Understanding the Requirements for Reporting PAMA Private Payer Lab Test Price Data

EXECUTIVE WAR COLLEGE CONFERENCE
MAY 2, 2019
Presented by

Diana W. Voorhees, M.A.
CLS, MT, SH, CPCO
Principal/CEO
DV & Associates, Inc.
dvassoc@aol.com
801.424.5274
Objectives

Relive the creation of PAMA and its intent to change the Clinical Laboratory Fee Schedule payment mechanism

Review reporting requirements and outcomes that raised concerns from the laboratory industry

Describe final rule requirements and discuss particular laboratory concerns and related CMS response

Determine where we are now regarding PAMA
Background Information
Clinical Laboratory Fee Schedule (CLFS)

Prior to 2018:
- Outpatient clinical laboratory services were paid based on a fee schedule in accordance with Section 1833(h) of the Social Security Act
- Payment was the lesser of the amount billed, the local fee for a geographic area, or a national limitation
- The national limits were set at a percent of the median of all local fee schedule amounts for each laboratory HCPCS code
- Each year, fees were updated for inflation based on the percentage change in the Consumer Price Index
Clinical Laboratory Fee Schedule (CLFS)

Prior to 2018, Cont.
- Legislation by Congress could modify the update to the fees
- Co-payments and deductibles do not apply to services paid under the Medicare clinical laboratory fee schedule
- Annually, new laboratory test codes were added to the clinical laboratory fee schedule and corresponding fees were developed in response to a public comment process.
CMS Concerns

◦ Current fee for service payments may be excessive especially when compared to private payer payment rates
  ◦ Example: 50% of Medicare allowables
  ◦ Evaluate private payer reimbursements
  ◦ Needed a mechanism to offset removal of the SGR
  ◦ The CMS original proposal indicated that 75 percent of all codes in the Healthcare Common Procedure Coding System (HCPCS) would realize payment reductions in 2018 – first year of revised fee schedule.
  ◦ CMS further estimated that these cuts would reduce overall Medicare spending for laboratory testing by nearly 11 percent or $670 million in 2018.
Protecting Access to Medicare Act (PAMA)

Section 216 of the Protecting Access to Medicare Act (PAMA) of 2014 made extensive changes to how reimbursement is determined under the Clinical Laboratory Fee Schedule (CLFS).

- PAMA repealed “technological changes” authority by CMS to make unlimited reductions to individual test codes without providing clear justification or rationale.
- Section 216 created a new reimbursement framework, basing Medicare payment rates for laboratory services paid under the CLFS on private payer rates that are reported to CMS by “applicable laboratories.”
Protecting Access to Medicare Act (PAMA)

Based on the final rule, applicable laboratories would begin reporting private payer rates, CMS would create a weighted median for each laboratory procedural code on the CLFS, and new payment rates would go into effect on January 1, 2017.

Schedule for implementation was delayed a year due to lack of a timely final rule, insufficient time for gathering and reporting information by laboratories and insufficient time to massage and analyze data.
Protecting Access to Medicare Act (PAMA)

The intent of PAMA was to ensure true market-based pricing by setting the fee schedule to a weighted median of the collected data from laboratories. The use of market data to establish CLFS payment rates will:

◦ Strengthen Medicare by paying more appropriately for laboratory services
◦ Save the Medicare program and taxpayers money
◦ Maintain beneficiaries’ access to high quality laboratory service
Protecting Access to Medicare Act (PAMA)

Additional Outcome:
- Local Fee Schedules eliminated
- Only one rate of reimbursement applicable to all geographic areas
The Basics
Definition of “Applicable Laboratory”

- A laboratory, (as defined in CMS’s CLIA regulations), using its National Provider Identifier (NPI), is considered an applicable laboratory if more than 50 percent of its total Medicare revenues are received from payments under the CLFS and physician fee schedule (PFS).

- Additionally, an applicable laboratory would also have to receive at least $12,500 in Medicare revenues received for CLFS services during a data collection period to be an applicable laboratory.

