Compliance & Regulatory Issues Associated with the PAMA and the CMS Final Rule for Reporting Private Payor Lab Test Prices: Risks, Consequences, and Often-Overlooked Requirements

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PAMA Framework

- The Protecting Access to Medicare Act of 2014 (PAMA) changed how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule (CLFS).
- Now, payment amount for most tests is the weighted median of reported private payor rates.
- Payment rates are updated every three years.
- All "applicable laboratories" are required to report "applicable information" as designated by PAMA in order for the CLFS to be appropriately updated pursuant to PAMA.

PAMA Framework

- *Applicable Laboratory*
  - Laboratory that meets the CLIA definition of a laboratory (42 CFR § 493.2) that:
    - Bills Medicare Part B under its own National Provider Identifier (NPI) or, for hospital outreach laboratories, bills Medicare Part B on the Form CMS-1450 under type of bill (TOB) 14x; and
    - Receives more than 50% of its Medicare revenues from one or a combination of the CLFS or the Physician Fee Schedule (PFS) in a *Data Collection Period* ("majority of Medicare revenues" threshold); and
    - Receives at least $12,500 of its Medicare revenues from the CLFS in a *Data Collection Period* ("low expenditure" threshold).

PAMA Framework

- Current three year cycle:
  - January – June, 2019: Collect data *(Data Collection Period)*
  - July – December, 2019: Analyze data
  - January – March, 2020: Report data *(Data Reporting Period)*

- Next update to CLFS will take effect January 1, 2021

PAMA Framework

- *Applicable Information*
  - Specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test;
  - Each private payor rate for which final payment has been made during the data collection period; and
  - Associated volume tests performed corresponding to each private payor rate.
- Does not include information about a test for which payment is made on a capitated basis.

PAMA Framework

- *Advanced diagnostic laboratory test (ADLT)*
  - Clinical diagnostic laboratory test offered and furnished by a single laboratory; and
  - not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of that laboratory; and meets one of the following criteria:
    - (1) The test -
      - Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;
      - When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies);
      - Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
      - (iv) May include other assays.
    - (2) The test is cleared or approved by the Food and Drug Administration.

Certification

- To certify data integrity,
  - the President, CEO, or CFO of a reporting entity,
  - or an individual who has been delegated authority to sign for, and who reports directly to, such an officer,
- Must sign the certification statement and be responsible for assuring that the data provided are accurate, complete, and truthful, and meets all the reporting parameters required.

Penalties

- Noncompliance has the potential to be expensive.
- Civil monetary penalties of up to $10,000/day for each failure to report or each misrepresentation or omission
  - As updated by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015

Enforcement

Strategy 1: Enhance outreach to labs to ensure that labs know whether they meet criteria and report as required

- CMS could create targeted methods to reach out to high-volume labs that did not report in 2017 and ensure that they report during the 2020 data reporting period.
- CMS could use feedback from labs and industry associations to create responsive guidance to ensure that labs know about and understand reporting requirements.

For the initial implementation, CMS did not independently verify the accuracy of labs' self-determination

- Labs used CMS guidance to determine whether they met reporting criteria and what data to collect and report.
- Although 37 percent of reporting labs may not have met the low-expenditure threshold, CMS relied on labs' attestation that they met reporting criteria.
- OIG identified more than 20 high-volume labs that did not report their data in 2017.
- CMS has stated that it does not have the information necessary to identify all labs that were required to report.

Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests
Strategies To Ensure Data Quality

July 2018
OEI-09-17-00050

https://oig.hhs.gov/oei/reports/oei-09-17-00050.pdf

Enforcement

Strategy 2: Enhance data quality assurance activities to help ensure that labs report as required

- CMS could assess the effectiveness of its data quality assurance activities and adjust as necessary.
- For future data reporting periods, CMS could develop a process to address labs that do not comply with reporting requirements. This process may include a plan to issue civil monetary penalties, as appropriate.

For the initial implementation, CMS did not exercise authority to issue civil monetary penalties

- PAMA gives CMS the authority to issue civil monetary penalties if labs fail to report data, or if they misrepresent or omit reported data.
- CMS stated in 2016 that it did not intend to issue civil monetary penalties for the first data reporting period.
- CMS did allow labs more time to collect and report their data by adding a 60-day "enforcement discretion period" to the end of the data reporting period.

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CMS Resources

- *Main CMS PAMA page*
  - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html
    - *Summary of Private Payor Rate-Based Medicare Clinical Laboratory Fee Schedule*
      - https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2019-CLFS-PrivatePayor-RateBased-Summary.pdf

Selected CMS FAQs
Additional Considerations

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