



Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests

Strategies To Ensure Data Quality

OEI-09-17-00050

July 2018

Why we did this review

This review focuses on the Centers for Medicare & Medicaid Services' (CMS's) initial implementation of Medicare's new payment system for clinical diagnostic laboratory (lab) tests.

- This new system was mandated by the Protecting Access to Medicare Act of 2014 (PAMA).
- This review follows up on the 2016 OIG report *Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests*, which evaluated CMS's progress through August 2016.
- This review focuses on CMS's implementation activities in 2017 and the new payment rates that took effect on January 1, 2018.
- A list of prior OIG work is included in Appendix A.

About Medicare payments for lab tests

- Medicare paid \$6.8 billion under Part B for lab tests in 2016.
- More than 60% of Part B payments in 2016 were for the top 25 tests, based on Medicare payments.
- Medicare Part B covers most lab tests ordered by physicians and pays 100% of allowable charges.
- Beneficiaries do not have a copay for lab tests under either the new payment system or the old one.



PAMA ties Medicare payment rates for lab tests to those paid by private payers

Before PAMA, rates were based on historical lab charges and adjusted for inflation.

- Previous OIG studies found that before PAMA, Medicare rates were 18-30% higher than rates paid by other payers.

New rates are based on lab-reported data: rates paid by private payers such as private health insurers, Medicaid managed care organizations, and Medicare Advantage plans.

- Although only certain labs are required to report data, new payment rates apply to all labs paid through Medicare Part B.

About the Protecting Access to Medicare Act of 2014

- PAMA is the first reform to the Clinical Laboratory Fee Schedule since 1984.
- PAMA sets payment rates on the volume-weighted median of private payer data reported by labs that meet certain criteria.
- Under PAMA, rates for most tests are updated every 3 years.
- PAMA mandates that OIG conduct analyses it determines appropriate with respect to the implementation and effect of the new payment system.



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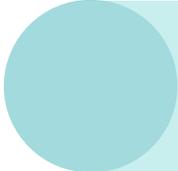
Challenges and risks of CMS's initial implementation of PAMA

Strategies to address challenges and ensure that future payment rates are based on complete data





Results of CMS's initial implementation of PAMA
and description of new payment rates



Challenges and risks of CMS's initial
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Strategies to address challenges and ensure that
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Labs use two criteria to determine whether they must report their data

The **majority criterion** excludes labs that operate as part of larger systems, such as hospitals, that receive most of their Medicare revenues from other services.

- Many hospital labs bill for lab services using the provider's NPI rather than a unique lab-specific NPI.

The **low-expenditure threshold** exempts small physician offices and rural labs from reporting requirements, reducing their reporting burden.

- CMS established the low-expenditure threshold—as authorized by PAMA—through the rulemaking process.

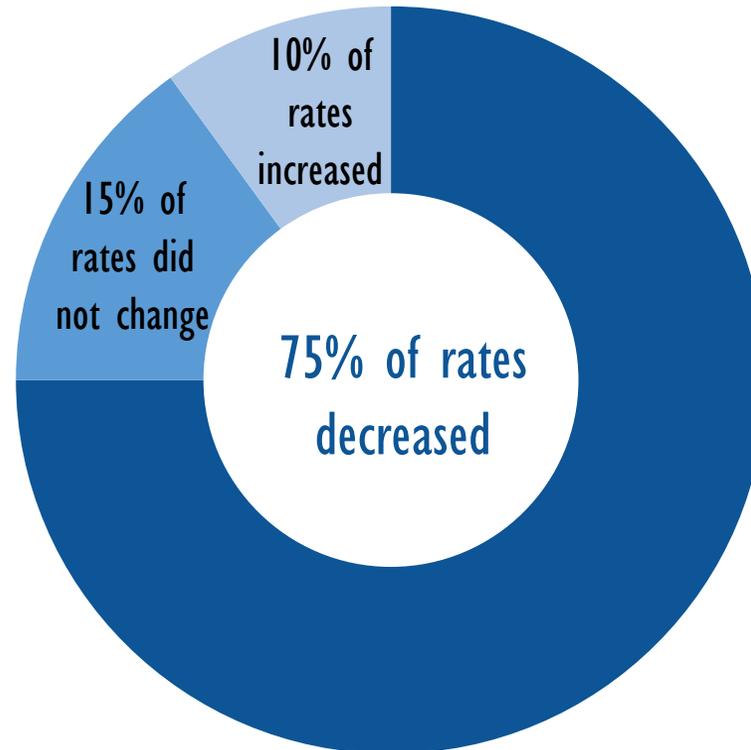
PAMA and CMS established the criteria that labs used to determine whether they should report private-payer data

