



# Payment & Policy Outlook for Labs in 2020

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# Learning Objectives

## PAYMENT & POLICY OUTLOOK FOR LABS IN 2020

### **After this webinar, you will be able to:**

- Examine how the third round of Medicare cuts under PAMA is altering the financial and competitive dynamics of the laboratory industry
- Anticipate how pending legal and legislative measures will impact PAMA policy in 2020 and beyond
- Assess how laboratory operations would be affected by proposed changes under Stark and federal anti-kickback regulations; CLIA revisions; guidance surround EKRA; FDA actions affecting pharmacogenetics testing; and lab data breeches and HIPAA requirements

# Agenda

- Key Market Trends and Challenges
- Reimbursement Outlook for 2020
- PAMA Update and Implications
- Regulatory Changes and Impact
- Health Issues and 2020 Election Landscape

# Key Healthcare Trends



- Healthcare Reform Splinters
- Growth of Medicare Advantage plus spike in Medicaid Demos
- Providers Seek Financial Sustainability Amid Churning Market
- Changing Consumer Demands, Needs & Expectations
- Behavioral Health Epidemic
- Emergence of Non-Traditional Players Entering Healthcare
- Growth of Machine Learning & Artificial Intelligence
- Healthcare Industry Becomes Prime Target of Cyber Crime

# Key Challenges & Trends for Laboratories

- Grim payment climate imperils financial viability
- Growth of value & integrated care
- Dwindling number of private physician practices
- More labs excluded from payer networks
- Imperative for operational effectiveness & efficiency
- Cybersecurity & compliance threats



# Lab Reimbursement 2020



- Third round of PAMA cuts implemented
- Medicare sequester cuts of 2% per year to continue thru 2028
- Private payor pricing further erodes
- More prior authorization & coding edits
- Focus on patient collections via high deductible plans
- Medicare rates for pathology services stable in 2020 but significant cuts set for 2021

# PAMA Going Forward

**Additional  
reductions  
on tap for  
2020**

**New law  
delays  
PAMA  
reporting  
in 2020**

**Status of  
appeals  
court  
ruling**

**What's the  
“bottom  
line” going  
forward**

# PAMA Refresher

PAMA requires that CLFS payment amount will be equal to the weighted median of private payor tests determined for each test based on data from applicable labs

Data is collected during a specified data collection period and reported to CMS during a specified data reporting period

**PAMA**

Starting in 2018, there is a six-year phase-in for any payment cut

From 2018-2020, no more than a 10% reduction permitted per year and from 2021-2023, no more than a 15%



# 2020: PAMA Year 3

- Final year for phasing-in 10% maximum annual cuts
- Many high-volume tests due for another 10% cut for total of 30% rate reduction over 2018-20 period
- Any hangover cuts from 2018-20 will be absorb in 2021

## Among tests cut +30%:

80053	Comp Metabolic panel (-37%)
80061	Lipid panel (-39%)
82607	Vitamin b-12 (-35%)
82728	Ferritin (-35%)
84153	Total PSA (-35%)
85025	CBC w/ auto diff (-35%)
87086	Urine Culture/colony count (-35%)

# High Volume Test Rate Reductions

2018 - 2020

Test	2017 Medicare NLA	2020 Payment
Comp Metabolic panel	\$ 14.49	\$ 10.56
Lipid panel	\$ 18.37	\$ 13.39
Vitamin B-12	\$ 20.58	\$ 15.08
Ferritin	\$ 18.70	\$ 13.65
Folic Acid	\$ 20.17	\$ 14.70
Total PSA	\$ 25.23	\$ 18.39
CBC w/ auto diff	\$ 10.56	\$ 7.77
Urine Culture	\$ 11.07	\$ 8.07

