# NYS Clinical Laboratory Association 2018 Annual Meeting

# National Update On Issues Impacting Laboratories

**Sharon West, ACLA**

June 7, 2018

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# Clinical Labs Strengthen the National Economy

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- Employ 277,000 people
- Pay more than $21B in wages
- Contribute more than $13B in state and federal taxes

# Clinical Labs Strengthen NY Economy

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- NY labs create jobs for over 16,000.
- NY labs pay over $1.44 billion in wages.
- NY labs pay over $960 million in total taxes.

# ACLA Membership Represents a Diverse Cross-Section of Labs

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- Not-for-profit founded in 1971
- Approximately 30 clinical and anatomic pathology members laboratories including national, regional, specialty, ESRD, hospital and nursing home laboratories

# Associate Membership Allows Health Care-Related Companies to Work with ACLA

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- 17 Associate Members
  - Billing Companies
  - Consultants
  - Diagnostic Manufacturers
  - Information Technology Companies
  - Law Firms
  - Pharmaceutical Companies
  - Non-Profits

# DC Landscape

American Clinical Laboratory Association

- Crowded agenda
- Opioids, drug pricing, etc.
- Health care fatigue
- Cost consciousness for all policy decisions

# Today's Topics

American Clinical Laboratory Association

- **PAMA**
- Medicaid
- Diagnostic Reform
- Prior Authorization
- Other Medicare Issues

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# PAMA – Why was it enacted and how did we get here?

- Static fee schedules viewed as antiquated
- OIG reports on Medicare reimbursement
- CLFS targeted for cuts
- Need for “pay fors” for doc fix

# ACLA Supported PAMA & Continues To Support A Market-Based Fee Schedule

American Clinical Laboratory Association

**ACLA NEWS**

*American Clinical Laboratory Association Supports Senate Passage of Provisions for Clinical Laboratory Fee Schedule in SGR Extension Legislation*

**April 01, 2014** Categories: *ACLA News, News, Reimbursement and Coverage, Featured News, ACLA Press Releases*

WASHINGTON, D.C. – The American Clinical Laboratory Association (ACLA) – a not-for-profit association representing the nation's leading national and regional clinical laboratories on key federal and state government reimbursement and regulatory policies – voiced support for provisions in the SGR extension legislation passed by the U.S. Senate today that reform the Clinical Laboratory Fee Schedule (CLFS) by providing a more rational process for transitioning to changes in reimbursement.

"The ACLA worked diligently with Congress on many of the lab industry's key priorities and we are pleased that the Senate included in the SGR extension bill several of our proposals for modernizing how Medicare reimburses clinical laboratories," said Alan Mertz, President of the ACLA. "When the president signs this bill, clinical labs will avoid another potential round of indiscriminate, across-the-board payment cuts and most importantly, seniors' access to diagnostic testing will be protected."

Mertz noted the SGR extension legislation will bring predictability in reimbursement over the next several years, provide more transparency, and allow more time for laboratories and other stakeholders to prepare for changes as well as ensure that Medicare reimbursement for anatomic pathology services will not suffer significant cuts. In addition, it will provide more opportunity for stakeholders to work with the Centers for Medicare and Medicaid Services (CMS) on implementing these important reforms.

https://www.acla.com/american-clinical-laboratory-association-supports-senate-passage-of-provisions-for-clinical-laboratory-fee-schedule-in-sgr-extension-legislation/

# What PAMA Did

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- Required “applicable labs” to report private payor rates and volumes to CMS
- Called for new CLFS rates to be the weighted medians of those private payor rates; payment reductions phased in
- Established data collection periods and data reporting periods
- Granted authority for CMS to impose civil monetary penalties for non-reporting, omissions, misrepresentations

# PAMA – Applicable Labs

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Definition:

- A laboratory that bills Medicare under its own NPI
- During a data collection period, receives a majority of its Medicare revenue (Parts A, B, C, and D, including co-pays/deductibles) under the CLFS and/or Physician Fee Schedule
- Receives more than $12,500 in CLFS revenue during a data collection period

