

Current Reimbursement Issues: Regulatory Trends, Market Dynamics, and Strategies Post-PAMAgeddon

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How Did We Get Here and What's Next?

Historical Rates

- Based on lab charges in 1984–1985, adjusted annually for inflation
- 57 local fee schedules

in 2014

- Congress imposed across the board reductions to pay for SGR
- CMS proposed further reductions to reflect "Technical Adjustments"

PAMA

- No cuts 2014-2017
- Reductions capped at 10% **each year** 2018-2020
- Repeal CMS authority for "Technical Adjustment" cuts

Industry Impact

- Positive and negative impacts by Medicare's revised CLFS
- Elimination of ATP payment will result in legitimate hikes in reimbursements
- "Gaming" the system might cause serious compliance problems for labs

WHAT'S NEXT ?

- Fiscal leadership = insight on contractual process reviews and reimbursement due diligence
- Operational Efficiency
- ACLA lawsuit status
- Getting ready for the next PAMA data collection period – reporting on actual

PAMA 2018 Pricing Cuts & Other Considerations

Here's the bottom line:

10%
INCREASE

Only 10% of rates for codes on the CLFS increased

75%
DECREASE

Rates for three quarters of all codes on the CLFS decreased

	Year 1	Year 2	Year 3	3-Year Total
CBO ¹	-\$100 million	-\$400 million	-\$400 million	-\$1.0 billion
OMB ²	-\$390 million	-\$700 million	-\$620 million	-\$1.7 billion
CMS ³	-\$670 million	-\$1.2 billion	-\$1.7 billion	-\$3.6 billion

¹ CBO Cost Estimate for the Protecting Access to Medicare Act of 2014 (Mar. 26, 2014).

² 81 Fed. Reg. 41097.

³ CY 2018 – Preliminary Private Payor Rate-Based CLFS Payment Rates and Analytics.

- ✓ Relief on 14 day rule – labs can now bill directly
- ✓ CPT editorial panel adding and deleting new codes used for BRACA
- ✓ Bundling and incremental pricing for AMCC eliminated
- ✓ Medicaid rates will be cut to be below 2018 CLFS and in some states as a percentage of CLFS
- ✓ Decoupling Private Payor Contracts from the Medicare CLFS
- ✓ NCD draft released – just because you have a code doesn't mean coverage. Get payor alignment prior to PLA code change



PAMA Impact by Sector (Cumulative)

Segment	Medicare/ Medicaid % of Revenue	2018 Impact	2019 Impact	2020 Impact	No Cap
Pathology	35%	-1.50%	-2.88%	-4.07%	-5.32%
Molecular	26%	0.03%	-0.16%	-0.31%	-0.61%
Clinical	31%	-2.00%	-3.77%	-5.33%	-7.04%
Pain/PGx	40%	-0.63%	-0.12%	-0.15%	-0.73%
Hospital	12%*	-0.82%	-1.55%	-2.18%	-2.81%
Nursing Home	51%**	-3.59%	-6.75%	-9.44%	-12.06%

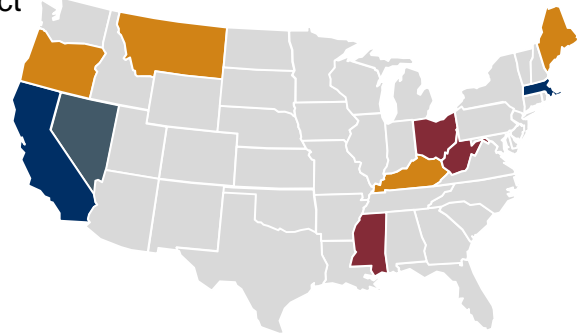
* Excludes test included in OPSS

** Excluded Part A



Medicaid Impact

- State Medicaid programs cannot reimburse at a rate greater than the Medicare rate
- States that have established rates at a percentage of Medicare will have the greatest impact