- **Majority criterion:** PAMA established that reporting requirements apply only to labs that receive the majority of their Medicare revenues from lab and physician services.
- **Low-expenditure threshold:** CMS established that labs with less than \$12,500 of Medicare revenues from lab services during the 6-month data collection period are exempt from reporting requirements.
- CMS selected the NPI as the identifier that labs should use to determine revenues.
 - NPI: National Provider Identifier, the number that providers use to bill Medicare.



PAMA's initial implementation resulted in lower Medicare payment rates for most lab tests

- CMS analysis shows that new rates, effective January 2018, could save an estimated \$670 million for the calendar year.
- Through 2020, decreases to payment rates are limited to 10% each year, as required by PAMA.

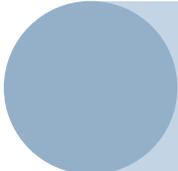


Source: CMS Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule, September 2017.

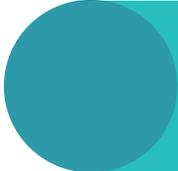
How CMS set new payment rates

- January–June 2016: Labs collected private payer rates during the data collection period.
- January–March 2017: Labs reported their data to CMS via a web-based portal during the data reporting period.
 - CMS extended the 2017 data reporting period through May 2017 with a 60-day “enforcement discretion period.”
 - Labs certified the accuracy and completeness of their data, as required by PAMA, during the reporting process.
 - CMS received data from 1,942 labs.
- In 2020, labs will report data collected from January–June 2019.





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Challenges and risks of CMS's initial
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Strategies to address challenges and ensure that
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Labs reported difficulty in determining whether they met criteria and needed to report data

Although some labs reported difficulty in interpreting reporting requirements, CMS modeling demonstrated that increased reporting from more labs would not have had a meaningful effect on 2018 payment rates.

- OIG identified at least 20 high-volume independent labs that likely met the majority criterion but did not report their data in 2017.
- CMS determined that 37% of reporting labs may have been exempt because they may not have met the low-expenditure threshold.

Limited reporting may not have had a meaningful effect on 2018 rates; however, it remains a risk in future data reporting periods.

CMS provided outreach and guidance to help labs determine whether they met criteria and needed to report

- CMS issued the final rule in June 2016, finalizing the criteria and reporting requirements.
- After publishing the final rule, CMS provided additional outreach and guidance:
 - Offered two outreach calls in 2016
 - Published subregulatory guidance documents in 2016 and 2017
 - Updated a Frequently Asked Questions document in 2016 and 2017
 - Updated the PAMA page of the CMS website
 - Established the Inquiries Mailbox for PAMA-related questions and clarification



CMS relied on labs' self-certification of their reported data and performed limited quality assurance checks

Labs reported difficulty in retroactively removing excluded payment rates from their data systems before the end of the data reporting period.

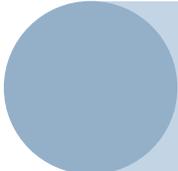
- CMS data quality assurance activities included identifying outliers and removing inaccurate data reported by four labs.
- CMS did not take steps to determine whether labs reported payment rates that were excluded by PAMA.