# PAMA – Applicable Information

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Definition:

- Each private payor rate for which final payment is made during a data collection period
- Associated volume of tests corresponding to each private payor rate
- Specific HCPCS code associated with the rate
- Capitated payments excluded

# Reporting Requirements Exacerbate Applicable Lab Issue

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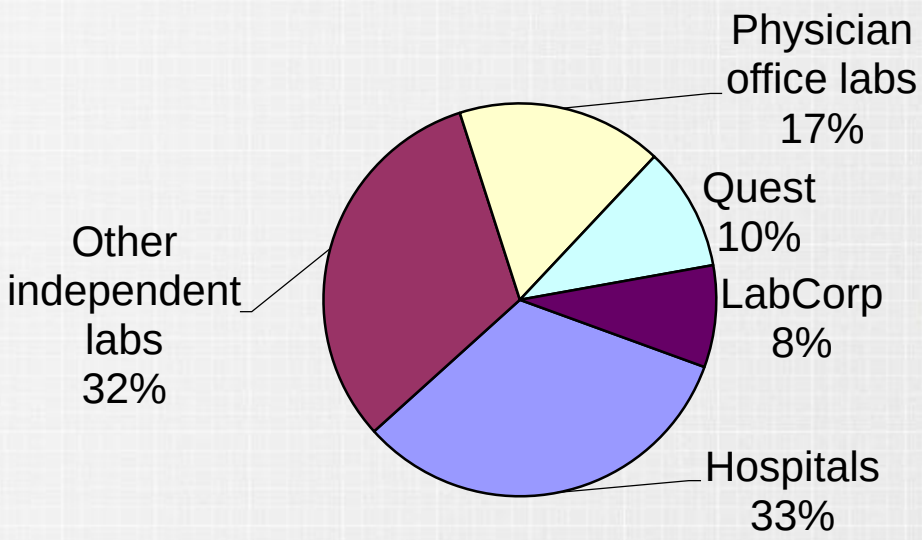
- Final rule requires submission of hundreds of millions of private rate data points
- Even sophisticated expended hundreds of FTEs to amass the required data, including manual input of paper claims (as required by the rule)
- Continued errors in the CMS data portal increased the burden and uncertainty of data reporting
- The cost and burden of reporting have given pause to additional laboratories from engaging and seeking to submit data

# Medicare Spending on Clinical Lab Tests

American Clinical Laboratory Association

**2015 Medicare Spending, Clinical Lab Tests - $8.3B**




Source: Direct Research, LLC analysis of Medicare LDS SAF 5% claims files,

# OIG Estimates of Who Will Report?

American Clinical Laboratory Association

**Figure 5. Which Labs Will Be Required to Report Their Private Payer Data?**

| INDEPENDENT LABS | PHYSICIAN OFFICE LABS | HOSPITAL LABS |
|---|---|---|
| Independent labs that received **at least $12,500** from Medicare Part B for lab tests during the first half of 2016 or any labs that perform advanced diagnostic lab tests will be required to report | Physician-office labs that received **at least $12,500** from Medicare Part B for lab tests during the first half of 2016 will be required to report | Generally, no hospital labs will be required to report, because 50% or **less of their Medicare revenue** is for Clinical Laboratory Fee Schedule or Physician Fee Schedule services |
| **1,398 out of 3,211**: Estimated number of labs that will be required to report | **11,149 out of 235,928**: Estimated number of labs that will be required to report | **0 out of 6,994**: Estimated number of labs that will be required to report (excludes hospital outreach labs, which function as independent labs) |
| **$3.8 billion out of $3.9 billion**: Medicare payments to reporting labs | **$1.0 billion of $1.4 billion**: Medicare payments to reporting labs | **$0 of $1.7 billion**: Medicare payments to reporting labs |

Source: OIG analysis of Medicare Part B lab test payments, 2016. See endnote 10 for more information about the criteria identifying applicable laboratories, i.e., laboratories that will be required to report.

Note: Figures regarding how many labs will be required to report are estimates. We assumed that all independent labs and physician office labs will receive more than 50 percent of their Medicare revenue from the Clinical Lab Fee Schedule or Physician Fee Schedule.