- The $12,500 will not apply to certain laboratories with respect to the ADLTs they offer and furnish.
Advance Diagnostic Laboratory Test (ADLT)

Section 216(a) of PAMA established a new subcategory of clinical diagnostic laboratory tests (CLDTs) known as Advanced Diagnostic Laboratory Tests (ADLTs) with separate reporting and payment requirements.

- CDLTs are defined by CMS as tests that include blood tests, urinalyses, tests on tissue specimens, and some screening and other tests that are furnished by applicable laboratories and covered under Medicare Part B
ADLT Definition, Cont.

- PAMA defines ADLTs as a laboratory test (CDLT) that is “covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and that meets one of the following criteria:
  - The test must meet either
    - *Criterion (A)* (analysis of multiple biomarkers of DNA, RNA, or proteins) or
    - *Criterion (B)* (cleared or approved by the U.S. Food and Drug Administration (FDA)).
ADLT Definition, Cont.

- Other similar criteria may be established by the Secretary of Health and Human Services
- None exist to date
- Additionally, an ADLT test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result
ADLT Exclusion

CMS finalized its proposal to exclude single laboratories offering and furnishing an ADLT from the $12,500 threshold.

- This means that applicable information for an ADLT would need to be reported, regardless of whether the laboratory falls within the low-expenditure threshold.

A laboratory that has less than $12,500 in Medicare revenues, but offers both ADLTs and CDLTs, must still report private payer data for the ADLT

- But prohibited from reporting data on its CDLTs
ADLT Payment

- New ADLTs will be paid at a rate equal to their actual list charge during a new ADLT initial period of three calendar quarters.
- After the initial period, the payment amount for a new ADLT is based on the weighted median of private payer rates from data collected by the laboratory during the new ADLT initial period.
TIN versus CLIA versus NPI

- **TIN**
  - Frequently not associated with just laboratory testing
  - Hospitals are a good example: laboratory reimbursement won’t qualify when compared to overall Medicare income

- **CLIA**
  - Every laboratory has one
  - Medical center may have several CLIA numbers under one entity

- **NPI – winning number**
  - All billing providers have a NPI somewhere
  - Hospital outpatient services now bundled
  - Services may be included if meet threshold & NPI
Definition of “Applicable Information”

- The reporting entity must report applicable information for each CDLT furnished by its component applicable laboratories.
- Applicable information is the private payer rate for each test for which final payment has been made during the data collection period, the associated volume for each test, and the specific HCPCS code associated with the test.
- If an applicable laboratory has more than one payment rate for the same private payer for the same test, or more than one payment rate for different payers for the same test, the reporting entity will report each such payment rate and the volume for the test at each such rate.
Definition of “Applicable Information”

Reference:

Medicare Learning Network article SE1619
“Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payer Rate-Based Payment System”

(1) The specific HCPCS code associated with the test;
(2) The private payer rate for each test for which final payment has been made during the data collection period; and
(3) The associated volume for each test.
Information Not Applicable

- Test codes paid only under the PFS
- $0.00 (denied) payments
- Unresolved appeals
- Capitated payments
- Payments where the associated test volume cannot be determined
Frequency for Reporting

Reporting entities are required to report applicable information:

- Every three years for CDLTs
- Every year for ADLTs
  - Except for an ADLT in its initial data collection period
  - Report by the end of the second quarter of the new ADLT initial period
- Need to register laboratory in order to process information
Period for Data Collection

CMS revised its proposed data collection period from a full calendar year to 6 months

2016
- The data collection period was January 1 through June 30, period preceding the next data reporting period.
- CMS finalized a 6-month period of time between the end of the data collection period and the beginning of the data reporting period to provide an opportunity for laboratories and reporting entities to review and validate applicable information to ensure the data are complete and accurate before it is reported to CMS.
Period for Data Collection

2017
- Applicable information will be reported for a data collection period between the January 1 through March 31 data reporting period.
- CMS calculates rates

2018
- New rates implemented January 1
- Now in next reporting period
Data Certification

Certification of accuracy and completeness of applicable information by:

- President, CEO, or CFO of an applicable laboratory
- Or a direct report to whom the individual above has delegated authority
Penalties

The statute authorizes CMS to impose civil monetary penalties of;

- CMP up to $10,000 per day for
  - each failure to report or
  - each misrepresentation or omission in reporting applicable information.
- Adjusted for inflation as required by the Inflation Adjustment Act Improvements Act of 2015
Limitations for Payment Reductions

PAMA limits the reduction of the payment amount for an existing test as compared to the payment amount for the preceding year.

