

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL



HHS OIG Data Brief • September 2015 • OEI-09-15-00210

Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data

AT A GLANCE

In 2014, Medicare Part B paid \$7.0 billion for 451 million lab tests

For the top 25 lab tests in 2014, based on Medicare payments:

Medicare Part B payments totaled \$4.2 billion

Independent labs accounted for the majority of Medicare Part B payments

A small portion of labs accounted for the majority of Medicare Part B payments

The tests fell into seven categories, predominantly the chemistry category

Molecular pathology tests cost the most per test

The Protecting Access to Medicare Act (PAMA) of 2014 requires reform of the payment system for clinical laboratory (lab) tests—the first such reform in 3 decades.¹ The current payment rates, which are based on lab charges from 1984 and 1985, will be replaced with recent rates paid by private payers. PAMA calls for the Centers for Medicare & Medicaid Services (CMS) to begin collecting private-payer rate data from labs in 2016 and to begin paying new, potentially lower rates for lab tests in 2017. The Congressional Budget Office estimates that the new payment system will save the Government \$2.5 billion over 10 years.²

To provide oversight, PAMA mandated that the Office of Inspector General (OIG) monitor Medicare payments for lab tests and the implementation of the new payment system.³ Specifically, PAMA requires OIG to publicly release an annual analysis of the top 25 lab tests based on Medicare payments and to conduct analyses that OIG determines appropriate regarding the implementation and effect of the new payment system.

This data brief

- Presents initial, baseline analyses of the top 25 lab tests in 2014, based on Medicare payments.
- Introduces key statistics and metrics that OIG will use for ongoing monitoring of Medicare's implementation of the new payment system.
- Is the first in a series of congressionally mandated OIG products on Medicare lab test payments. The series builds on previous OIG work on Medicare's payments for lab tests.⁴

BACKGROUND

Lab Test Payment Rates: 1984-2016

The system that Medicare currently uses to determine payment rates for lab tests has remained largely unchanged since 1984. Each Medicare claims processing contractor established its own fee schedule of payment rates for lab tests based on local lab charges to Medicare in 1984 and 1985.⁵ This created a total of 57 fee schedules, collectively known as the Clinical Laboratory Fee Schedule. The payment rates on the Clinical Laboratory Fee Schedule are adjusted annually to account for inflation. However, the base rates have not been updated since 1984 to reflect changes in test methods that affect test costs.

To contain costs, Medicare also established a national limitation amount that caps payment rates for each test. In each jurisdiction, Medicare pays the lower of lab charges, the jurisdiction's payment rate, or 74 percent of the median rate for each lab test across the 57 fee schedules. This last rate is known as the national limitation amount.⁶

Lab Test Payment Rates: 2017 and After

Beginning in 2017, Medicare will update the Clinical Laboratory Fee Schedule using data on rates paid by private payers.⁷ For each lab test, Medicare will use the median of private payer rates, weighted by the payers' test volume, to set a new payment rate. The payment rates will apply nationally. Medicare will update payment rates for lab tests every 3 years using data reported by labs.⁸ Figure 1 compares the current and future payment systems for lab tests.

Lab Tests

What are they?

Lab tests are performed on specimens taken from the human body. The tests provide information integral to preventing, diagnosing, and treating disease.

Where are they performed?

Lab tests are usually performed in independent labs, hospitals, and physicians' offices.

How do lab tests differ?

There are different categories of lab tests. For example, chemistry tests measure levels of specific substances, whereas molecular pathology tests analyze genetic material to detect variants in genes.

What does Medicare cover?

Medicare Part B covers most lab tests ordered by physicians and pays 100 percent of allowable charges. Beneficiaries do not have a copay, under the current or new payment system.