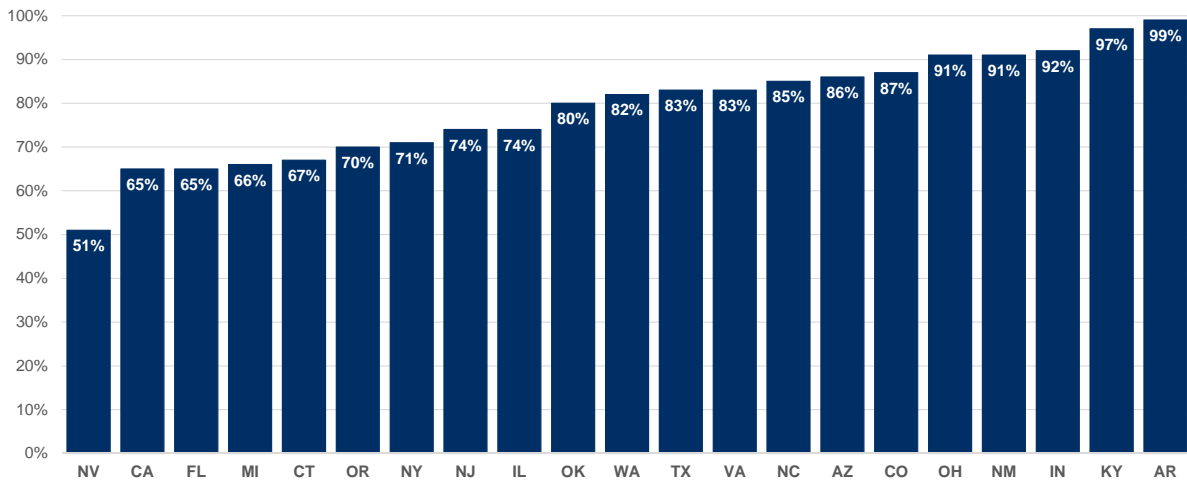


- States that have established fees significantly below Medicare, but not directly tied to the CLFS as a percentage will have the least impact



State Medicaid FFS Lab Test Rates

Medicaid FFS Lab Test Rates as a Percentage of Medicare CLFS 2017



Source: Laboratory Economics from state health departments



Four Key Issues to Challenge PAMA

1

Definition of
“applicable lab”

2

Retrospective data
collection period
resulted in inaccuracies
in reporting

3

Clear and transparent
mechanism for
aggregation of data

4

Potential fixes to
calculation
methodologies for the
future

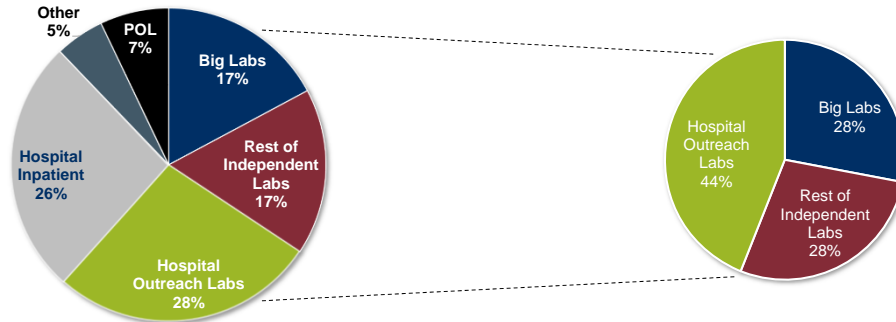


	Proportion of CLFS Volume ¹	Proportion of Applicable Information by Volume	Potential Over- or Under-Representation
Independent Labs	50%	90.1%	40.1% over
POLs	23%	7.5%	15.5% under
Hospitals	27%	1.0%	26.0% under

¹ 2016 Physician/Supplier Procedure Summary file; 2015 Outpatient Standard Analytic file.



PAMA Test Volume by Facility Type



Lab Type	Percent of Total	Weighted Average Impact %
Big Labs	28%	(44.8%)*
Rest of Independent Labs	28%	8.0%*
Hospital Outreach Labs	44%	32.1%*
Total	100%	3.8%

Source: XIFIN analysis based on XIFIN PAMA data set



Labs' Concerns with PAMA implementation

Serious ramifications
for many labs
& healthcare
industry

- CMS created prices for tests not on CLFS at full reduction vs. 10% cap
- Clear intent of Congress under PAMA was to insure payments on the CLFS reflected private market rates
- Congress did not expect PAMA methodology to result in:
 - ✓ Reporting of incomplete and inaccurate data
 - ✓ Extremely costly
 - ✓ Burdensome to produce data
 - ✓ Not reflect market prices





Market Trends & Strategies



Private Payor Reimbursement vs. 2018 CLFS

Payor Group	Lab NPI	Hospital NPI	Service Specialties	Lab NPI	Hospital NPI
Blue	-23%	426%	Therapeutic Drug Analysis	-27%	163%
Aetna	-20%	60%	Panels	-22%	213%
Cigna	-22%	95%	Tier 1 Molecular	-18%	206%
Humana	-36%	93%	Tier 2 Molecular	-15%	342%
UHC	-25%	0%	Microbiology	-29%	140%