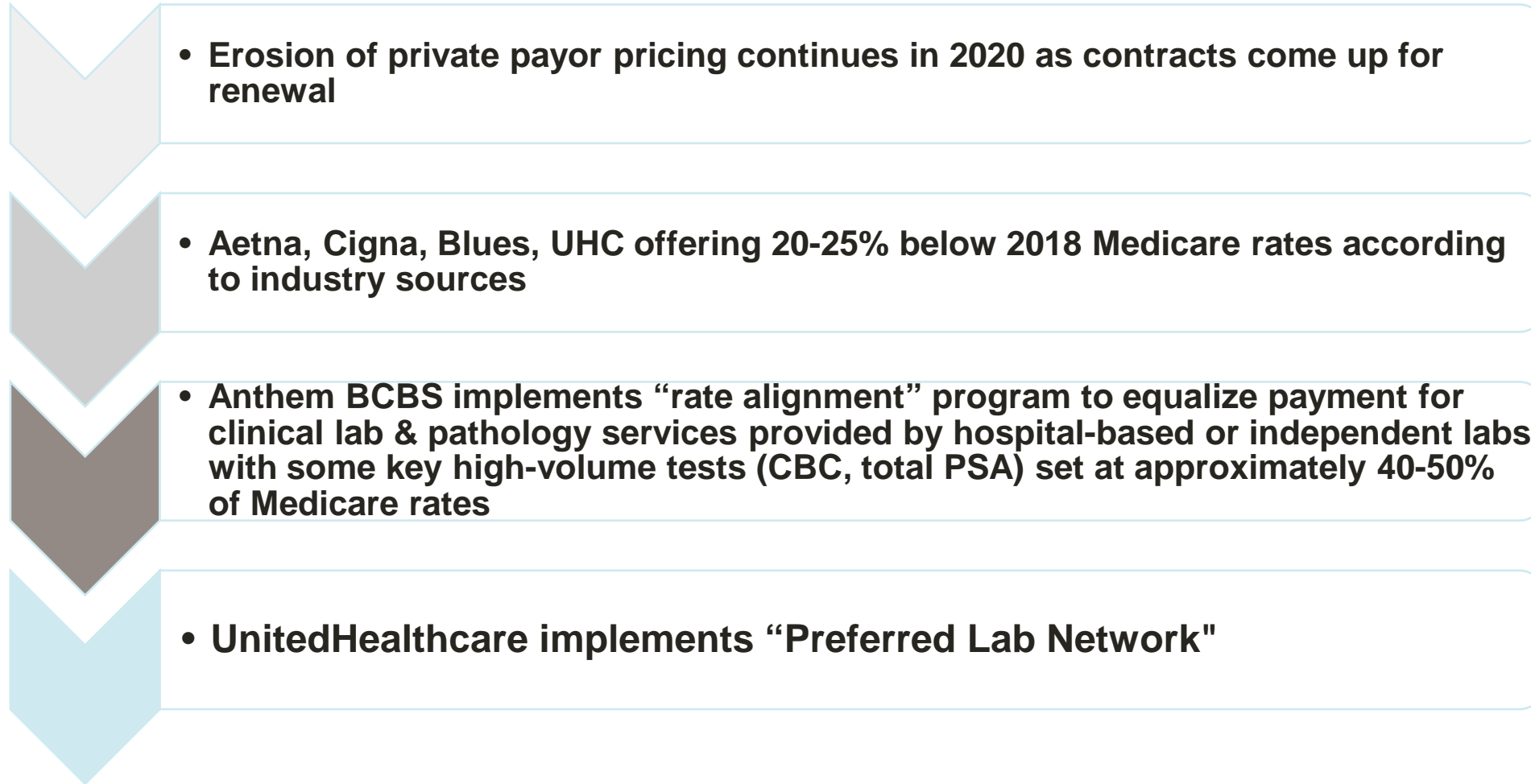
# Laboratory Access for Beneficiaries (LAB) Act

- Congress passes LAB Act as part of year-end spending bill
- Provides one-year delay of PAMA data reporting with the next round of data reporting now set for Jan - Mar 2021
- Requires study by Medicare Payment Advisory Committee (MedPAC) in consultation with CMS to assess how to improve PAMA implementation to better reflect congressional intent of a market-based fee schedule
- Potentially allows better reporting by hospital labs but their willingness to do so remains in doubt
- Gives industry additional time to pursue legal challenge

# Status of PAMA Legal Challenge

- U.S. Court of Appeals for D.C. ruled in favor of ACLA lawsuit against HHS regarding implementation of PAMA
- Appellate ruling overturned by D.C. District Court decision dismissing ACLA lawsuit on grounds that PAMA prohibits judicial review of lab payment amounts established by CMS
- On Oct 14, ACLA filed a motion of summary judgment before U.S. District Court challenging flawed PAMA implementation in final HHS rule
- ACLA motion asks Court to strike down final rule as unreasonable and contrary to PAMA requirements
- No Court decision expected until later in 2020

# PAMA's Ripple Effect



# PAMA's Bottom Line

- Medicare market-based payment system has substantial competitive impact industrywide
- Significant financial damage has already occurred with 3 years of PAMA cuts effective before legal and/or legislative action can modify PAMA payment process
- PAMA payment methodology creates winners & losers with specialty labs having payment advantage with proprietary tests (ADLTs) while smaller community and nursing home labs hard pressed to survive

# Regulatory Watch

Proposed Stark &  
Anti-Kickback  
Regulations

CLIA Revisions in  
Works

Lack of Guidance  
for EKRA

FDA Actions  
Against  
Pharmacogenetics  
Testing

Lab Data  
Breeches & HIPAA

# Stark & Anti-Kickback Regulatory Proposals

- Issued last fall by CMS & OIG, proposed anti-kickback and Stark law regulations signals some notable softening of compliance requirements for healthcare interests
- Creates a new anti-kickback safe harbors for certain “value-based” arrangements & eases compliance with existing ones
- Creates similar new exceptions to Stark and adds a new safe harbor under the civil monetary penalties (CMP) statute



