

# The First Cut Isn't The Deepest: Final Clinical Lab Fee Schedule Under PAMA

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# Learning objectives

- Discuss the changes to payment rates for tests paid on the Clinical Lab Fee Schedule.
- Identify the 2018 payment rates for CPT codes including which codes are increasing/decreasing.
- Recognize which CPT codes will have phased in rate reductions due to per annum caps.
- Identify the payment changes to panel based tests, molecular diagnostic tests, etc.
- Illustrate the impact to your clinical laboratory based upon the 2018 rates.

# Protecting Access to Medicare Act (PAMA)

## 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
- CMS “technological changes” authority

# PAMA

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

# PAMA

- Creates a new category of test – advanced diagnostic laboratory test (ADLT) with its own data reporting and payment rules
- Sets forth coding requirements for new and existing tests
- Creates Advisory Panel on Clinical Diagnostic Laboratory Tests to assist CMS
- Original effective date of new rates of January 1, 2017 pushed back to January 1, 2018

# Timeline

## January 1 – June 30, 2016

- First data collection period
- Applicable labs collect private payor rate and volume information

## September 22, 2017

- Preliminary rates were released and public could review and comment

## January 1, 2018

- New rates take effect

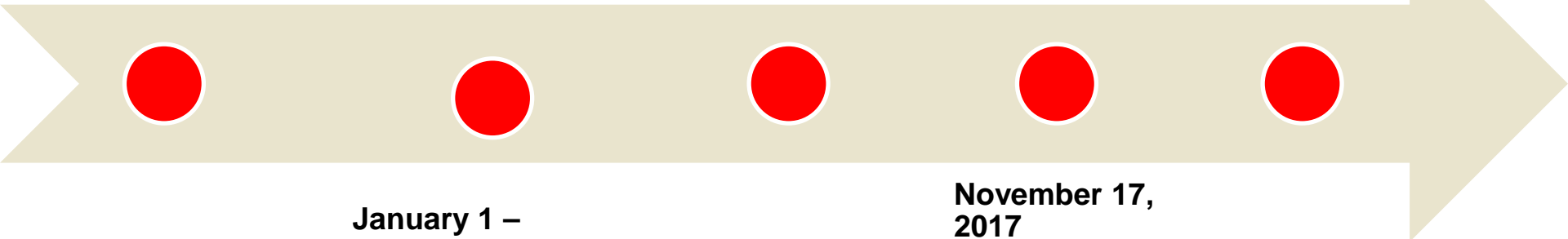
## January 1 – March 31, 2017

(Enforcement Discretion  
Until 5/30/17)

- First data reporting period
- Applicable labs report private payor rate and volume information to CMS

## November 17, 2017

- Final rates were released



# PAMA Recap

- Preliminary rates released 9/22/17
- Public review and comment
- Final rates released 11/17/17
- Effective 1/1/18

# How much could rate change?

- PAMA includes a limit for each of the first six effective years of the law for how much a rate can be reduced from the prior year:

2018	2019	2020	2021	2022	2023
10%	10%	10%	15%	15%	15%



# Less than 1% of Labs Reported Data

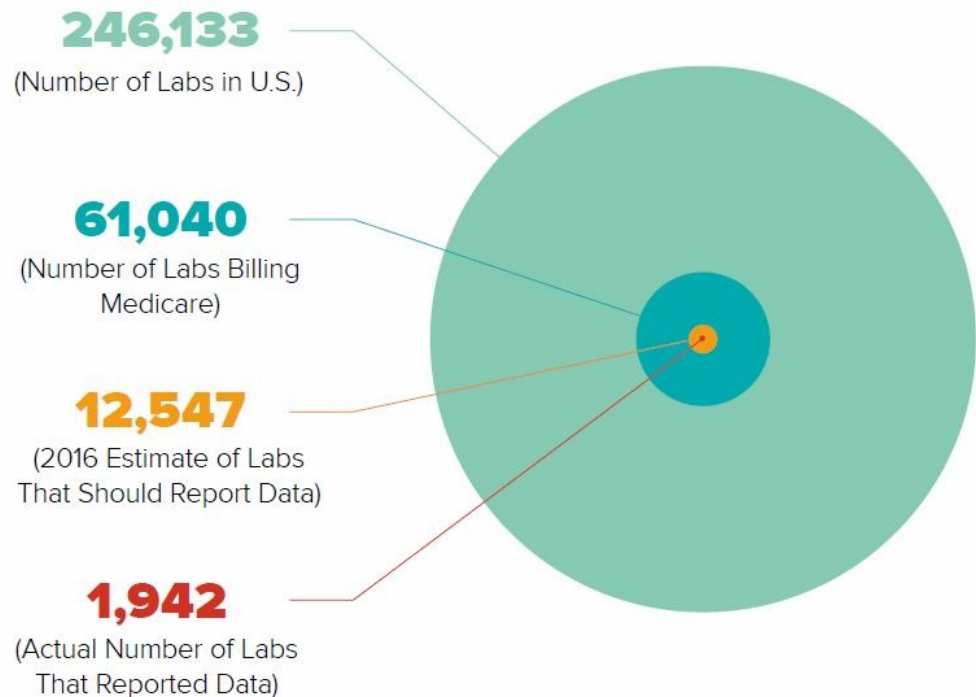


## Patient Access at Risk

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.

## Less Than 1% of All Labs Reported Data



# Flaws in PAMA Data

- Data set excludes 99.3% of the laboratory market as identified by OIG
- Hospital labs only contributed 1% of the data compared to 24% share of Medicare CLFS spending
- Physician Office Labs (POLs) only contributed 7.5% of data compared to 20% share of Medicare CLFS spending
- 2.4 million \$0.00 prices were submitted as compared to 2.3 million data points from all reporting hospital NPIs

# Flaws in PAMA Data continued



- 3.7 million data points are likely inaccurate outliers, creating questions of pricing errors which are not obvious as outliers
- 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.

# Key Issues With PAMA Rates



- Complexity of establishing a brand new payment system revealed issues not contemplated by Congress or CMS
- Limited data collection
- Not representative of broad laboratory market
- Inadequate instruction
- No ability to validate the data
- Specific issues
- Codes with no NLA
- Automated test panels
- Drugs of abuse test codes
- Physician Office Laboratory (POL) tests

# Next Steps



- Laboratory stakeholders – including ACLA, AdvaMedDx and others – continue to seek delay in final implementation
- Developing principles for improving the CLFS payment system
- Developing legislative and administrative strategies for improving process and underlying statute in 2018 and beyond

# Summary



- PAMA creates new reimbursement methodology for all tests paid on the CLFS – moves to a weighted median of private payor rates
- Applicable laboratories MUST report or civil monetary penalties can be assessed
- A new category of test is created – advanced diagnostic laboratory test (ADLT) with its own data reporting and payment rules
- First data reporting period was January 1 – March 31, 2017 requiring applicable labs to report private payor rate and volume information to CMS
- CMS released preliminary rates on September 22, 2017 and public was able to review and comment
- Final rates released on November 17, 2017
- New reimbursement rates in effect Jan 1, 2018
- Limited data collection (less than 1% of all labs reported data) led to a dataset that is unrepresentative of the private market

# Resources



## CMS PAMA Website

- <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>

# Questions?

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*The information in this presentation is provided for educational purposes only and is not legal advice. It is intended to highlight laws you are likely to encounter, but is not a comprehensive review. If you have questions or concerns about a particular instance or whether a law applies, you should consider contacting your attorney.*



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# Thank you



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