Source: XIFIN analysis based on XIFIN data



Genetic Testing Reimbursement Metrics

50%

XIFIN genetic testing labs collect 50% more than hospital labs performing genetic testing based on higher adjudication rates alone (only 35% of denials are prior auth-related today but growing fast)

Primary Drivers

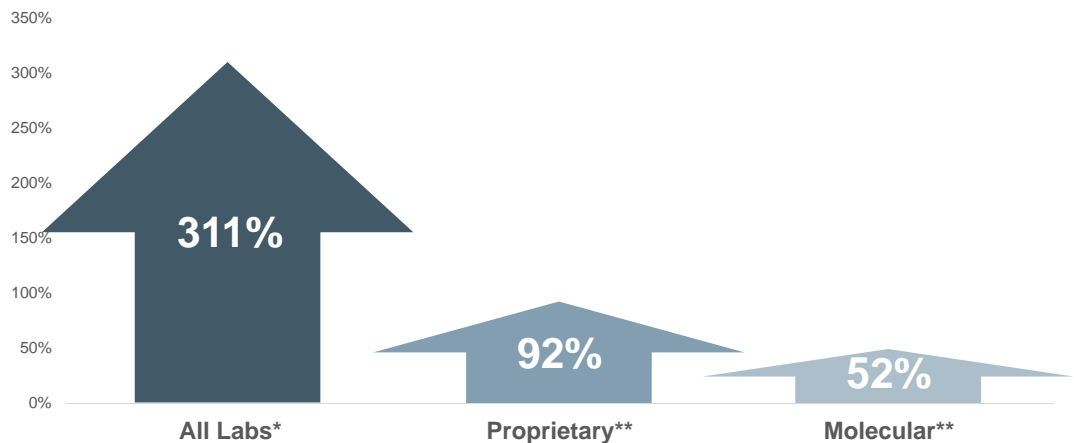
- ✓ Workflow configurability to address different testing segments' specific needs
- ✓ Streamlined appeals and claim attachment capabilities
- ✓ Automated workflow to assist with compliant management of larger patient responsibilities (e.g., Patient Assistance Programs, flexible payment plans, etc.)
- ✓ Standardized Prior Authorization, Claim Attachment, Denial Workflow and Appeals capabilities across all market verticals



