

Clinical Lab Payment Reform under PAMA: Reimbursement, Reporting and your New Responsibilities

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Objectives



- Interpret the provisions of the Final Rule of Section 216 of PAMA which reforms payment to laboratory tests paid under the Clinical Lab Fee Schedule
- Identify and apply the new reporting responsibilities for their laboratory and understand the reporting timeframes and the impact it will have on their laboratory
- Recognize the methodology and opportunities to engage with CMS on the proposed payment rates before they become final

Overview

- Historical perspective
- Final Rule highlights
- New laboratory roles and responsibilities
- Questions and answers



Historical perspective

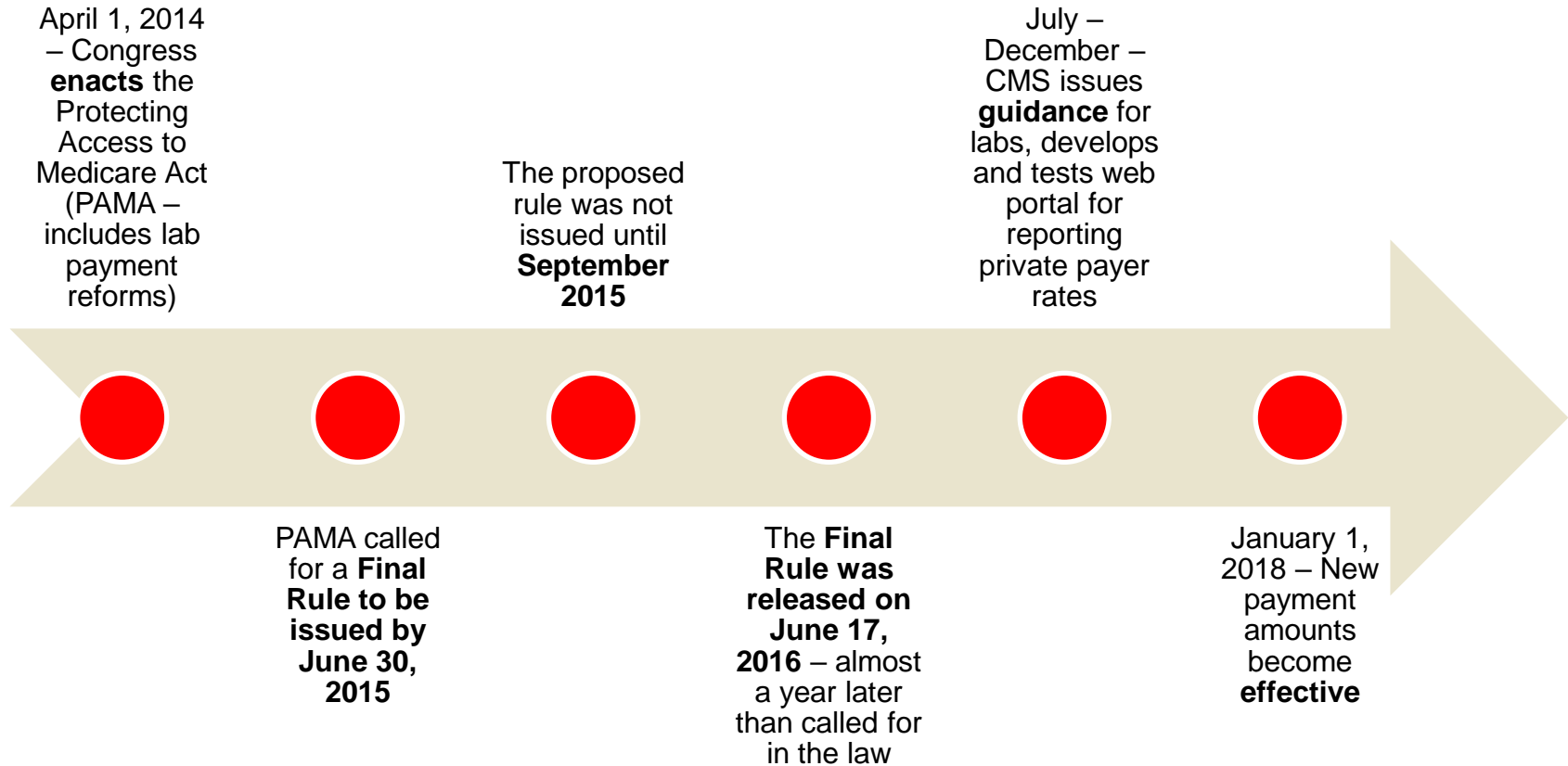
- Since early 1980s, laboratory tests paid based on Clinical Laboratory Fee Schedule (CLFS)
- Payment rates originally based on charge data
- CLFS updated annually – increases or decreases applied across the board to all tests
- Payment for new tests – based on one of two methods:
 - Cross-walking
 - Gap-filling
- Congress often froze or cut CLFS payments to pay for other programs (e.g., SGR)
- In 2013, CMS finalized “technological changes” authority
- AdvaMed, ACLA and other lab organizations worked together