Labs experienced some one-time challenges in complying with a new policy, but CMS's limited quality assurance efforts present an ongoing risk.

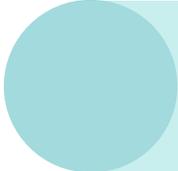
CMS issued the final rule toward the end of the data collection period, giving labs limited time to prepare their data

- CMS published the PAMA regulation on June 23, 2016, 7 days before the end of the data collection period (January–June 2016).
- PAMA excludes certain payment rates, such as those made under bundled or capitated arrangements.
- As required by PAMA, labs certify the accuracy and completeness of their reported data. CMS relied on labs' self-certification and used certified data to set new payment rates.





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Strategies to address challenges and ensure that
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Strategies that CMS could use to ensure that future payment rates are based on complete and accurate data

CHALLENGES

STRATEGIES

OUTCOMES

1

Labs reported difficulty in determining whether they met criteria and needed to report data.

Enhance outreach to labs to ensure that labs know whether they meet criteria and that they report as required.

CMS actions result in payment rates based on data from the labs required to report.

2

CMS performed limited quality assurance checks and relied on labs' self-certification of their reported data.

Enhance data quality assurance activities to help ensure that labs report as required.

CMS actions result in payment rates based on complete and accurate data.



Strategy I: 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.



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.



Conclusion

Complete and accurate data are essential to setting payment rates for lab tests, and CMS should address challenges from 2017 to ensure data quality in the future.

- Effective outreach can help ensure that all required labs report data for future data reporting periods.
- CMS can help ensure data quality by assessing quality assurance efforts and compliance activities.



OIG's next steps

To provide oversight, PAMA mandated that OIG monitor Medicare payments for lab tests and the implementation of the new payment system.

OIG will continue to issue:

- An annual analysis of the top 25 lab tests, based on Medicare Part B payments.
- Other analyses that OIG determines appropriate regarding the implementation and effect of the new payment system.



Acknowledgments and contact information

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To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

This analysis was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.



Appendix A: Prior OIG reports

<u>Variation in the Clinical Laboratory Fee Schedule</u>	OEI-05-08-00400	July 2009
<u>Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings</u>	OEI-07-11-00010	June 2013
<u>Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data</u>	OEI-09-15-00210	September 2015
<u>Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress</u>	OEI-09-16-00100	September 2016
<u>Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data</u>	OEI-09-16-00040	September 2016
<u>Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data</u>	OEI-09-17-00140	September 2017



Appendix B: Implementation timeline

- 2014: PAMA is enacted
 - PAMA, P. L. No. 113-93, § 216(a) (adding Social Security Act, § 1834A, 42 U.S.C. §1395m-1)
- September 25, 2015: CMS issues proposed rule
 - November 10, 2015: CMS holds listening session on the proposed rule
- June 17, 2016: CMS issues final rule
 - June 23, 2016: CMS publishes final rule at *81 Fed. Reg. 41036–41101 (June 23, 2016)*
- January–June 2016: Retrospective data collection period
- January–March 2017: Data reporting period
 - April–May 2017: 60-day “enforcement discretion period”
- November 2017: CMS issues 2018 fee schedule
- January 1, 2018: New fee schedule takes effect
- 2020: Second data reporting period
- January 1, 2021: Second fee schedule takes effect

CMS guidance documents may be found at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>



Appendix C: Methodology

To provide an update on the 2017 data reporting period, we:

- conducted four interviews with CMS staff (February–June 2017)
- conducted one interview with representatives from lab industry associations (June 2017)
- reviewed CMS guidance and other documentation regarding lab outreach
- analyzed Medicare claims data to identify the biggest labs by Medicare payments that likely met criteria but did not appear in the raw set of lab-reported data
- synthesized CMS analysis of lab-reported data and final payment rates

This report describes CMS's activities as of February 2018.

