Lab Payment & Policy Update in the Era of COVID-19

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Learning Objectives

- Examine the role of testing in the COVID-19 pandemic and the challenges that existed due to politicization of the pandemic
- Learn how COVID-19 impacted government policies and the financial health of labs
- Discover how scheduled PAMA reimbursement cuts and reporting requirements for labs are changed for 2021 and beyond
- Identify key regulatory initiatives that will impact labs this year
- Find out how a new Administration and Congress will influence policy changes for labs in 2021

Agenda

- Testing at the Core of COVID-19 Challenges
- Lab Payment and Policy Update in Pandemic Era
- How Congress Modified PAMA Deadlines
- Regulatory Update for Labs
- What Labs Can Expect in 2021

COVID-19 Pandemic and Diagnostic Testing

- Diagnostic testing plays central role throughout COVID-19 pandemic
- FDA and CDC address key technical and bureaucratic challenges in approving COVID-19 tests
- Fallout from politicization of COVID-19 pandemic
- No federal testing or contact tracing strategy - mixed messaging at the national and state government levels

Labs Front and Center in Fighting COVID-19 Pandemic

- 255 million COVID-19 tests reported in U.S. as of Jan 3, 2021 with more than 80 million PCR tests done by labs in 2020
- All 84 state and local public health labs in 50 states and DC were using a CDC-validated COVID-19 diagnostic test by March 15, 2020
- Commercial and hospital labs compete for basic testing supplies such as test kits, swabs and reagents and personal protective equipment - supply issues remain
- Insufficient testing capacity and backlogs created turnaround problems for labs, particularly in earlier months of pandemic

Approving LDTs for COVID

- During COVID-19 crisis, public health emergency labs applied for emergency use authorization (EUA) to speed approval of laboratory-developed tests (LDTs) for COVID-19 to market
- Exact number of approved LDTs for COVID-19 is unknown, but FDA reportedly granted hundreds of EUAs
- HHS directed FDA to stop requiring EUAs for COVID-19 testing, determining the agency had no jurisdiction over LDTs without rulemaking, leaving oversight to CMS under CLIA

Congress Responds to COVID-19 Pandemic

- The Coronavirus Aid, Relief and Economic Stimulus (CARES) Act contained a wide variety of provisions to help businesses and workers during the economic crisis caused by COVID-19
- Allocated $2 trillion in COVID-19 relief but no discrete funding allocated for labs as recommended by the industry
- Required health plans/insurers to cover COVID testing without cost sharing and prior authorization for both hospitals and labs

How Labs Fared Under CARES Act

- Authorized $100 billion in grants to providers based on their share of Medicare fee-for-service spending during portion of 2019
- Commercial labs received hundreds of millions of dollars in Provider Relief Fund payments with the largest amounts going to Quest ($138M) and LabCorp ($132M) — both companies voluntarily returned the money when their financial performance improved in the third quarter
- Authorized up to $10 million loans for small businesses including labs and pathology groups under Paycheck Protection Program (100% loan forgiveness)

Key Medicare Provisions Under CARES Act

- Suspended Medicare “sequestration” - the across-the-board annual 2 percent reduction in Medicare payments to providers including labs - from May 1, 2020 to Dec 31, 2020
- Expanded eligibility for and benefits of accelerated and advanced Medicare payments for providers, including labs, having cash flow problems
- Increased payment by 20% for Medicare beneficiaries hospitalized for COVID-19

CARES Act Freezes Medicare Lab Fees

- Medicare Clinical Laboratory Fee Schedule (CLFS) payment rates under PAMA are frozen at 2019 levels in 2021
- This delays the scheduled PAMA fee cuts until 2022 when the maximum pay cut moves to 15%
- Delays labs' responsibility to report their private-payor data to CMS under PAMA by another year, from January to March 2022

Reimbursement for COVID-19 Testing

- For high-throughput COVID-19 PCR diagnostic tests (200+ specimens per day), Medicare (HCPCS U0003/4) pays $100
- For low-throughput COVID-19 diagnostic tests (>200 specimens per day), Medicare (HCPCS U0002 or CPT 87635) pays $51.33
- For COVID-19 Antibody Tests, Medicare pays $45.23 for CPT 86328 (point-of-care tests) and $42.13 for CPT 86769 (lab-based multi-step methods)
- Private insurers initially paid comparable rates to Medicare except lower amount for antibody tests

COVID-19 Reimbursement

- CARES Act set COVID non-Medicare reimbursement at the negotiated rates for contracted labs
- Non-contracted labs are to get paid their list price but are required to publish their test price on their website
- Effective Jan 1, 2021, Medicare will only pay the $100 high-throughput rate for labs completing testing within two calendar days of the specimen being collected and $75 for labs taking longer than two days

Reporting of COVID-19 Test Data

- All COVID-19 testing sites including CLIA labs must report data for all completed diagnostic and screening testing (both positive and negative results), which includes molecular, antigen and antibody testing for all individuals tested
- This data must be reported daily, within 24 hours of test completion, to the appropriate state, tribal, local, or territorial public health department based on the individual's residence
- Failure to report COVID test data may result in civil monetary penalties of up to $1,000 a day for the first day and $500 for each subsequent day

COVID Stimulus Package

- Under the 2021 Consolidated Appropriations Act, states receive $20 billion for their COVID test and tracing programs
- Sets $285 billion for additional loans to small businesses including labs under Paycheck Protection Program
- Extends suspension of Medicare “sequestration”
- Allows $3 billion to help mitigate scheduled 2021 reductions to physicians under the PFS
- Protects patients from “surprise” medical bills from out-of-network physicians at in-network hospitals