Protecting Access to Medicare Act (PAMA) of 2014



- Requires reporting of private payer rates and volumes to CMS – **“applicable information”** – by **“applicable labs”**
- Calls for new CLFS rates to be the **weighted medians** of those private payer rates; payment reductions **phased in** – PAMA called for the new rates to be effective January 1, 2017
- Establishes **data collection periods** and **data reporting periods**
- Authority for CMS to impose **Civil Monetary Penalties** for non-reporting, omissions, misrepresentations
- Creates a new category of test – **“advanced diagnostic laboratory test”** or **ADLT**, with its own data reporting and payment rules
- Sets forth **coding requirements** for certain new and existing tests
- Creates **Advisory Panel** on Clinical Diagnostic Laboratory Tests to assist CMS with technical aspects

Timeline



Highlights of Final Rule – Applicable Labs

- **Applicable Laboratories** must report private payer data to CMS
- **Applicable Laboratory Defined:** A lab having the majority of its Medicare revenues paid under the CLFS or PFS
 - CLIA laboratory meeting the “majority of Medicare revenues” threshold
 - Applicable lab identified by NPI
 - Low Expenditures Threshold = \$12,500 (in payment period)
 - *Note: Low expenditure threshold does not apply to single laboratory furnishing an ADLT*

Highlights of Final Rule – Applicable Labs



- ***Applicable Laboratory (continued)***
- Final rule includes hospital labs, in cases where:
 - Lab has its own NPI (not shared with the hospital); and
 - Meets “majority of Medicare revenues” threshold; and
 - Low Expenditures Threshold = \$12,500 (in payment period)

Highlights of Final Rule – Applicable Info



- ***Applicable Information Defined:***
 - The specific HCPCS code associated with the test
 - Each private payer rate for which final payment has been made during collection period
 - The volume of tests corresponding to each private payer rate
 - Does NOT include: unresolved appeals; payments that do not reflect HCPCS level; remittances; denied payments
 - This DOES include payments adjudicated during reporting period even if performance of test fell prior to reporting period

Highlights of Final Rule – Applicable Info



- ***How will applicable information be reported?***
 - The “reporting entity” is the **TIN-level entity**, which will report all of its NPI-level entities that meet the definition of “applicable laboratory”
 - CMS has issued **data reporting template**
 - Applicable laboratories will submit information on CDLTs **every three years**; they will submit on ADLTs **every year**
 - Completeness and accuracy of the information **certified** by President CEO or CFO of the reporting entity (or someone designated to sign for and who reports directly to one of these officers)

Highlights of Final Rule – ADLT's

- ***Advanced Diagnostic Laboratory Test (ADLT)***
 - Clinical diagnostic laboratory test covered under Medicare Part B that is:
 - Offered and furnished by a single laboratory
 - For use only by original developing laboratory
 - Must meet one of the following criteria:
 - The test is an analysis of multiple biomarkers of DNA, RNA or proteins, combined with a unique algorithm to yield a single patient-specific result; OR
 - The test is cleared or approved by the FDA; OR
 - The test meets other similar criteria established by Secretary
 - ***The test must provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests***

Highlights of Final Rule – ADLT's

- A laboratory **has to apply to CMS** for ADLT designation
- CMS will issue **subregulatory guidance** on how a lab will show the test is offered and furnished by a single lab, not sold for use by another lab, provides new clinical information not otherwise obtainable, has an empirically-derived algorithm, etc.
- Application would have to be made **both for a new ADLT and an existing ADLT**
- Concerns about **confidentiality** of information in ADLT application—
 - Statute does not specifically protect the information from disclosure
 - Not automatically exempt from a FOIA request

“Because there is no guarantee such information will be withheld [from disclosure], however, laboratories will have to decide for themselves whether to apply for ADLT status and risk the possibility of public disclosure of information they do not want to be publically disclosed.”

Highlights of Final Rule – Collection & Reporting

- Final Data Collection and Reporting Periods for CDLTs:

Data collection period	Six month window	Data reporting period	Used for CLFS rate years
1/1/2016 – 6/30/2016	7/1/2016 – 12/31/2016	1/1/2017 – 3/31/2017	2018 – 2020
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021 – 2023
Continues every 3 rd subsequent calendar year	Continues every 3 rd subsequent calendar year	Continues every 3 rd subsequent calendar year	New CLFS rate every 3 rd year

Highlights of Final Rule – Collection & Reporting

- Final Data Collection and Reporting Periods for New ADLTs – Initial Period
(example from Final Rule below)

Test is covered by Medicare Part B	ADLT status is granted	New ADLT initial period (actual list charge)	Data collection period	Data reporting period	Data used for CLFS (weighted median private payor rate)
4/6/2018	5/1/2018	7/1/2018 – 3/31/2019	7/1/2018 – 12/31/2018	By 12/31/2018	4/1/2019 – 12/31/2020

