



Overview of PAMA – How Labs Are to Report Market Data & Related Issues

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National Independent Laboratory Association (NILA)

- Community-based, multi-regional laboratories
- Full service, anatomic, specialty, molecular, genetic labs
- Serve physician practices, hospitals, skilled nursing facilities, assisted living, homebound patients
- Geographically diverse in rural and urban markets
- High percentage of Medicare patients; between 30-60 percent of practice



Why Did Congressional Reform Happen?

- Belief that CLFS is an outdated system
- CMS would reform the CLFS if Congress did not
- OIG, GAO, others saying that labs are overpaid
- Lack of understanding about the value of traditional tests – Are these tests overused? Are they commodities?
- Battle of the old tests versus new tests – How to get coding, coverage, and reimbursement for advanced diagnostics



Overview of Reform Law

Widely Ordered Tests

- Labs to report test prices paid by all private payors and their volumes every three years, beginning in 2016
- Medicare lab reimbursement to follow private market rates, beginning in 2017

Advanced Diagnostic Lab Tests

- New designation for sole-sourced molecular diagnostics, FDA cleared tests, and others
- Paid list price for portion of first year, then requires annual price reporting, beginning in 2016

Coding and Coverage

- Expedites coding
- Requires MACs to follow LCD process
- Potential consolidation of MACs that address coverage policies



What Really Happened?

- Mandatory reporting by some laboratories
- Reporting of all non-capitated/bundled private market rates and test volume (per test) starting in 2016 (every 3 years for most tests)
- Reimbursement rates calculated for each test based on weighted median of reported rates
- New reduced Medicare lab reimbursement rates starting in 2017 – phased in over six years – transparency of the process unlikely



Flaws of So-Called Market Reform

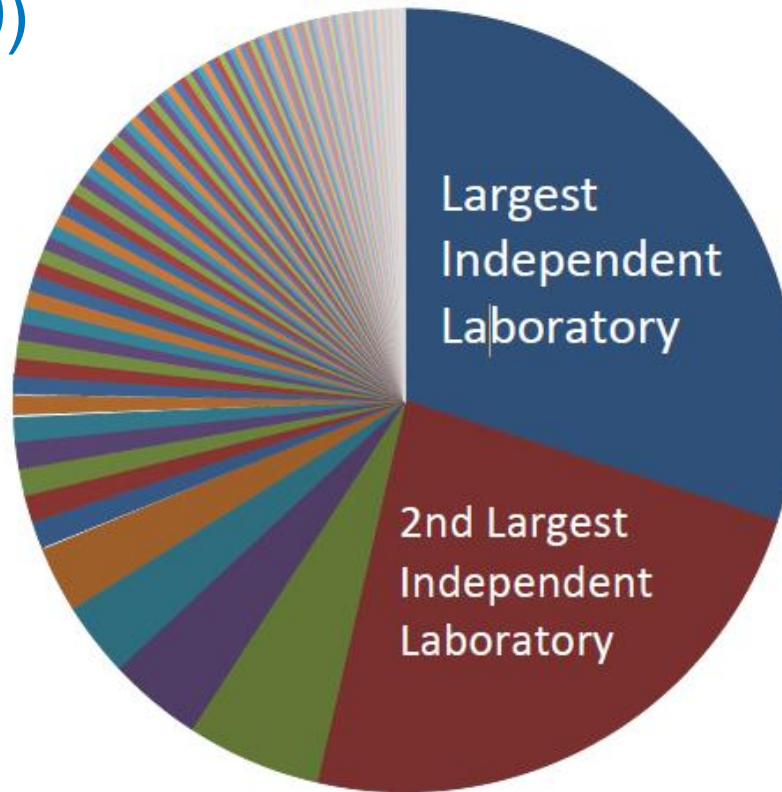
- May exclude large segments of lab market
- Data will be dominated by the largest players
- Complexity of commercial payer contracts
- Complexity of discount arrangements
- Risk of a process that is not transparent
- Rate adjustments without consideration of market effect and patient access
- Restricted adjustment to specimen collection