# Flaws in PAMA Data

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- Data set excluded 99.3% of the laboratory market as reported by OIG.
- Hospital labs only contributed 1% of the data.
- Physician Office Labs (POLs) only contributed 7.5% of data.
- 2.4 million $0.00 prices were submitted whereas 2.3 million data points were collected from all reporting hospital NPIs.
- Alternative CMS simulations incorrectly assume additional labs would report pricing volume and distribution identical to data already captured
- CMS selectively corrected or omitted data that would have resulted in higher than expected weighted medians.

# PAMA Data Inadequate - Hospitals

3,043: # of hospital laboratories that provided more than $12,500 in *just* CLFS billed services in the first two quarters of CY 2016 (the period used to qualify as an applicable laboratory)

26%: % of Medicare CLFS payments hospitals represents as reported by the HHS OIG, yet only 1% submitted data.

21: Only 21 hospital NPIs reported data. Actual number of reporting hospitals/TIN entities is likely even fewer.

# PAMA Data Inadequate - POLs

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5,962: # of POLs that exceeded $12,500 in CFLS claims in Q1 and Q2 of 2016

18%: % of Medicare CLFS payments paid to physician offices in 2016

8%: Actual percentage of data reported by POLs under PAMA

# PAMA CLFS Reform As Implemented

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PAMA changed the CLFS from a static fee schedule to a fee schedule based on the private market rates of Medicare lab providers. CMS, however, has implemented PAMA in an arbitrary way that ignores Congressional intent and threatens beneficiary access.

| PAMA's Intent | PAMA as CMS implemented | Detail |
|---|---|---|
| Market-based system | CMS cherry-picked highest volume, lowest priced tests in market-place | System neither follows private market make-up nor the Medicare market make-up |
| Data from all market segments | Skewed data excluding market segments | Over 99% of laboratories were prohibited from reporting, especially hospital labs |
| Predictable and sustainable | Arbitrary and unsustainable | Agency cherry-picked lowest pricing labs to report and arbitrarily applied regulations to the data set, resulting in unpredictable and unsustainably low reimbursement |
| Fair and accurate rate-setting | Rate cuts 3-4x greater than government estimates | Top 25 tests cut by average of 32%, rural hospital labs cut by average of 28.5% |
| Medicare beneficiary access | Beneficiary access threatened | Vulnerable beneficiaries at greatest risk of losing access to laboratory services, including rural, nursing home and home health patients |