Denials for Prior Authorization

Based on all XIFIN Cross Customer Data

Increase in Prior Auth Related Denials

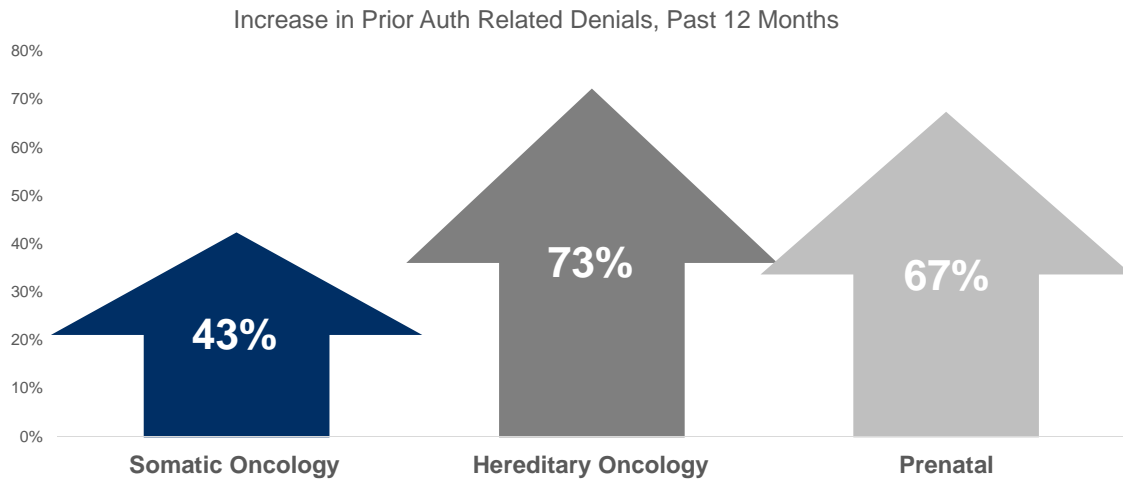


*Period from 2016-17
** Past 12 months

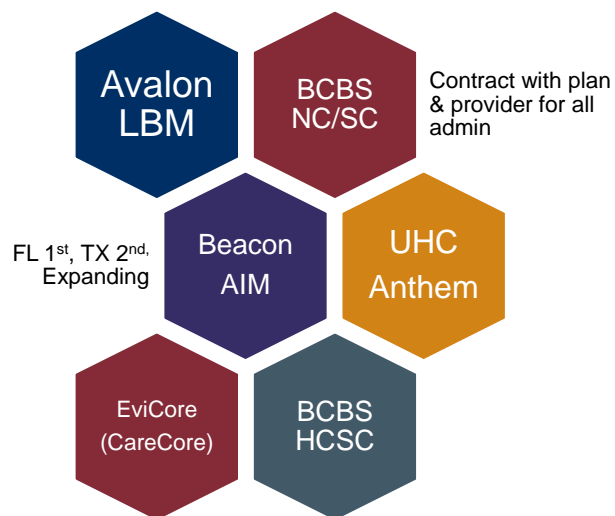


Trends Specific to Genetic Testing

Based on all XIFIN Cross Customer Data



Outsourcing Examples



PAMA Data Collection – Round 2

Second round of PAMA may cut individual test payment rates by up to

15%

Solid reporting from labs is the key to mitigate future price cuts

- ✓ Report on actual collections versus expected
- ✓ Validate accuracy of payments
- ✓ Optimize appeals activity to avoid reporting under payments

REPORTING

- PAMA statute allows penalties of \$10K/day for each failure to report, error in reporting or omission in reporting applicable information.
- Correct contracting problems prior to reporting period
 - Eliminate coupled contracts
 - Evaluate fees for each CPT to determine outliers that need to be re-negotiated
- Establish financial systems with appropriate reporting capabilities and retain source documents



Industry Readiness

Financial Integrity in Billing Systems

Financial reporting and analysis required to identify problems

- Procedure level detail
- Analysis of “billed price” to reflect market pricing

Adherence to Transaction Standards

PROVIDERS & PAYORS

- Inaccurate return of units in ERA
- Payment amount different from contract rate
- Contractual allowance calculations & identifying discrepancies (sequestration)
- Inaccurate denials or inappropriate classification of patient responsibility
- Contracting with intermediaries that circumvent standards (Avalon)



Contracting Discipline



Contracting at a percentage of Medicare

- Eliminate contracts tied to CLFS in favor of market based contracts that are a percentage of billed or CPT based contracts that reflect a cost basis
- Contracts tied to CLFS that cannot be eliminated should be fixed to 2017 CLFS



Contracting without consideration to the market value of testing

- Calculate the fully loaded and incremental cost for each lab test (RVUs as guideline)
- Establish a standard fee schedule proportionally aligned with cost
- Establish a minimum contracting rate for each test that is above payor allowables
- Identify & Renegotiate Low Pricing/Pricing Below Cost



Patient – Physician – Payor Engagement

- Partner with payors to develop appropriate coverage criteria
- Active engagement in optimizing physician's diagnostic orders and therapy decisions
- Pricing transparency with patients



Payment for Automated Chemistry Tests

No change to claims submission

- ✓ Providers still bundle to panels listed in AMA CPT manual
- ✓ Additional AMCC ordered individually billed separately with their specific CPT

MEDICARE

WILL NOT

Utilize AMCC reimbursement formula that pays only a small incremental fee for each additional AMCC*

- 14 (CMP 80053) to 18 AMCC tests priced at the same rate
- ~\$0.50 increments for each additional two components up to 23 total AMCCs

WILL

Pay CLFS for each individual CPT submitted if it is not part of an AMA panel that is also performed on the same day

*Medical Manners MAC instructions regarding ATP bundling (section 9837.6 and 9837.7)



Market Trends – Independent Clinical Labs



Growth in specialty labs and a decline in standard test menus

- Investor funding for fast growing specialty labs with limited menus or proprietary assays improves, paving the way for faster growth
 - Independent clinical lab trend to specialization likely to accelerate
 - Specialty labs (cardiovascular, Pain, PGX, Genetic, Molecular testing) will continue to increase as the fastest growing segments
- Specialty labs fight to maximize specialty physician referrals
- Decline in number of independent labs offering standard test menus continues

Increase in consolidations, partnerships, and joint ventures

- Labs with a high Medicare/Medicaid mix (regional; NH labs) will likely decline, ceding ground to regional Hospital Outreach labs
- Reference labs performing esoteric testing will continue to leverage economies of scale to partner with outreach labs
- Industry consolidation acceleration to gain economies of scale
- Independent labs seek joint venture with hospital labs