New Rates for CLFS

Year	Maximum Reduction/Test	CPT 82025 CBC w/Auto Diff
2014 (Base)	--	\$10.94
2017	10 percent	\$ 9.85
2018	10 percent	\$ 8.87
2019	10 percent	\$ 7.98
2020	15 percent	\$ 6.78
2021	15 percent	\$ 5.76
2022	15 percent	\$ 4.89

Estimated Concentration of Independent Laboratory Market (2009)



Timeline

2015

- CMS to conduct rulemaking on data collection and reporting requirements by June 30, 2015 (no rule as of May 6, 2014)
- Advisory committee to be established to guide market process and address new test coding issues

2016

- Labs to begin reporting private market rates/volumes on January 1
- CMS to calculate new rates based on weighted median of reported tests

2017

- New rates are effective (No other updates – CPI)



What Happens with all of the Data

- New CLFS payment rates to be set using weighted median of reported rates (by volume for each payer)
- No requirements for transparency in pricing adjustments



Advanced Diagnostics

- A new category of testing established under law for tests offered and furnished by the developing laboratory
- Interim pricing between April 1, 2014-December 31, 2016 under traditional gapfill and crosswalk
- Beginning January 1, 2017 for new advanced diagnostics tests paid “actual list charge” for first three quarters
- Private payer rates must be reported by end of quarter two; reported annually thereafter
- Rates to be set at volume-weighted median of private payer rates

Other Provisions

- Pricing of new tests proceed under traditional gapfill and crosswalk methodologies
- CMS to adopt temporary HCPCS codes for new tests (and also advanced diagnostic tests) to serve as a bridge (for two-years or less) before obtaining a permanent HCPCS code
- There is supposed to be increased oversight of coverage decisions
- Creation of Advisory Committee on coverage and payment of new tests (and more)
- CMS may designate one or more (up to 4) MACs to establish coverage policies OR coverage policies and claims processing (similar to DME)

Major Concerns with PAMA

- May exclude large segments of lab market
- Data will be dominated by the largest players
- Complexity of commercial payer contracts
- Complexity of discount arrangements
- Risk of a process that is not transparent
- Rate adjustments without consideration of market effect and patient access
- Limited adjustment to specimen collection and billing complexities
- GAO “post-mortem” report is too little too late

Key Regulatory Questions

- How will CMS define an “applicable laboratory”? (hospitals???)
- How will CMS define Medicare revenue? (in-plan rates only, copays, etc)
- What will be the reporting time period? (12 mos, 6 mos, etc)
- How will CMS require data to be reported?
- How will CMS determine the accuracy of data reported (apples to apples)?
- Who will serve on the new advisory committee?
- What tests will CMS review? (all CLFS tests or limited number of tests)
- How will “single laboratory” be determined for ADx?
- Will CMS expand the definition of ADx?



Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**QUESTIONABLE BILLING FOR
MEDICARE PART B CLINICAL
LABORATORY SERVICES**



Suzanne Murrin
Deputy Inspector General
for Evaluation and Inspections

August 2014
OEI-03-11-00730

Immediate Challenges Continue:

- OIG digging in
- CMS/MAC - new test coverage/payment
- Offsets for health care costs
- Cost of reporting system
- Transition to ICD-10



Labs Must Engage Now

- Influence PAMA implementation
- Ensure Congress understands the problems and implications and weighs in/reconsiders
- Push for transparency
- Data collection (labs and third parties)
 - Unfunded mandate
 - Cost to implement
 - Threat to beneficiaries



Spring/Summer 2015 – Primary Laboratory Business and Policy Priorities of Focus

- Two major issues on parallel tracks
 - Implementation of laboratory payment reform
 - FDA oversight of laboratory developed tests
- Some committee overlap – champions on both?





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