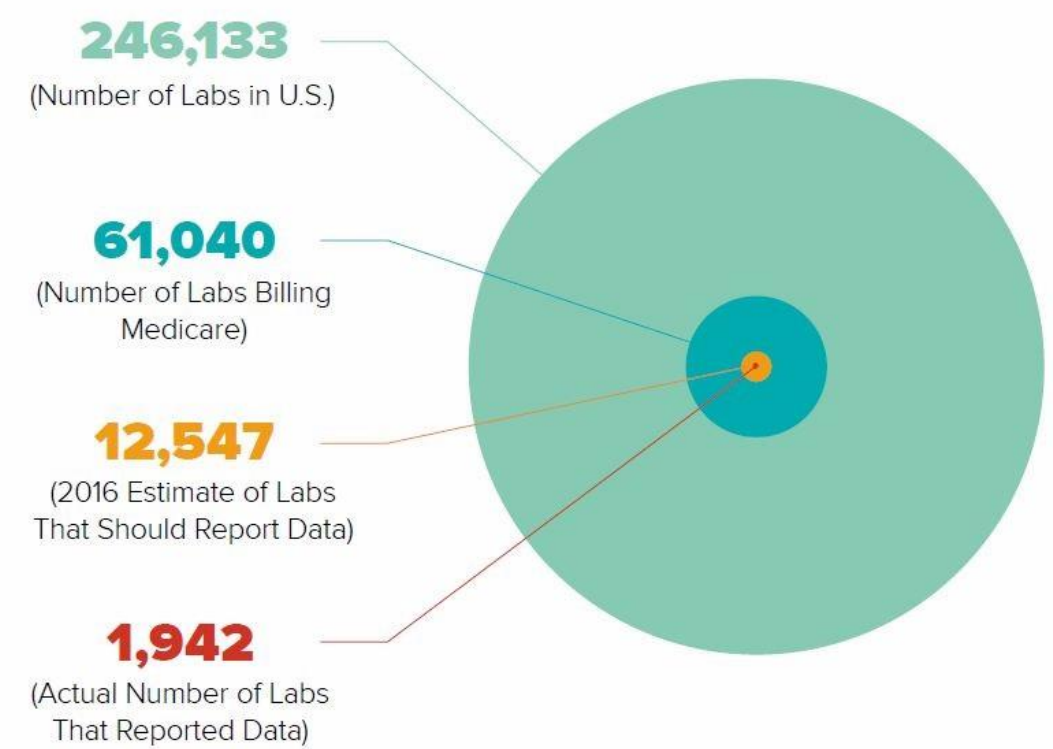
# Less than 1% of Labs Reported Data

American Clinical Laboratory Association

## Patient Access at Risk

**Proposed rate cuts will likely force clinical labs in rural and underserved areas to close and limit the lab tests they offer, resulting in test result delays for Medicare Beneficiaries.**

The US clinical lab market is composed of nearly 250,000 labs, including hospital labs, physician office labs, and independent labs. In 2016, the Department of Health & Human Services estimated that 12,500 labs would report their private market lab data to calculate the new Medicare rates. Ultimately, ***fewer than 2,000 labs reported rates,*** creating a dataset that is unrepresentative of the private market.