Highlights of Final Rule – Collection & Reporting

- Final Data Collection and Reporting Periods for New ADLTs – Reporting After Initial Period:

Data collection period	Six month window	Data reporting period	Used for CLFS rate years
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021
1/1/2020 – 6/30/2020	7/1/2020 – 12/31/2020	1/1/2021 – 3/31/2021	2022
Continues every year	Continues every year	Continues every year	New CLFS rate every year

Highlights of Final Rule - Payment



- ***How will CMS release the rates?***

- **Preliminary rates** released around September of a reporting year
- CMS plans to “**show its work**”:
 - Will release weighted medians of private payor rates and associated HCPCS codes
 - Public file with summary or aggregate-level private payor rate and volume data for each code (unweighted median private payor rate)
 - Range of payor rates
 - Total, median, and mean volume
 - Number of labs reporting
 - May release raw, unaggregated data
- Public will have some opportunity to **review and comment** on preliminary rates
- Will post **final rates** by November 1 in a reporting year (at least 60 days before the effective date of the rates)

Highlights of Final Rule - Payment



- Payment for Existing Tests (CDLTs):
 - Paid for under the CLFS prior to January 1, 2018
 - Beginning January 1, 2018, payment will be based on weighted median private payer rate
 - The weighted median becomes the new CLFS payment rate
 - If no applicable information is received, CMS must use cross-walking or gap-filling to price the test

Highlights of Final Rule - Payment

- Payment for New ADLTs:
 - Payment is the actual list charge for the test for the first 3 full calendar quarters (during “initial period” after a Medicare Part B coverage determination or ADLT status granted by CMS)
 - After New ADLT Initial Period – Payment amount based on weighted median private payer rate
 - *If CMS determines the actual list charge was greater than 130% of the weighted median private payer rate, CMS will recoup the difference*

Highlights of Final Rule - Coding



- Coding Under PAMA 216
 - The AMA creates CPT codes that are used to identify medical services and procedures; CMS creates HCPCS level II codes for products and services not included in the CPT codes
 - PAMA requires temporary HCPCS codes to identify new and existing ADLTs and new and existing CDLTs that are cleared or approved by the FDA
 - In the absence of an existing test code, CMS will establish G codes
 - New AMA new code section “Proprietary Laboratory Analysis” or PLA codes

How are “Weighted Medians” set?

	Test 1		Test 2		Test 3	
	Private payor rate	Volume	Private payor rate	Volume	Private payor rate	Volume
Lab A	\$5.00	1,000	\$25.00	500	\$40.00	750
Lab B	\$9.00	1,100	\$20.00	2,000	\$41.00	700
Lab C	\$6.00	900	\$23.50	1,000	\$50.00	500
Lab D	\$2.50	5,000	\$18.00	4,000	\$39.00	750
Lab E	\$4.00	3,000	\$30.00	100	\$45.00	850

Test 1

- Volume reported is 11,000
- Range of rates from \$2.50 on the low end to \$9.00 on the high end
- Different volumes at different rates

How much could rates change?

- The new rates that are based on the weighted medians of private payor rates will stay in place until the year after the next reporting period (three years for a CDLT)
- Law 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 (based on the CY 2017 NLA) – CMS included this in the regulations and pushed everything back a year to account for delayed implementation

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

Example

CY 2017 NLA	Weighted Median	10% Max. Reduction	CY 2018 Rate	10% Max. Reduction	CY 2019 Rate	10% Max. Reduction	CY 2020 Rate
\$20.00	\$15.00	\$2.00	\$18.00	\$1.80	\$16.20	\$1.20 < 10%	\$15.00

Laboratory roles and responsibilities



- Am I an applicable lab?
 - Applicable laboratories **required** to report
 - Laboratories that do not meet the applicable laboratory definition **prohibited** from reporting
 - Laboratories not meeting definition may want to obtain NPI for future reporting
- How do I report applicable information?
 - CMS data reporting template
 - HCPCS Code
 - Payment Rate
 - Volume
 - National Provider Identifier (NPI)

Laboratory roles and responsibilities



- CLFS Data Reporting System
 - All users must register to obtain a valid user name and password
 - Enrollment in PECOS
 - CLFS Submitter
 - CLFS Certifier
 - Data upload or manual entry

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
- Reporting will be done via a CMS portal with a provided template
 - Both submitters and certifiers must register on CMS and PECOS
- CDLT's reported every 3 years; ADLT's reported annually
- Laboratories have the option for applying for ADLT status for tests.
 - Even if test meets criteria, lab does not have to apply if they so choose
- CMS will release preliminary data in Sept 2017 and public will be able to review and comment
- Final rates released Nov 2017
- New reimbursement rates in effect Jan 1, 2018



Resources



CMS PAMA Website

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

CMS CLFS Quick User Guide

- <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1620.pdf>

CLFS Help Desk

- clfshelpdesk@dcca.com
- 844-876-0765

Questions?



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