Figure 1. Comparison of Medicare Payment Systems for Lab Tests

| | Current | Future | |
|-------------------------|----------------------------------------------------------------------|------------------------------------------------------------------------|--|
| Year Implemented | 1984 | 2017 | |
| Basis of Payment Rates | Lab charges in 1984–1985, adjusted annually to account for inflation | Private payer rate data, updated every 3 years using then-current data | |
| Number of Fee Schedules | 57 regional fee schedules | Single national fee schedule | |

RESULTS

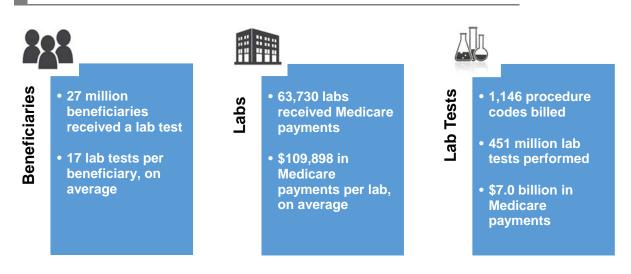
In 2014, Medicare paid \$7.0 billion for lab tests that, beginning in 2017, will be subject to the new payment system

It is common for Medicare beneficiaries to receive lab tests. As shown in Figure 2, just over half of Medicare beneficiaries (27 million) received at least one lab test in 2014. On average, these beneficiaries each received 17 tests, and 1 percent of beneficiaries each received 95 or more tests. Lab tests accounted for about 3 percent of total Medicare Part B payments in 2014. 10, 11

Tens of thousands of labs received payment from Medicare for performing tests in 2014. Medicare paid 63,730 different labs an average of \$109,898 each. The top three labs, by volume, performed a combined 69 million tests in 2014. For these tests, they received more than \$250 million each—almost \$1 billion combined—from Medicare Part B. Each of the 3 labs performs tests at multiple locations—1 lab performs tests at more than 100 locations—which may account for their high volume. In contrast, half of all labs received less than \$1,019 each.

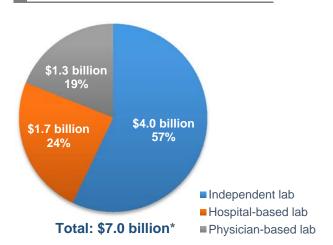
In 2014, Medicare Part B paid for 451 million tests using 1,146 procedure codes from Medicare's Clinical Laboratory Fee Schedule. These procedure codes include many categories of lab tests, from common chemistry tests (such as a thyroid-stimulating hormone test) to less frequently used but more complex molecular pathology tests (such as a gene analysis test). In addition to including codes for lab tests, the Clinical Laboratory Fee Schedule includes two procedure codes for venipuncture (drawing blood from a patient). In 2014, Medicare paid a total of \$239 million for 80 million venipuncture services.

Figure 2. Use of Lab Tests Covered by Medicare Part B in 2014



Almost all lab tests paid under Medicare Part B occurred in one of three settings: independent labs, hospitals, and physicians' offices. As shown in Figure 3, over half of Medicare Part B payments for lab tests went to independent labs (i.e., labs that are independent of an institution or a physician's office). Hospital-based labs accounted for about a quarter of the total payments. This amount does not include the majority of lab tests performed in hospitals, which are part of a packaged payment for the beneficiary's hospital services. ¹³ Physician-based labs accounted for the remaining 19 percent of the total Medicare Part B payments.

Figure 3. Medicare Payments for Lab Tests by Setting in 2014



Source: OIG analysis of Medicare Part B lab test payments, 2015.
* The total payment also includes \$32.0 million that Medicare paid for lab tests that were performed in other settings, such as skilled nursing facilities and dialysis facilities.

The top 25 lab tests, based on Medicare payments, totaled \$4.2 billion in 2014

Examination of Medicare Part B payments for lab tests performed in 2014 shows that 25 tests represented over half (60 percent) of payments for all lab tests. Once the new market-based pricing goes into effect in 2017, potentially lower payment rates for these tests could have a significant impact on overall Medicare payments for lab tests.

The top three lab tests based on Medicare payments—all three of which are blood tests—each accounted for over \$400 million in 2014, or a combined 19 percent of total Medicare Part B lab test payments:

blood test for thyroid-stimulating hormone (procedure code 84443): \$477 million
 blood test for a group of blood chemicals (procedure code 80053): \$453 million
 complete blood cell count automated test (procedure code 85025): \$431 million

Figure 4 on the next page lists the top 25 lab tests based on Medicare Part B payments in 2014, along with a description and key statistics for each test.

