Reimbursement & Policy Outlook for Clinical Laboratories in 2019

Presented by: Dennis Weissman, President

Dennis Weissman & Associates LLC

Washington, DC

CardinalHealth™

Learning objectives

After this webinar, you will be able to:

- Assess the current reimbursement environment for clinical laboratories in light of the ongoing cuts being made by Medicare and their impact on commercial insurers
- Understand the differing industry legal and legislative strategies involving PAMA plus the congressional outlook for modifying the law
- Examine what recent steps FDA has taken affecting laboratory developed tests (LDTs) and the outlook for LDT action on Capitol Hill
- Discuss changes in CLIA and Stark self-referral requirements being considered by CMS and the timetable for further action

Today's agenda

- Key Market Trends Impacting Labs
- State of Lab Reimbursement
- PAMA Perspective & Outlook
- Lab Market Fallout & Consequences
- Top Policy & Regulatory Challenges for 2019
- Lab Compliance Issues Under New Opioid Law

Key market trends

- Relentless reimbursement pressure on providers
- Emphasis on contracting & value-based care
- Increasing patient financial responsibility
- Growing numbers of physicians are becoming employees
- Rise of healthcare consumerism plus move to retail environment
- Integrating personalized medicine into clinical practice — molecular diagnostics, genetic testing & gene sequencing/NGS

National trends impacting labs

- Medicare Advantage (Part C) in which private insurers contract with the federal government to administrator program benefits has grown by 32% since 2015 to reach an enrollment of 22.4 million in 2019 or 36.7% of all Medicare beneficiaries

- 2016 marked first year where less than half of practicing physicians owned their own practices — 47.1 percent according to AMA data

- Percentage of people under 65 with private insurance in a high deductible plan increased from 43.7% in first quarter of 2017 to 47% in 2018

Where the laboratory market stands today

- National spending for clinical laboratory services, including anatomic pathology, grew by 3 percent during 2010-2017, to reach $96.6 billion
- Market projected to be essentially flat during 2018-2020
- As percentage of total national health spending, lab testing will decline from 3.3 percent to 2.8 percent by 2020

* U.S. Clinical Laboratory Industry: Forecast & Trends 2018-2020, *Laboratory Economics*

2017 lab revenue data

- Hospital lab revenue was $46.7 billion for a 48.4 % share of total market
- Combined Quest Diagnostics ($7.7B) & LabCorp ($7.2B) was $14.9B for a 15.5% market share
- Revenue for all other independent labs was $18.7B for a 19.4% share
- POLs had $14.3B in revenues for a 14.5 market share

Source: Laboratory Economics

CardinalHealth™

2017 lab revenue by test category

Test category	Lab revenue
Routine testing	73.1% ($70.6 billion)
Anatomic pathology	10.9% ($10.5 billion)
Molecular & genetic	9.8% ($9.5 billion)
Drug testing	4.1% ($4.0 billion)
Pap & HPV testing	2.1% ($2.0 billion)
Total revenue	**$96.6 billion**

Source: Laboratory Economics

Growth rates for testing segments: 2012 - 2017

Test category	Growth rate
Drug testing	+14%
Molecular & genetic	+12%
Routine testing	+4%
Anatomic pathology	-4%
Pap & HPV testing	-5%

Source: Laboratory Economics

Protecting Access to Medicare Act – PAMA Prompt

- PAMA is the first reform of the Clinical Laboratory Fee Schedule (CLFS) since 1984
- For the first time, it ties Medicare payment rates for lab tests to those paid by private payers rather than based on historical charges made by labs at local level as done previously
- It creates a single national fee schedule with no geographic adjustment, annual update or budget neutrality adjustment
- There continues to be no Part B copayment or deductible for lab services

Market-based lab payment

- Effective Jan. 1, 2018, CLFS payment will be equal to the weighted median of private payor rates determined for each test based on data from applicable labs
- Data is collected during a specified date collection period and reported to CMS during a specified data reporting period
- New subset of tests on the CLFS is introduced: Advanced Diagnostic Laboratory Tests (ADLTs) — have different data collection, reporting and payment policies associated with them

Defining an ADLT

- Covered under Medicare Part B
- Offered and finished by only one lab
- Not sold for use by a lab other than the lab that designed the test or a successor
- Either cleared or approved by the FDA or,
- Is an analysis of multiple biomarkers of DNA, RNA or proteins, and
  - When combined with a unique algorithm, yields a patient specific result, and
  - Provides new clinical diagnostic information that cannot be obtained from any other tests to combination of tests, and
  - May include other assays

Most labs excluded from first data collection period

- Starting in 2016 and every 3 years thereafter, applicable labs receiving 50% of CLFS & PFS revenue are required to report private payor data to CMS

