PAMA and the Clinical Laboratory Fee Schedule: 2019 Update

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“When Congress makes a joke, it’s a law and when Congress makes a law, it’s a joke.”

-Will Rogers
Regulatory Impact on Laboratory

*10% cut 2019-20

- $2.5
- $2.0
- $1.5
- $1.0
- $0.5
- $0.0
- $0.0

2016 2017 2018 2019 2020

OPPS PAMA 18 PAMA 19* CLIA PT PAMA 20*

Billions
Protecting Access to Medicare Act (PAMA)

- Passed April 1, 2014 for the “Doc Fix”
  Section 216 reforms the Clinical Laboratory Fee Schedule (CLFS)
- Final Rule June 23, 2016
- The implementation date moved from January 1, 2017 to January 1, 2018
- Definition of Applicable Laboratory changed from TIN to NPI
Applicable Laboratories Definition Must Report Data

- Have a CLIA certificate
- Bill using their own lab NPI
- Bill using the physician NPI if no lab NPI
- Bill on the 14X Type of Bill (TOB) using the hospital NPI ("Outreach")
- More than 50% of Medicare revenue from the PFS and CLFS
- Medicare CLFS payments >$12,500 for the 6 month reporting period
All health care providers that are HIPPA covered entities must have an NPI

1) Type 1 – Individuals
2) Type 2 – Organizations
3) Type 2 Subparts conducting HIPAA transactions separately
“Majority of Medicare” Calculation
At NPI Level

\[
\% = 100 \times \frac{\text{All PFS + CLFS Revenue}}{\text{All Medicare Revenue}}
\]
Reporting Laboratories
5% of POLs, 44% of Independents and 21 hospitals

CLFS payout is $6.8 billion

Spending
- SNF, Other: $4.0 billion
- POL: $1.7 billion
- $0.032

Reporting
- 72% Unreported
- 27% Independent
- 1% POL
- 0% Hospitals

Payment data left out

Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040)
Applicable Payers

- All private payers including group health plans
- Does not include Medicaid fee for service
- Does not include other governmental payers
- Does not include capitated plans
- Does not include Medicare Advantage
Frequency of Reporting

- For most Clinical Diagnostic Laboratory Tests (CDLTs), every three years
- Annually for advanced diagnostic laboratory tests (ADLTs)
Time Flies

- Time flies like an arrow
- Fruit flys like bananas
Collection and Reporting Periods

- Updates for CDLTs every three years
- For update year CY 2021:
  Collection = January 1, 2019 – June 30, 2019
  Reporting = January 1, 2020 – March 31, 2020
- Annually for ADLTs
Rate Setting Process

- CMS will calculate the weighted median price for each code (midpoint of the data set)
- Rate will be national without geographical variation
- In effect for 3 years with no inflation update or productivity decrease – except ADLTs annually
- Subject to sequestration
- If no data is received for a given HCPCS, CMS will use cross walking or gap filling to price the test
Payment Reduction Limits

- PAMA requires a savings but each HCPCS code is limited to 10% reduction each year for 3 years and 15% the next 3 until the rate gets down to the median

- New median rates will result from data analysis every three years
Payment Reduction Limits

- Each MAC may currently have a different price on a HCPCS
- CMS will use the National Limitation Amount (NLA) to do the calculation of 10% or 15% decrease and not the MAC levels
CMS Reduction Estimates

- Projected $390 million reduction in FY2018 payments
- $670 million actual reduction FY2018
Process for New Tests

- New CDLTs will be priced similar to existing process using cross-walk and gap fill until the next data reporting cycle.
- These will be discussed by the PAMA payment Advisory Panel.
- Opportunity for public comment.
Advanced Diagnostic Laboratory Tests (ADLT)

- Tests offered by a single lab and must meet one of the following criteria:
  - Include DNA or RNA and use an algorithm to yield a single-patient specific result
  - FDA cleared or approved
- A small number of tests and labs
OIG Concerns 2016

- Complete and accurate data
- CMS does not plan to:
  - Identify applicable labs
  - Identify whether all labs reported
  - Verify quality and accuracy of data
- Advisory Panel financial interests
Medicare Part B paid $6.8 billion for lab tests in 2016 – down from $7B 2014-15

The top 25 lab tests by Medicare payments totaled $4.3 billion

The top 6 lab tests totaled $2.4 billion
OIG Study 2018

- 1,942 labs reported private payer data
- CMS’s modeling demonstrated that increased reporting from more labs would not have had a meaningful effect on 2018 payment rates
Final rule violates the PAMA statute
Final rule is unreasonable
Final rule is arbitrary and capricious
Definition of Applicable Laboratory