# Proposed Changes to Stark & Anti-Kickback Laws

- Modifies Stark regulations by proposing provider-friendly interpretations of terms such as “fair market value” and “commercially reasonable” that have long caused angst for labs
- Proposes special compensation rule to provide an objective test for determining whether it takes into account the volume or value of referrals, or the value of other physician-generated business
- Proposes two separate special rules for non-fixed compensation to address compensation from and to a DHS entity & a physician
- Expands existing personal services/management contracts safe harbor & creates new safe harbor to protect certain outcome-based payments

# Cybersecurity & EHR Technology Exceptions



- Proposed parallel rules which would make donations of certain technology beyond the reach of Stark and AKS
- Proposed new cybersecurity technology exception & safe harbor would protect donations of software or other non-hardware information technology that are “necessary and used predominantly” to “protect information by preventing, detecting and responding to cyber attacks”
- OIG solicits comments on the types of donors who should be protected under the AKS safe harbor
- Comments were due to CMS & OIG by Dec 31, 2019

# CLIA

## Revisions

- CMS announced it will increase CLIA user fees by 20% to keep the program going through FY 2021
- CMS issued proposed CLIA rule on Feb 4 to revise proficiency testing regulations related to required analytes (29 new ones) and microbiology subspecialties and their associated criteria for acceptable performance
- Expect another CLIA-related rule soon with proposed changes affecting personnel, PT referral & histocompatibility requirements
- Effective Sep 26, CMS updated its State Operations Manual, Special Procedures for Laboratories (QSO-19-20-CLIA) — revision to establish quality lab policies & procedures

# Eliminating Kickbacks in Recovery Act (EKRA)

- EKRA enacted in response to concern that federal anti-kickback statute (AKS) was not broad enough to cover abusive payment arrangements related to opioid addiction treatment centers
- Relates to arrangements with recovery homes, clinical treatment facilities, and laboratories
- EKRA is similar to AKS except it applies to all payors and has an exception for employment compensation that is much narrower than the AKS's safe harbor
- Applies to all labs that perform testing related to substance abuse and endangers commission payments to lab sales reps
- No interpretative guidance yet from OIG or Justice Department

# FDA Steps Up Action Against PGx Testing



- FDA has publicly indicated its intent to regulate PGx testing
- Since mid-2019 FDA intensified regulatory actions against labs offering pharmacogenetics services without premarket clearance or approval
- Agency targeted labs performing PGx tests that predict a patient's response to certain medications
- Industry criticized FDA's communications to labs as vague & lacking specific guidance as to what labs need to do to comply
- Some labs have interpreted FDA action as a way to expand its power to regulate laboratory-developed tests (LDTs)

# Lab Data Breaches & HIPAA

- Estimated 24 million clinical lab patients have had their protected health information (PHI) stolen as part of several data breaches in 2019 involving multiple labs
- More than a dozen labs including LabCorp, BioReference Labs & Quest Diagnostics had patient data hacked via a web page operated by American Medical Collection Agency (AMCA), a third-party debt collection firm that subsequently declared bankruptcy
- Under the Health Insurance Portability & Accountability Act (HIPAA) covered entities including labs and business associates are responsible for the security of patient PHI
- Also covered are lab vendors who receive patients' PHI to complete their service contracts

# HHS Lowers Limits for HIPAA Violations

- Previously, any violation of HIPAA could result in huge civil monetary penalties (CMP) ranging as high as \$1.5 million annually for various violations
- HHS recently announced lower culpability limits for HIPAA violations & lower annual fines for providers
- Key change is that organizations that have taken measures to meet HIPAA's requirements will face much smaller maximum penalties than those which are found neglectful
- Concern is HHS want too far in reducing penalties for providers that could cause some to relax strict PHI policies

# How Important Health Policy Will Play in the 2020 Election

- Healthcare among top issues in 2020 election cycle
- Controlling prescription drug costs key priority with Trump Administration pushing drug import plan while Democrats supporting House-passed bill to allow U.S. to negotiate lower drug prices
- Expect the White House to also focus on Medicaid block grants, healthcare transparency and deregulation including greater involvement and flexibility for states
- Watch for Democrats to back universal health coverage with debate surrounding Medicare-for-All





# Top Health Issues Going Into 2020

- I.** Flashpoint for Democrats are costs associated with “Medicare for All” & whether to go with public plan option in lieu of supporting makeover ending private insurance
- II.** Big majority of Americans support the government negotiating with pharma companies to lower the cost for those on Medicare and private insurance
- III.** Expect regulatory and legislative measures to control drug costs to become major campaign issues for both parties
- IV.** Other top health issues include opioid crisis, women’s health & surprise medical billing

**Thank You!**