# More $0.00 Prices Were Reported than Prices Reported from Hospitals

American Clinical Laboratory Association

# PAMA Impact

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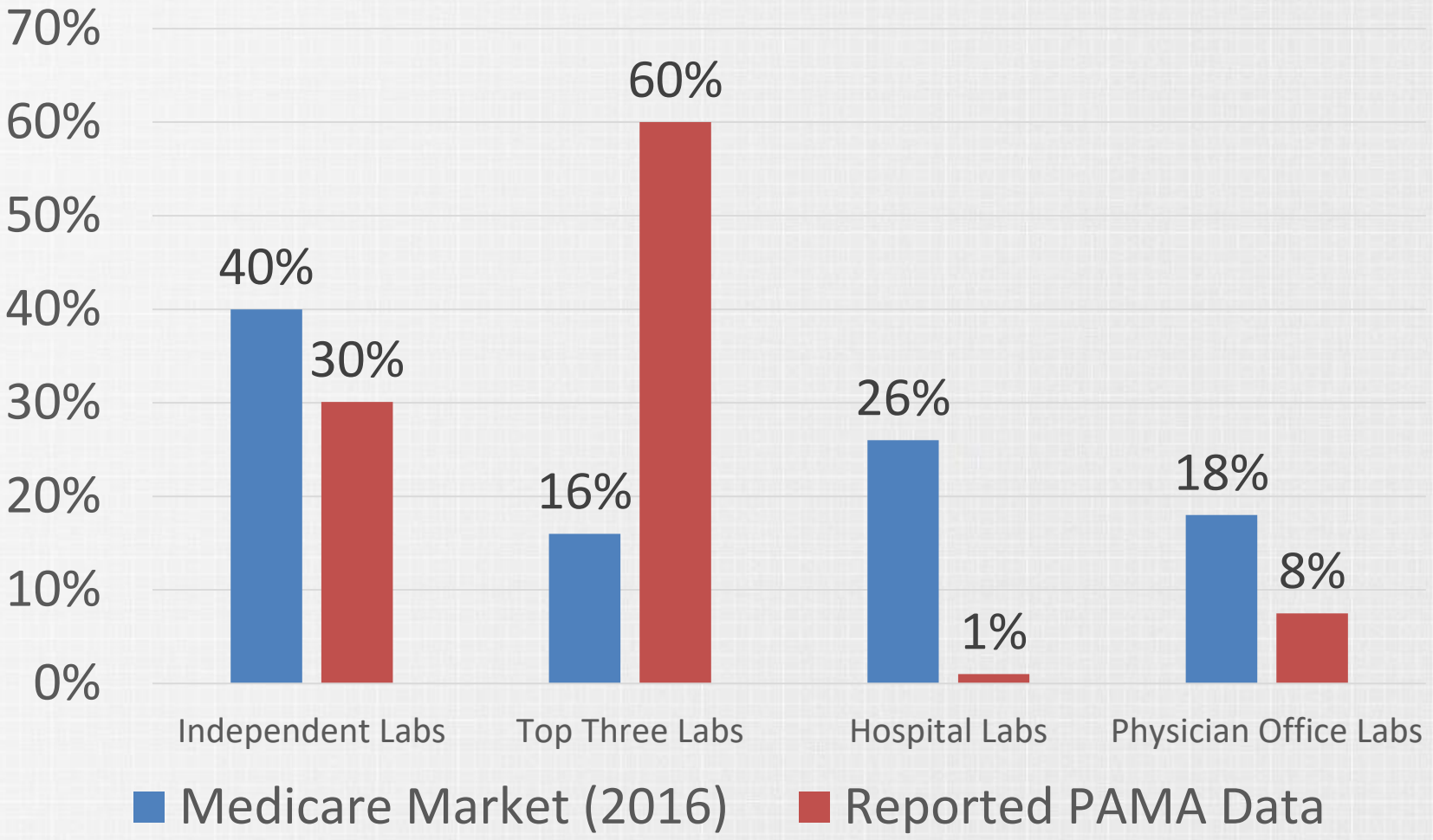
- CLFS cuts in 2018 will total **$670** million compared to
  - 2014 CBO score of **$100** million and
  - OMB score of **$520** million.
- On average CMS projects top 25 codes will be cut by 24.6% by 2020.
- 58% of CLFS codes will receive phased in cuts over 2018, 2019 and 2020, as the cuts exceed the 10% annual threshold.
- 75% of CLFS codes receiving a cut in 2018.