- For the first three years after implementation, the statute limits the reduction to 10 percent per year
  - 2018-2020
- And to 15 percent per year for the following three years.
  - 2021-2023

- The phased-in payment amount limit per year for existing tests paid under the CLFS prior to January 1, 2018 will be applied using the 2017 national limitation amount (NLA) for the existing test as the baseline payment amount.

- To determine the application of the phased-in payment reduction limit for a test, the weighted median private payer rate calculated for CY 2018 will be compared to the CY 2017 NLA.
So What Happened?
PAMA Questionable Analysis

According to the CMS:
- 90 percent of the test payment data came from independent laboratories
- Represent 5% of all US laboratories
- 9 percent came from physician office laboratories and hospitals,
  - POLs and hospitals reportedly represent more than 43 percent of Medicare Part B lab payments.
- Services usually associated with higher payment levels
- 1.85 percent of data was collected from laboratories serving rural areas
PAMA Questionable Analysis

Of note:

◦ The Senate Appropriations Committee forwarded a report with language regarding the Labor, Health and Human Services funding bill

◦ Urged CMS to work with stakeholders to ensure that the new CLFS rates represent "the full spectrum of laboratories, including hospital, independent, and physician office laboratories"
PAMA Questionable Analysis

Estimate:

◦ Over ten years, the cuts may total as much as $13 billion, which is more than three times the estimate of $3.9 billion Congress originally anticipated

◦ Laboratory Industry questioning adequacy of data gathered and thus, the accuracy of the analytic process to report reliable weighted medians for individual procedural codes
PAMA – What Happened?

On September 22, 2017, the Centers for Medicare and Medicaid Services (CMS) released its proposed new payment rates for laboratory tests included in the CLFS

On November 17, 2017, CMS published the final determinations for 2018 CLFS payments
  ◦ There would be no delay in using the Final data weighted medians
  ◦ Codes with no NLA were capped at a 10% reduction

Congress asked to intercede

Suits anticipated
PAMA & ACLA

The judge with the U.S. District Court for Washington, DC dismissed ACLA’s lawsuit that claimed the CLFS changes under PAMA were incorrectly calculated

◦ September 21, 2018 decision
◦ Section 216 of the PAMA statute prohibits administrative or judicial review regarding the setting of payment amounts
◦ The court does not have “subject matter jurisdiction”
◦ CMS’s determination of payment rates cannot be challenged
◦ Additional 10% cuts at issue as well as original 2018 pricing
ACLA Website

October 19, 2018 - The American Clinical Laboratory Association (ACLA) filed its notice of appeal in its lawsuit against the U.S. Department of Health and Human Services (HHS) challenging its implementation of the Protecting Access to Medicare Act (PAMA)

◦ “While the District Court ruled on narrow procedural grounds, its opinion acknowledges that ACLA’s ‘arguments on the merits raise important questions,’ about HHS’s actions. We believe it is critically important for ACLA to be able to address these issues in court. While ACLA continues to pursue legal action, we also call on Congress to reform and modernize the Clinical Laboratory Fee Schedule to ensure that beneficiaries can continue to access the lab services and diagnostics they need.”
Industry Response

The laboratory community called on Congress to pass "freeze-bridge" legislation to delay this next round of PAMA cuts.

- The proposal would freeze the 2018 rates in both 2019 and 2020 allowing time to develop an accurate methodology to implement PAMA.
- Additionally, the second round of data collection, scheduled to occur early in 2019, would also be delayed until a new methodology is in place.
Industry Response

During the two-year freeze period, Congress would require the National Academy of Medicine to conduct a study

- Publish recommendations on how to best implement the least burdensome, statistically valid data collection that is representative of the laboratory markets
- Establish appropriate rate-setting methodology that is representative of the market
- Ensures sustainable patient access.