Market Trends – Physician Office Labs



Shift commodity tests to point of care

- Physician office lab automation and associated declining cost of tests will shift commodity tests to point of care
- Physician office lab menus continue to expand as a result of increasing waived tests and the miniaturization of analyzers
- Physicians strive to achieve early diagnosis and manage chronic patients to reduce hospitalization

Partner with hospitals

- Quality reporting will drive physicians to partner with hospitals for integrated healthcare needs

Partner with specialty labs

- Physician specialists will partner with specialty labs for personalized medicine



Market Trends – Hospital Labs



A shift in hospital labs from Cost Center to Profit Center

- 92% of hospitals operate their own lab*
- 76% of health systems run an outreach program*
- Average annual outreach revenue doubled in past 10 yrs to \$25M*
- Average hospital lab contribution margin of 33% is 3X commercial labs'
- Hospital labs have growth capacity

Hospital Outreach labs with higher margins to gain market share

- Integrated healthcare & population health management key driver
- Outreach volume optimizes lab utilization against costly inpatient testing
- Outreach can service regional lab needs more efficiently
- Hospital selection of reference and joint venture partners more strategic than cost based

Leveraging lab to optimize patient management and reduce cost

*National Hospital/Health System Laboratory and Outreach Survey



Outreach Volume Contribution to Cost Structure

Case Study & Data Analysis: Urban Hospital, ~350 Beds

	With Outreach	Without Outreach
Inpatient Test Volume	1,800,000	1,800,000
Outreach Test Volume	2,500,000	0
Test Volume (Total)	4,300,000	1,800,000
Fixed Cost per Test	\$3.50	\$5.25
Variable Cost per Test	\$3.90	\$3.90
Cost per Test (Total)	\$7.40	\$9.15
Net Impact		+\$1.75 (24%)

*Source: Mayo Medical Laboratories analysis of client-submitted hospital laboratory data, October 2015



Hospital Lab Should Leverage Financial Advantages



- ✓ In Network Status
- ✓ Reimbursement Rates
- ✓ Shift in Competing Labs Service Menus
- ✓ Competing with commodity labs
- ✓ Rural Market
- ✓ Complementary Partnerships for Reference Testing
- ✓ MACRA



Hospital Labs Can Manage Financial Disadvantages



- ✓ Reimbursement Rates
- ✓ Limited Menu
- ✓ Phlebotomy Center
- ✓ Cost Structure
- ✓ Inadequate Financial Systems and Financial Reporting



Strategies for Labs to Offset PAMA Impact



Private Payor contract negotiations

- Leverage hospital to negotiate better lab pricing
- Leverage regional presence and value based pricing concepts



Diversify testing menu and expand specialty testing capabilities



Cost reduction efforts

- Workflow automation to remove clerical decision making and achieve labor efficiencies
- Reduce total cost of billing to below 4% while achieving bad debt targets

5-20% POTENTIAL A/R COLLECTIONS

Update technology infrastructure

- ✓ Web based systems - WS integration capabilities for real time bi-directional connectivity
- ✓ "Service based architecture" that allows functionality to be used at point of need

Select accounting based billing software

- ✓ Financial integrity (GAAP, SOX compliant)
- ✓ Referential integrity
- ✓ Enterprise BI reporting capability

Patient engagement automation

- ✓ High deductibles now for 50% of beneficiaries
- ✓ Patient portal, IVR, Electronic secondary insurance filing



Macro Healthcare Trends – Industry Disrupters

Consumerism and Data Analytics Shape the Future of Healthcare Delivery

Amazon – Chase – Berkshire Hathaway Alliance

- Already obtained licenses for DME distribution in 48 states
- Could partner with PBMs
- Amazon and Echo capabilities (schedule office visit; virtual house calls)
- AI based in-home healthcare & diagnostics

CVS – Aetna Merger Cigna/Express Scripts

- Both mergers designed to control rising medical costs and provide data analytics
- CVS has 9700 pharmacies & 1100 walk in clinics
 - Minute Clinic vs. ER option or Physician visit
- 3 largest PBMs become vertically integrated with insurers (UHC/Catamaran)

Walmart – Humana

- Combining retail pharmacies with a PBM
- Data analytics building a 360 view of consumer
- Medicare Advantage growth – better care at lower cost
- Delivering care close to consumer

Pharma Invests in Labs

Novartis, Roche, Opko

- Companion Dx drive therapeutic drug sales
- Big Data (NGS) identifies cancer related DNA
- Big Data helps physicians optimize test orders and treatment choices
- Big Data helps manage population health and control medical costs





Thank You

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