# PAMA Data Not Representative of the Private Market; Top Three Independent Labs 3X Overrepresented in Rates

American Clinical Laboratory Association



# Cuts are 360% More than CBO Estimates –$3.6B Over 3 Years

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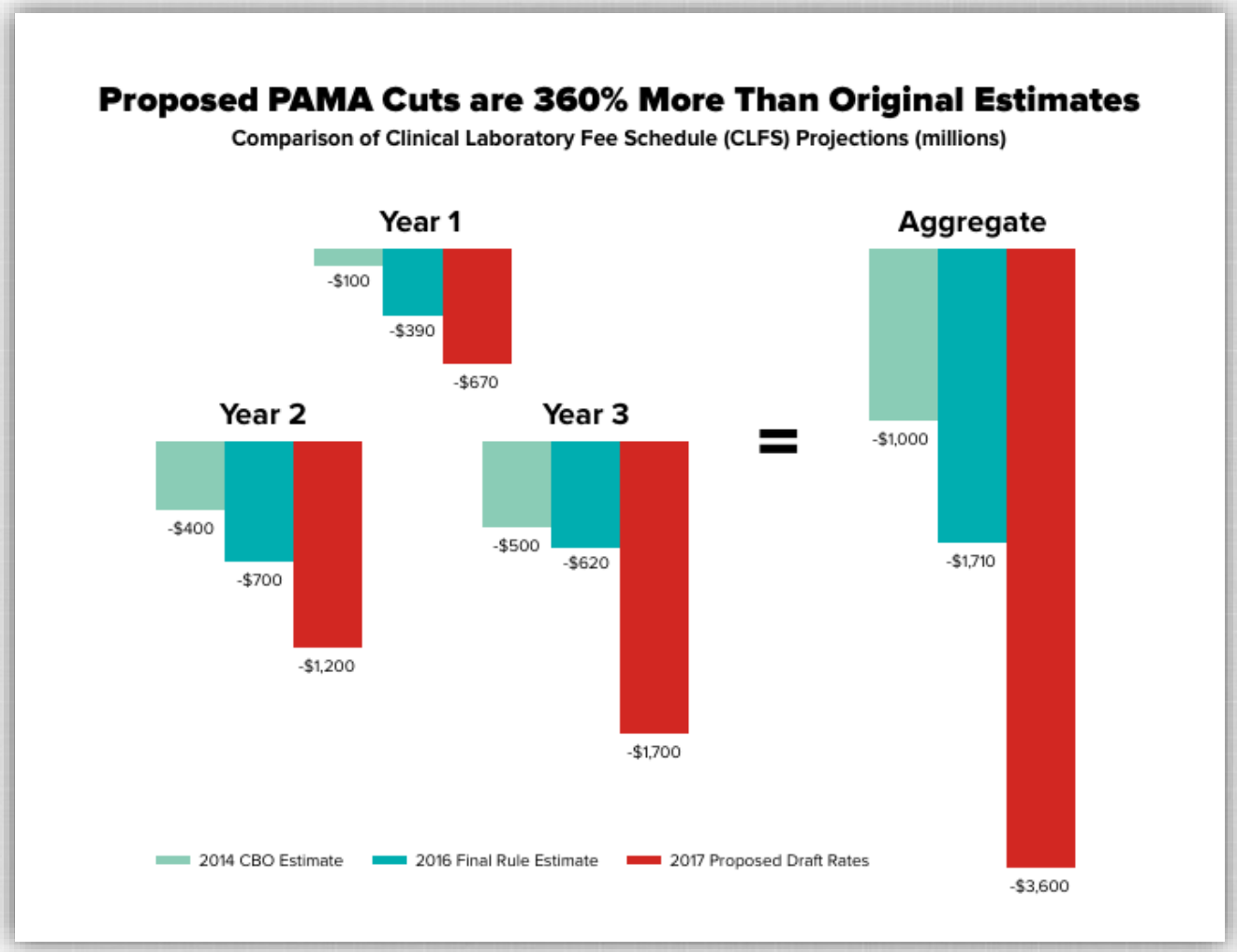

# New York

## Proposed Medicare Cuts to Clinical Laboratories

American Clinical Laboratory Association

Instead of creating a market-based system as intended by Congress, CMS has used flawed and incomplete data that will arbitrarily slash reimbursement to unsustainable levels and harm beneficiary access to laboratory services which help to diagnose, screen, and monitor disease for millions of patients everyday.

| PAMA 10 Year Cut Impact | |
|---|---|
| National CLFS Impact | -25.6% |
| New York Labs | -27.8% |
| New York Lab Segments: | |
| Independent Labs | -28.6% |
| Physician Office Labs | -27.0% |
| Hospital Labs Overall | -27.3% |
| Hospital Labs Urban | -27.1% |
| Hospital Labs Rural | -28.7% |

| Clinical Laboratories in New York | |
|---|---|
| **Employment** | 16,627 Jobs |
| **Economic Impact** | $2.54 Billion |
| **Wages** | $1.44 Billion |

Impact estimate compares fully implementing the draft weighted medians to if 2017 CLFS rates were held constant in the 10 year window

# PAMA Cuts May Harm Beneficiary Access to Lab Services

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- Nursing home labs and labs in rural areas particularly at risk of closure or reduction in services
- Labs with high percentage of Medicare also at higher risk
- Reduced test menus
- Longer wait times for results

# ACLA Supports Legislation to Fix PAMA

American Clinical Laboratory Association

- Ensure data sample reflective of the market
- Reduce data reporting burden
- Recalculate PAMA rates
- Cap cuts to labs to original 2014 PAMA CBO score

# ACLA Files Lawsuit On Highly Flawed PAMA Data Reporting Process

American Clinical Laboratory Association

*CMS Ignored Congressional Intent in Implementing New Clinical Lab Payment System Under PAMA, ACLA Charges in Suit*

**December 11, 2017** Categories: Issues, Protecting Access to Medicare Act, ACLA News, News, Featured News, Patient Access to Lab Services, ACLA Press Releases

(Washington, D.C.) – The government agency that runs the Medicare program failed to follow a congressional directive to implement a market-based laboratory payment system, thereby jeopardizing Medicare patients' access to vital laboratory services, according to the American Clinical Laboratory Association (ACLA) in a lawsuit filed today against the Acting Secretary of the U.S. Department of Health and Human Services (HHS) in the U.S. District Court for the District of Columbia.