- During first round of data collection and reporting most hospital outreach labs were excluded from reporting since only those labs using its National Provider Identifier (NPI) were considered an “applicable lab” if more than 50% of total Medicare revenues received under both CLFS & PFS

- Only 21 hospital outreach labs reported data with majority of independent labs & POLs didn’t have to report since they did not meet $12,500 low volume threshold

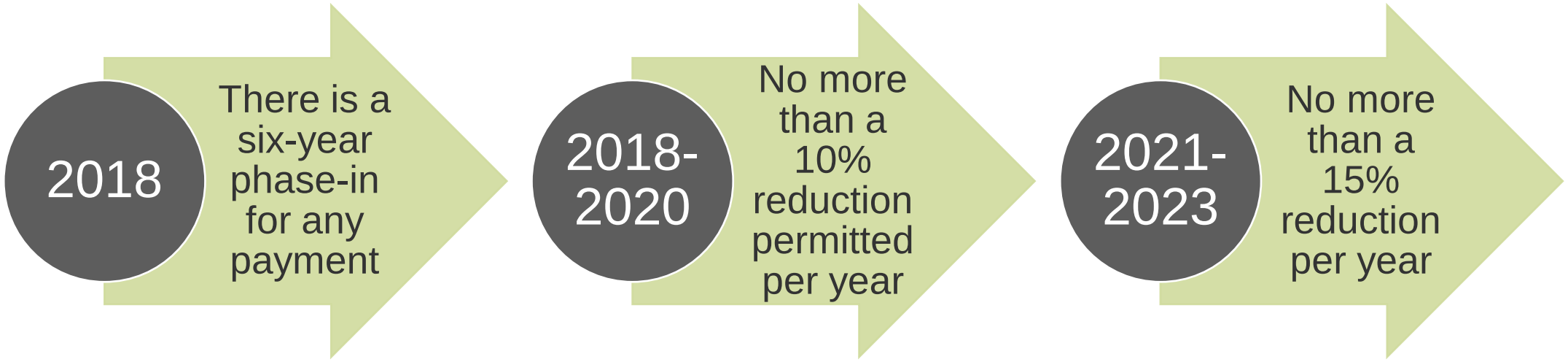
Hospital outreach labs must collect data starting in January

- CMS increased the number of labs that qualify as “applicable labs” by amending PAMA regulations in its final rule updating the 2019 physician fee schedule
- The agency removed payments received by Medicare Advantage (MA) Plans for determining applicable lab status
- Most significantly, it requires hospital outreach labs that receive at least $12,500 in Medicare CLFS revenues billed on CMS-1450 14X bill type during first six months of 2019 to collect private payer data & report it to CMS during first three months of 2020
- This means that most hospital outreach labs are now required to collect & report data to CMS under PAMA

Hospital data could make big difference in revised CLFS in 2021

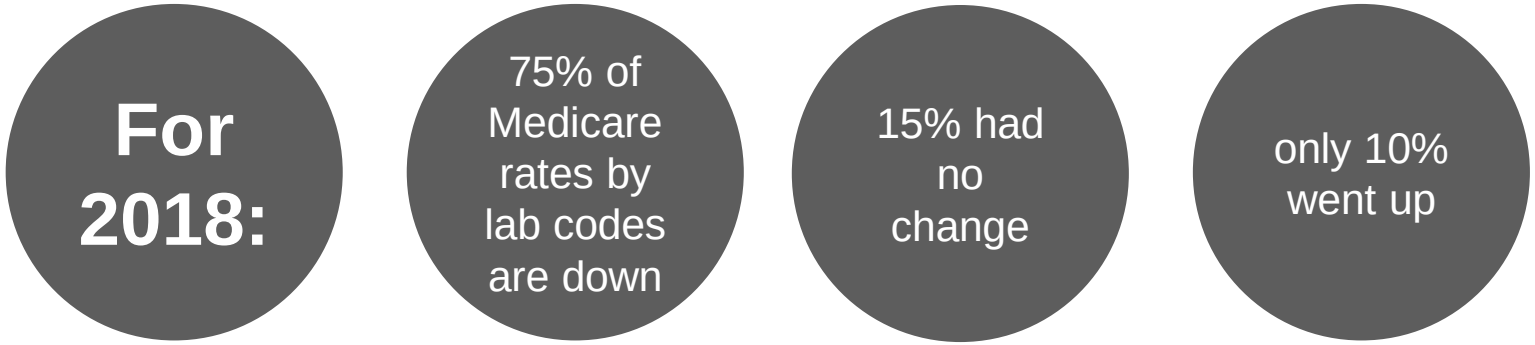
- That's because hospital pricing for lab tests are normally higher than for same test provided in other settings
- So if its included in CLFS data pool, it should result in higher median price level
- But this will only happen if large majority go hospital outreach programs report data
- Civil monetary penalties up to $10,000 per day may be imposed on "applicable labs" that fail to report, or for each misrepresentation or omission in reporting