ASCLS has setup a grass roots page to make it easy to urge Congress to take action:
www.votervoice.net/ASCLS/campaigns/61741/respond
MPFS Final Rule 2018
Final Rule – MPFS

November 1, 2018

CMS announced that it was including Medicare Advantage Program services in the definition of “applicable Laboratory” under PAMA

◦ “..we believe that modifying our definition of applicable laboratory so that we may receive applicable information from more laboratories that furnish tests to a significant Medicare Part C population, which are less likely to qualify for applicable laboratory status under the current policy, outweighs the additional reporting burden placed on these laboratories”

◦ “..directly supports our goal of collecting as much applicable information as possible from the broadest representation of the national laboratory market on which to base CLFS payment amounts”
Final Rule – MPFS

CMS announced that it was including hospital outreach laboratories in the definition of “applicable Laboratory” under PAMA

“..we are finalizing the revision of the definition of applicable laboratory at §414.502 to include a hospital laboratory that bills Medicare on the Form CMS1450 14x bill type and its electronic equivalent.”
Final Rule – MPFS

Impact in question
- MA programs
- CMS 1450, Bill type 14X
- L1 deleted (2016)
- Separate NPI
- IP/OP bundling
Now What?
Time for Second Round of Reporting

2019
- The data collection period will be the January 1 through June 30, period preceding the next data reporting period.
- 6-month period of time to provide review and validate applicable information to ensure the data are complete and accurate before it is reported to CMS.

2020
- Applicable information will be reported between January 1 and March 31
- CMS calculates rates

2021
- New rates implemented January 1
A recent November report related to PAMA rates for CLFS reimbursement has raised an alarm by stating that:

- Maximum payment rates were used as a baseline rather than actual payment rates
- NLA comparison for 2017 payment
- Projected $733M in increased payments in 3 yr. phase-in
- The practice of paying a bundled rate for certain group of tests was eliminated
- ATP procedure codes
  - ATP02-ATP23
- Bundled tests now have separate payment
- Projected $10.3B in increased payments in 3 yr phase-in
Senator Grassley Criticism Ongoing

Senator Charles Grassley  sensitized by report
  ◦ Iowa Republican
  ◦ Chair of Senate Finance Committee
  ◦ Send letter with questions to CMS
    ◦ Believes response was inadequate
    ◦ Requests rate revision
Laboratory Push-Back

Accuses GAO of making flawed and dangerous assertions based on a serious misunderstanding of real world billing practices

- Projections overblown
- Laboratories have not changed billing practices
ACLA Lawsuit Appeal

February 25

- The Department of Health and Human Services (HHS) filed its response to ACLA’s appeal of its lawsuit
- ACLA has argued that HHS improperly implemented the Protecting Access to Medicare Act of 2014 (PAMA) by excluding private-payer data from nearly all hospital outreach labs when CMS derived new rates for 2018
- HHS disagreed with ACLA’s stance and noted that the PAMA law bars any “administrative or judicial review” to the “establishment of payment amounts” in the new private-payer-rate-based CLFS.
ACLA Lawsuit Appeal

HHS Brief continued:
- “In short, plaintiff seeks higher payment amounts through an attack on the Secretary’s definition of ‘applicable laboratory.’ However framed, that challenge to the payment amounts is barred by the plain text of the statute,”
- Oral arguments for the appeal are scheduled to take place on April 23, and a decision by the U.S. Court of Appeals for the District of Columbia Circuit will be issued.
Hospital Issues
Diligence Required

- Determine if and who are “Applicable Laboratories”
- Develop a PAMA team
- Register with vendor collecting data
- Assess IT systems and capabilities
- Acquire needed IT software and resources
- Gain appropriate advice and tips for process.
- Collect “applicable information”
- Massage data to ensure it is complete and accurate
- Demonstrate compliance with law
- Report data in required format
- Stay tuned
Discussion
Thank you for your courtesy!

Diana