PAMA Refresher

- PAMA requires that the Medicare CLFS payment is equal to the weighted median of private payor tests determined for each test based on historical data from applicable labs
- Data is collected during a specified data collection period and reported to CMS during a specified data reporting period
- Starting in 2018, a six-year phase-in for payment cuts
- From 2018-2020, no more than a 10% cut is permitted per year and from 2021-2023, no more than a 15% reduction
- PAMA legal challenge under review by federal district court

Congress Modifies PAMA

- Laboratory Access for Beneficiaries (LAB) Act of 2019 delayed the PAMA reporting requirements for one year until January 1 to March 31, 2021
- The CARES Act enacted March 2020 further delays the reporting period until January 1 to Mar 2022
- In addition, the CARES Act specified the 15% cuts required under PAMA for 2021 are delayed until 2022
- The practical effect of the changes is that Medicare payment rates determined by data reported by labs in 2017 will continue through the end of 2022

Summary of Lab Reimbursement in 2021

- Medicare payments for labs under PAMA are frozen at 2019 levels (tests were subject up to a 10% cut)
- Delay labs' responsibility for reporting private-payor data to CMS under PAMA until January to March 2022
- Suspend Medicare "sequestration" cut of 5% to providers, including labs, through March 31, 2021
- Mitigate scheduled 2021 Medicare PFS cuts for pathologists' professional rates by an average of 9% and cuts for technical fees by an average of 5%

COVID Impact on Labs

- Lab financial viability during 2020-2021 dependent on ability to perform COVID-19 testing
- Good payment rates set for COVID testing
- Delay of elective procedures cut routine lab volume
- ‘Have’ and ‘have-not’ labs - test volumes up for COVID-testing labs and flat for other labs, particularly community labs and POLs
- Some good news in key Medicare policies affecting lab reimbursement

Balance of Power Impacts Biden Health Agenda

- Joe Biden wins presidency, but Democrats have smaller House majority while Senate control depends on 2 Georgia runoff seats
- Democrats win both Georgia Senate races creating 50-50 Senate, putting Democrats in control of 117th Congress with VP Kamala Harris breaking tie
- Slim Democrat majority allows Biden Administration to advance its health priorities though more compromise required with Republicans

Biden Administration 7-Point COVID-19 Plan

- Ensure access to regular and reliable diagnostic testing
- Implement nationwide mask mandates
- Fix personal protective equipment problem
- Provide consistent guidance to local communities
- Equitably distribute treatments and vaccines
- Protect older Americans and others at high-risk
- Prepare for future pandemics

Biden Administration Health Policy Priorities

- Protect and expand the Accountable Care Act to include a public option that everyone can buy into
- Spend extra $750 billion on healthcare over 10 years
- Increase the value of tax credits to lower premiums and extend coverage to more Americans under ACA
- Expand insurance coverage to low-income Americans

More Biden Policy Initiatives

- Lower Medicare's eligibility age from 65 to 60
- Allow Medicare to negotiate prescription drug prices, hold price increases to inflation
- Allow consumers to buy prescription drugs from other countries
- Double federal investment in community health centers
- More public health funding and revamp infrastructure

ACA Before the High Court

- Affordable Care Act challenge was heard by more conservative Supreme Court this past November
- GOP attorneys general from 18 states, backed by the Trump Administration, argued the ACA should be struck down because Congress eliminated the individual mandate in 2017
- Final decision not expected until mid 2021— if Court should invalidate the ACA, look for the Biden Administration to quickly push for new health law

Lab Regulatory Update

- Final federal anti-kickback safe harbor and physician self-referral (Stark Law) rules effective January 19, 2021
- New safe harbors: to promote value-based care, tele-health; donations of cybersecurity technology and related services; limited physician renumeration
- Modifies existing Stark exceptions, including fair market compensation, which allows its use for office and equipment leases
- New definitions of “commercially reasonable” and “general market value” plus revised definition of “fair market value”

Updating CLIA PT Requirements

- CMS and CDC issued proposed rule in to revise proficiency testing regulations under CLIA related to required analytes and microbiology subspecialties and their associated criteria for acceptable performance
- Proposed rule would address all current analytes for which the lab conducts testing and newer technologies plus make additional technical changes to PT referral rules to more closely align them with the CLIA statute
- Expect final PT rules to be published later in 2021

HIPAA Privacy Changes

- Proposes to strengthen individuals' rights to access their own health information, including electronic information
- To improve information sharing for care coordination and case management for individuals
- To facilitate greater family and caregiver involvement in the care of individuals experiencing health emergencies
- To enhance flexibilities for disclosures in emergency or threatening circumstances, such as the Opioid and COVID-19 public health emergencies
- To reduce administrative burdens on HIPAA covered health care providers and health plans, while continuing to protect individuals' health information privacy interests

What's Ahead in 2021

- Higher volumes of COVID-19 testing nationwide under Biden Administration
- Look for the appointment of national supply commander to oversee production and distribution of tests and utilization of Defense Production Act
- Lab interests push for statutory changes for PAMA under new Administration and Congress
- New HHS leadership moves to clarify FDA authority to oversee laboratory developed tests (LDTs)
- 117th Congress debates legislative initiatives determining which federal agency should take the lead in regulating LDTs

Questions?