Remember how PAMA phases-in cuts



PAMA takes a big toll from labs

- New market-based lab payments will save Medicare $670 million in 2018 (almost 10% lower than the $7B paid in 2017) and $3.96 billion over next decade



- Pricing for many high-volume lab tests are reduced 35% or more (10% cut per year during 2018-2020 period)
- Quest says its Medicare rates will drop 10% in both 2018 & 2019 with lower Medicare revenue of 4% last year ($37M) and LabCorp sees lower Medicare revenue of 6-8% both years

Look for more cuts in 2019

- Additional 10% rate cuts for many lab tests paid under Medicare CLFS - particularly high volume procedures - set to take effect this year
- State Medicaid lab rates will continue to be adjusted downward since they can be no higher than revised Medicare pricing
- Using Medicare's new market-based lab fee schedule as a benchmark, look for private/ commercial insurers to make adjustments to their lab payment rates beginning this year

What's the bottom line for labs?

- Lab industry will continue to encounter severe pricing pressure for the next few years (2020)
- Total national spending for lab testing will be flat through 2020 as first three years of Medicare's new market-based pricing take full effect
- Gradual drop in fee-for-service payments,, growing problems with being out-of network and more fixed fee arrangements such as contracting & bundling
- Growing patient responsibility will require labs to collect greater percentage of revenue from patients

PAMA cuts likely to start despite industry actions

- ACLA lawsuit to halt PAMA was rejected by federal court with appeal now pending but no decision likely before later this year at the earliest
- Lab groups push for legislation on Capitol Hill to amend PAMA including to freeze PAMA rates at 2018 levels but the odds of prevailing are long given policy paralysis gripping Washington and partisan divisions inside Congress
- Though legal or legislative action could result in changes to PAMA, it remains unlikely that rate reductions set to take effect thru 2020 will be rolled back

Some test categories do better than others under PAMA

- Advanced Diagnostic Laboratory Tests (ADLTs) get biggest boost since Medicare pricing for new ADLTs are initially based on the test list price and because labs having proprietary tests have better control over market pricing
- Molecular & genetic tests generally have more favorable pricing but not uniformly so
- Since last year Medicare has paid for 23 individual automated chemistry tests previously bundled into automated test panels (ATPs) because they hadn't clarified their authority under PAMA
- Warning: CMS says it will revise its policy in order to capture APT bundled rates for individual chemistry tests sometime this year

PAMA pricing is changing industry's competitive dynamics

- Labs focusing on ADLTs and proprietary tests have competitive edge in today's market under Medicare market-based pricing
- Many other labs including national labs see negative revenue impact in their Medicare business due to PAMA rate reductions
- Wall Street took note of impact of PAMA pricing with 2018 stock prices soaring for labs marketing proprietary tests like:
  - CareDx (+243%)
  - Genomic Health (+119%)
  - Foundation Medicine (+101+)
- But turning thumbs down on the Nation's two largest labs:
  - LabCorp (-21%)
  - Quest Diagnostics (-15%)

Look for changes in the hospital outreach market

With Medicare pricing now the same for all lab settings, hospital outreach programs face increasing pressure to evaluate their pricing to assure that its more competitive with independent labs in their market area

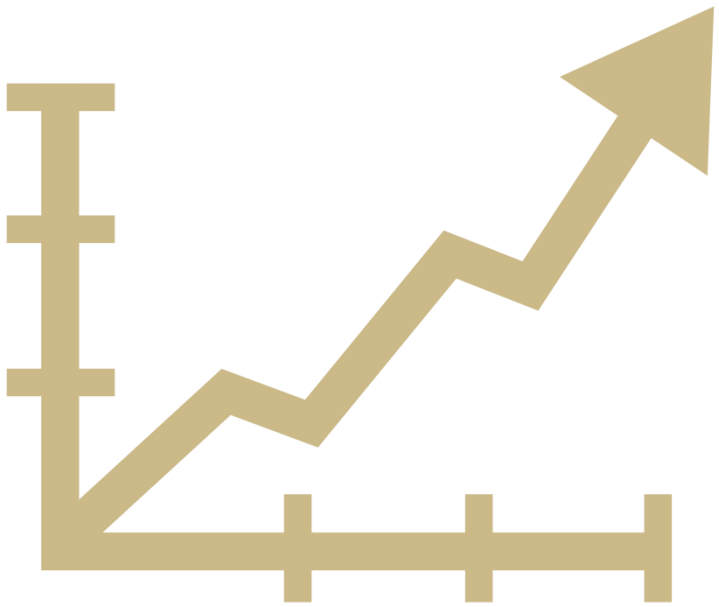
More health systems/hospitals are moving to determine the value of their lab outreach business including ROI as some decide to monetize their lab assets by divesting