The lawsuit asserts that the Centers for Medicare & Medicaid Services (CMS), operating under the purview of HHS, ignored congressional intent and instituted a highly flawed data reporting process in advance of setting market rates under the Protecting Access to Medicare Act (PAMA). Contrary to Congress's directives, the overwhelming majority of laboratories were prohibited from reporting private payer data. As a result, CMS failed to protect access to laboratory services for Medicare beneficiaries. This flawed process could cause serious financial harm to potentially thousands of hospital, independent and physician office laboratories, and make it harder for Medicare beneficiaries to get access to medical testing, particularly in remote rural areas and in nursing homes that depend on laboratory testing services.

ACLA PAMA LITIGATION MATERIALS AND RESOURCE KIT http://www.acla.com/about-us/acla-pama-litigation-materials-and-resource-kit/

# Today's Topics

American Clinical Laboratory Association

- PAMA
- **Medicaid**
- Diagnostic Reform
- Prior Authorization
- Other Medicare Issues

# Medicaid Cuts Layered On Top of PAMA

- Laboratory reimbursement rate adjustments
  - NV, MO, OH, MI, TX, SC
  - Stakeholder letter to CMS, ACLA Comments to MO, MI, TX
- Implementation of the PAMA Section 216
  - Unprecedented cuts in both Medicare & Medicaid Programs
    - 10% in 2018, 10% in 2019 & again in 2020
    - Savings Realized Absent State Action

# Missouri Impact

## 3 High Volume Laboratory Test Codes

| CPT Code | Description | 2017 Rate | 2018 Rate | Variance – 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|
| 80061 | Lipid Panel | $18.14 | $13.22 | -27% | -37% | -47% |
| 82306 | Vitamin D 25 hydroxy | $40.07 | $29.24 | -27% | -37% | -47% |
| 85025 | Complete CBC with auto diff WBC | $10.53 | $7.67 | -27% | -37% | -47% |

# Implications for Medicaid Beneficiaries

- Medicaid reductions layered on top of Medicare PAMA cuts
  - Drastic, unnecessary, and at a level that threatens access to critical laboratory services used in the prevention, diagnosis, and monitoring of disease.
- Access already at risk due to Medicare PAMA cuts especially for patients who are vulnerable and in rural & underserved areas with relatively few laboratory providers.
- Payments “sufficient to enlist enough provider so that services are available . . . to the extent . . . available to the general population in the geographic area” required
  - Rates less than costs may lead providers to discontinue laboratory services.

# Proposed Medicaid Access Rule

- Exemptions to regulatory requirements on public process & submission of specific information on access to care when proposing to reduce Medicaid provider payment rates for:
  - Risk-based Medicaid managed care enrollment rates › 85% total covered population
  - Overall reduction ≤ 4% of overall spending & ≤ 6% over 2 consecutive state fiscal years.
- Medicaid managed care rates tied to Medicare
- Ability to target a subcategory of services without having to speak to access implications

# Medicaid Access & Laboratories

- Deep concern about laboratory reimbursement cuts not subject to meaningful monitoring of impact on access
- Backward step on monitoring access
- Short-sighted especially given downstream effect
- Managed Medicaid Exemption:
  - More than 17 states meet 85% threshold
  - 11 currently between 75 – 85%

# Today's Topics

ACLA
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- PAMA
- Medicaid
- **Diagnostic Reform**
- Prior Authorization
- Other Medicare Issues

