts to both pathologists & pathology labs were based on a 3.75% decrease to the 2022 conversion factor plus budget neutrality adjustments needed to offset hikes going to primary care physicians
- 2021 Sequester Act provides a 1-year increase of 3% for services paid through the Medicare PFS, offsetting most of the scheduled 2022 cuts to pathology services
- Pathologists will also benefit in 2022 from suspension of the scheduled Medicare PAYGO cut of 4% plus the delay to Medicare sequester cuts

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Private payer initiatives

- Prior Authorization: Also known as pre-authorization or pre-certification, most private health insurers have requirements before a patient can receive certain health services, including specialized lab testing such as outpatient genetic and molecular tests
- UnitedHealthcare (UHC) manages its Genetic and Molecular Lab Testing Prior Authorization Program through its UHC Lab Tests Registry effective April 13, 2021
- No Payment for Pathology PC Component: Many private payers have ended paying for the professional component of AP services, with Cigna being one of the remaining payers to implement such a policy

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Key policy issues for labs to watch

- Laboratory-developed tests (LDTs) oversight in flux
- How ERKA law applies to labs
- Surprise billing regulations take effect January 2022
- Hospital price transparency now in play
- CMS & OSHA COVID guidance challenged in court

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LDTs in regulatory limbo

- In early 2020, labs developing their own laboratory-developed tests (LDTs) to provide COVID-19 testing and diagnosis were encouraged to seek emergency use authorizations (EUAs) for such tests from the FDA
- In August 2020, Trump Administration's HHS rescinded all informal policy documents issued by the FDA related to LDTs because it had not engaged in notice-and-comment rule making
- As a result, such products were no longer required to secure an EUA or other marketing authorization for non-COVID tests from the FDA prior to being launched commercially

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HHS reset on LDTs

- Well into 2021, FDA declined to review EUA requests from LDT developers and reprioritized those products to focus on at-home collection kits and tests and high-throughput, widely distributed tests
- In November 2021, President Biden's HHS officially withdrew the prior Administration's policy and issued a revised COVID testing policy
- New policy requires any clinical lab offering a COVID LDT test to obtain an EUA to continue performing and marketing such tests
- As FDA reasserts its oversight of LDTs as medical devices, the agency acknowledges that Congress ultimately will have to decide the issue

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VALID Act of 2021

- Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2021 was introduced with bipartisan support in both the House and Senate and remains pending before Congress
- Crafts new LDT regulatory framework for in-vitro diagnostics (IVDs), to be known collectively as in-vitro clinical tests (IVCTs)
- Creates a tiered, risk-based system for IVCT oversight
- Best bet for enactment is attaching bill to must-pass legislation in 2022 such as reauthorizing the Medical Device User Fee Amendments (MDUFA)

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ERKA remains risk for labs

- The Eliminating Kickbacks in Recovery Act (ERKA) was effective in 2018 but neither HHS or DOJ has issued any clarifying guidance yet
- Initially intended to target patient brokers who improperly profit from patients trying to recover from addiction, but law is applied more broadly to include clinical laboratories
- ERKA expands the federal anti-kickback statute to both public and private payors while extending its reach to all labs, not just toxicology facilities
- Despite no guidance, DOJ prosecutes multiple ERKA cases

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Lab risk under ERKA

- Labs should ensure compensation and marketing practices don’t run afoul of ERKA, which prohibits any form of volume- or value-based compensation
- Despite recent court case allowing commission payments to lab sales representative, ERKA remains a red flag for traditional lab employee or contractor sales commission programs
- Labs advised to have counsel review and advise on any existing employee or contractor sales commission programs

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No Surprise Act of 2021

- Effective January 1, 2022, law protects patients from “surprise” medical bills, such as those arising when out-of-network providers such as hospital-based pathologists utilize and provide services at an in-network facility and try to recover the differences between in-network and out-of-network charges not covered by payors
- Targets balance billing already prohibited under Medicare and Medicaid to patients insured through employer-sponsored and commercial health plans
- Interim final regs by HHS, Treasury and Labor sets up an Independent Dispute Resolution (IDR) process with insurers, hospitals, doctors and big employers still battling to tailor the fine print in their favor

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Hospital price transparency rule

- Final rule published by CMS in January 2021 to help patients identify the costs of hospital items and services before receiving care by requiring hospitals to provide clear, accessible pricing information
- Specifies that pricing required for 300 “shoppable services” of which 70 are specified by CMS including more than 25 related to lab and radiology services
- CMS increased monetary penalties due to high rate of hospital non-compliance
- Potentially puts competitive pricing pressure on labs in local markets

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Supreme Court split decisions on OSHA & CMS vaccine mandates

- An OSHA emergency temporary standard (ETS) requiring that workers at businesses with 100 or more employees get vaccinated or submit a negative Covid test weekly was blocked by a Supreme Court 6-3 ruling on January 13th
- A 5-4 court majority upheld a CMS Vaccine Mandate requiring that healthcare facilities participating with Medicare and Medicaid establish a policy ensuring eligible workers are fully vaccinated, with exemptions allowed based on religious beliefs or recognized medical conditions
- Covered employers in all states should take steps to comply with the CMS Vaccine Mandate following the lifting of temporary court injunctions
- For guidance on this vaccine requirement, visit cms.gov

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Questions?