1. Remove Medicare Advantage payments from majority of revenue calculations
2. Using Form CMS-1450 bill type 14X to determine majority of Medicare revenues and low expenditure thresholds
3. Using the Clinical Laboratory Improvement Amendments (CLIA) Certificate to define Applicable Laboratories
The Court has no jurisdiction
The matter is dismissed
The motion for judgement is denied as moot
Stakeholder Responses

- ACLA, NILA et. al. ask for Applicable Laboratory definition to be expanded
- AMA and AHA reject expansion of Applicable Laboratory definition
Based on comments we received and further analysis of the various options, we are amending the Applicable Laboratory definition to include hospital laboratories that bill for their non-patient laboratory services on the CMS 1450 14X TOB
Stakeholder Responses

- ACLA appeals PAMA lawsuit 12/05/2018
- CAP, AAB and AdvaMedDx file amicus briefs supporting ACLA 12/12/2018
Hospital outreach laboratories that bill for their non-patient laboratory services using the hospital's NPI must use Medicare revenues from the Form CMS-1450 14x Type of Bill (TOB) to determine whether they meet the majority of Medicare revenues threshold and low expenditure threshold.

Medicare Advantage plan payments are excluded from total Medicare revenues (the denominator of the majority of Medicare revenues threshold).
“Majority of Medicare” Calculation
(For Outreach Labs Billing using Hospital NPI)

Medicare 14X TOB revenue
(PFS + Laboratory)

\[
\% = 100 \times \frac{\text{Medicare 14X TOB revenue (Laboratory)}}{\text{Medicare 14X TOB revenue (Laboratory)}}
\]
Definition of “Hospital Outreach Laboratory”

- Furnishes laboratory tests to patients other than admitted inpatients or registered outpatients

- Bills Part B on the hospital’s NPI using the CMS 1450 14X TOB
Definition of “Non-Patient”

- For the purposes of determining whether a hospital outreach laboratory under the CLFS, a non-patient is a non-hospital patient.
- The patient is neither a registered hospital outpatient nor an admitted hospital inpatient.
Hospital outreach laboratory is responsible for reporting all applicable information attributed to the applicable laboratory.

All non-patient laboratory test services regardless of the TOB required by the payor for tests furnished to non-hospital patients.
2019 Reporting Data

- Specific HCPCS code associated with the test
- Private payor rate for each test for which payment has been made during the data collection period
- Associated volume for each test
Implications for Hospital Outreach

- Hospital systems may not be able to parse out applicable payer 14X reimbursements
- Hospitals may be registering outreach as outpatients
- Other payor rates based on Medicare CLFS
- Level playing field
Penalties

The statute authorizes CMS to impose civil monetary penalties of up to $10,000 per day, adjusted for inflation as required by the Inflation Adjustment Act Improvements Act of 2015, for each failure to report or each misrepresentation or omission in reporting applicable information.
MEDICARE LABORATORY TESTS

Implementation of New Rates May Lead to Billions in Excess Payments Report to Congressional Committees

GAO Report to Congress

- Medicare paid $7.1B for 433M tests in 2017
- GAO analyzed 2016 Medicare claims data and private-payer data CMS collected
- GAO also interviewed CMS and industry officials (ACLA and NILA)
Medicare will pay billions more than planned.

CMS used the maximum 2017 fees rather than the average fees as a starting point resulting in a $733M overpayment in 2018-2020.

CMS pays for individual tests not bundled panels and profiles which will result in a $10.3B increased payment for 2018-2020.
GAO Recommendations

1. Collect complete private-payer data from all laboratories required to report or address the estimated effects of incomplete data.

2. Phase in payment-rate reductions that start from the actual payment rates rather than the maximum payment rates Medicare paid prior to 2018.

3. Use bundled rates for panel tests.
Stakeholder Responses

- AdvaMedDx, American Clinical Laboratory Association (ACLA), College of American Pathologists (CAP), National Independent Laboratory Association (NILA) and Point of Care Testing Association (POCTA)

  GAO recommendations ignore statutory requirements and demonstrate a serious misunderstanding of actual, real-world billing practices of clinical laboratories
CLMA PAMA Impact Survey
Do you have an Outreach Program?

- Yes
- No

The chart shows that 100% of respondents have an Outreach Program.
Do You Support Expanding the Definition of Applicable Laboratory?

No

Yes
Do You Know the Breakdown of Revenue by Payor?

- No
- Yes
Has a Change in Revenue Based on the New CLFS Impacted Management Decisions?

No

Yes
How Concerned are You that Management Decisions Resulting from the New CLFS May Adversely Affect Patient Care?