# Laboratory Developed Tests

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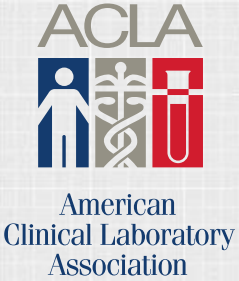
- Comprehensive statutory reform for oversight of LDTs and IVDs
- DAIA discussion draft = important step
- ACLA Principles for Diagnostic Reform, including:
  - LDTs are not devices
  - Grandfathering
  - Preemption
  - Modifications

# Diagnostic Reform's Long Road




- 1976: FDA Authority to Regulate IVDs Through Medical Device Amendments (MDA)
- 1988: CMS Authority to Regulate LDTs Through CLIA
- 2006 & 2007: FDA Published Draft Guidances on In Vitro Diagnostic Multivariate Index Assays (IVDMIAs) – Never Finalized
- June 2010: FDA Announced Decision to Exercise Authority over LDTs
- October 2014: FDA Issued Draft Guidance
- November 2016: FDA Announced it Will Delay Finalization of Guidance
- January 2017: FDA Released Discussion Paper with Possible Approaches
- March 2017: Reps. Bucshon and DeGette Release Diagnostic Accuracy and Innovation Act (DAIA) Discussion Draft

# Now is the Time for Comprehensive Diagnostic Reform

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- Ensure innovation and patient access to testing
- Provide certainty for current LDTs
- Provide assurance that tests are supported by clinical and analytical validity

# ACLA Key Principles to Maintain Patient Access and Foster innovation

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- LDTs are not medical devices
- LDTs must be grandfathered
- Reasonable transition to new system
- Preemption of state requirements
- Protections for modifications
- Clear CMS (CLIA)/FDA Boundaries

# Diagnostic Reform Supported by Growing List of Stakeholders

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- Laboratories (academic & other settings)
- IVD manufacturers
- Patient groups

# Diagnostic Reform Supported by Congress and the Administration

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- ***It is a bipartisan issue in Congress:***
  - In the House, Representatives Dr. Larry Bucshon (R-IN) and Diana DeGette (D-CO) have worked over the last year to develop a consensus legislative draft on diagnostic reform.
  - Senators Orrin Hatch (R-UT) and Michael Bennet (D-CO) have also signaled their interest in regulatory reform with the goal of enacting legislation this year.
- ***The FDA supports reform:*** The FDA Commissioner, Scott Gottlieb, has signaled on numerous occasions his willingness to work with Congress on legislative reform.

# Today's Topics

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- Medicaid
- Diagnostic Reform
- **Prior Authorization**
- Other Medicare Issues

# Prior Authorization

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- Game changing particularly since July 2017
- Administrative burden
- Impact on reimbursement & care
- ACLA Approach
  - Prior Authorization Work Group
  - Tenets
  - Stakeholder engagement

# ACLA Tenets

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- Implementation
- Provision of Services
- Transparency
- Administration
- Access to Services
- Turnaround Time

http://www.acla.com/wp-content/uploads/2018/05/ACLA-Prior-Authorization-Tenets.pdf

# Today's Topics

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- Diagnostic Reform
- Prior Authorization
- **Other Medicare Issues**

# Medical Documentation

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- Ongoing issue where burden falling solely on laboratories
  - 34% error rate in lab claims
- Clear, written guidelines needed for CERTs, MACs, physicians and labs
  - CMS Review of Specific Examples
- Patients Over Paperwork Opportunity?

# LCD Process Reform

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**Goal**: Increased Transparency & Efficiency

**Revision of Medicare Program Integrity Manual, Ch. 13**

- Roadmap with instructions to contractors & stakeholders in sequential order
- What to expect when dealing with MACs, how to engage effectively in the LCD process
- Better explanation of MAC rationale, reasoning
- Repurposing open meetings

# DOS Policy Changes - OPPS

American Clinical Laboratory Association

- DOS policy for outpatient molecular pathology tests and ADLTs performed post-discharge changed effective January 1, 2018 under final OPPS rule. If criteria met,
  - Performing lab bills Medicare directly
  - DOS = date of performance
- Full implementation scheduled for July 2, 2018
- Implementation challenges

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# Thank You

# Questions?