Look for hospitals to seek models for more cost-effective management of their labs including management services contracts with national labs, joint ventures or other innovative business arrangements with hospitals in their market area or independent labs

Industry consolidation intensifies

- Nation’s big commercial labs seek growth via acquisitions with leading targets being hospital outreach labs & specialized labs having specialized/proprietary tests
- Many smaller local & community labs will either have to merge, venture or close by 2020
- Major health systems will grow their outreach programs via deals/ventures with regional and community labs
- As more solo physicians become affiliated with hospitals or groups practices the number of POLs nationwide will decrease

Labs adopt new business and growth strategies



- Explore operational strategies to become more efficient & cost effective: expanding automation, artificial intelligence
- Enter into strategic ventures, mergers, joint ventures and partnerships
- Increasingly think outside the box to drive growth such as direct-to-consumer testing, contract research, data analytics, retail focus
- Adopt aggressive cost-cutting programs including inventory control & renegotiate contracts with outside vendors

Regulatory issues to watch: CLIA revisions

- **Fee Increase:** CMS announces that fees for labs certified under CLIA will increase 20 percent over 11 classification categories and affect about 251,000 labs nationwide. Certificate fees now range from $150 (low volume labs) to $7,940 per certificate. Labs have until March 1 to provide feedback to CMS on its notice.

- **Opening Up CLIA:** CMS issued request for information regarding personnel, fee, PT referral and histocompatibility regulations. Lab groups differ on whether a B.A. in nursing should qualify to meet CLIA requirements for moderate and high complexity testing personnel. No regulatory proposal published yet but once CMS does so, it will be a big deal since CLIA requirements have rarely undergone revision since 1992.

Regulatory revisions: Stark Self-Referral & LDTs

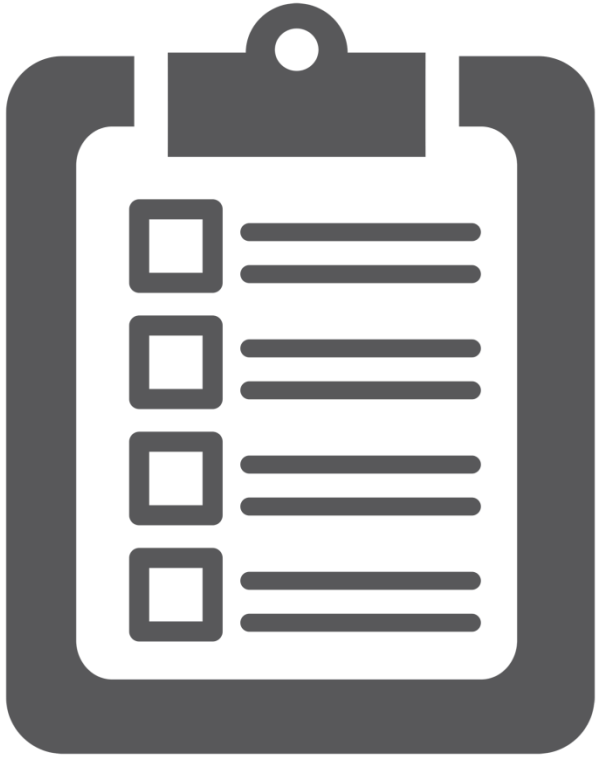
- In-Office Labs: CMS request for information on how the Stark law may impede value-based healthcare models has given labs groups an opening to ask CMS to narrow the in-office ancillary services exception by removing AP from list of services physicians are allowed to self-refer and perform in their own offices.

- FDA Backs Off LDT Regulation: After many years of pushing for oversight of laboratory-developed tests, FDA now says legislation is best way to regulate LDTs even as the agency takes steps to make it easier for labs to receive premarket approval of LDTs.

Unintended consequences for labs under new Opioid Law

- Eliminating Kickbacks in Recovery Act (EKRA), part of hastily passed 2018 opioid law, imposes criminal penalties for some conduct that is now allowed under Stark anti-kickback safe harbors
- Represents unprecedented expansion of federal authority over payment arrangements between providers and referral sources
- Fails to carve out lab testing that has nothing to do with opioid or drug abuse
- Law applies to all labs and all services covered by all payers

Common lab business practices thrown in doubt



- Commission-based employment agreements for lab sales personnel
- Placement of phlebotomists in physician offices and giving offices specimen collection device
- Lab fees to GPOs & donations for FQHSs
- Legal opinion mixed whether labs should evaluate their arrangements with referral sources for private pay patients
- Prosecutorial discretion may prevail but only real fix is for Congress to amend law so that it is more narrowly tailored to referrals for addiction treatment or recovery services

Questions?

Presented by: Dennis Weissman, President
Dennis Weissman & Associates LLC
Washington, DC