Figure 4. Top 25 Lab Tests Based on Medicare Part B Payments in 2014

| | Test Description | Procedure Code* | National Limitation Amount** | Total Number of Lab Tests (Millions) | Total Medicare Payments (Millions)*** |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|------------------------------------|--------------------------------------|---------------------------------------------|
| 1. | Blood test, thyroid-stimulating hormone (TSH) | 84443 | \$22.93 | 21.3 | \$477 |
| 2. | Blood test, comprehensive group of blood chemicals | 80053 | \$14.41 | 40.1 | \$453 |
| 3. | Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count | 85025 | \$10.61 | 41.5 | \$431 |
| 4. | Blood test, lipids (cholesterol and triglycerides) | 80061 | \$18.27 | 27.9 | \$386 |
| 5. | Vitamin D-3 level | 82306 | \$40.40 | 8.3 | \$323 |
| 6. | Hemoglobin A1C level | 83036 | \$13.24 | 18.1 | \$236 |
| 7. | Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), per patient encounter | G0431 | \$99.20 | 2.1 | \$193 |
| 8. | Opiates (drug) measurement | 83925 | \$26.54 | 2.5 | \$173 |
| 9. | Gene analysis (cytochrome P450, family 2, subfamily D, polypeptide 6) common variants | 81226 | \$451.59 | 0.4 | \$166 |
| 10. | Blood test, basic group of blood chemicals | 80048 | \$11.54 | 14.1 | \$137 |
| 11. | Blood test, clotting time | 85610 | \$5.37 | 23.9 | \$128 |
| 12. | Chemical analysis using chromatography technique | 82542 | \$24.63 | 2.0 | \$122 |
| 13. | Parathormone (parathyroid hormone) level | 83970 | \$56.31 | 2.0 | \$110 |
| 14. | Cyanocobalamin (vitamin B-12) level | 82607 | \$20.56 | 5.3 | \$108 |
| 15. | Gene analysis (cytochrome P450, family 2, subfamily C, polypeptide 19) common variants | 81225 | \$291.80 | 0.4 | \$106 |
| 16. | PSA (prostate specific antigen) measurement | 84153 | \$25.09 | 4.2 | \$104 |
| 17. | Bacterial colony count, urine | 87086 | \$11.01 | 7.3 | \$79 |
| 18. | Thyroxine (thyroid chemical) measurement | 84439 | \$12.30 | 6.6 | \$79 |
| 19. | Natriuretic peptide (heart and blood vessel protein) level | 83880 | \$46.31 | 1.5 | \$68 |
| 20. | Benzodiazepines level | 80154 | \$25.23 | 2.1 | \$67 |
| 21. | Ferritin (blood protein) level | 82728 | \$18.59 | 3.5 | \$63 |
| 22. | Complete blood cell count (red cells, white blood cell, platelets), automated test | 85027 | \$8.83 | 6.8 | \$58 |
| 23. | Folic acid level | 82746 | \$20.06 | 2.8 | \$55 |
| 24. | Methadone level | 83840 | \$22.28 | 1.9 | \$52 |
| 25. | Evaluation of antimicrobial drug (antibiotic, antifungal, antiviral) | 87186 | \$11.80 | 3.9 | \$50 |
| | | T B PAYMENTS | \$4,226 | | |

Sources: OIG analysis of Medicare Part B lab test payments, 2015. National limitation amounts are from the 2014 Clinical Laboratory Fee Schedule.

^{*} See endnote 12 for the American Medical Association (AMA) copyright notice.

^{**} The national limitation amount for a given lab test is 74 percent of the median rate or—for new tests performed after 2000 for which no limitation amount has been established—100 percent of the median rate for that test across the 57 fee schedules.

 $[\]ensuremath{^{***}}$ Figures do not sum to total because of rounding.

Independent labs accounted for the majority of Medicare Part B payments for the top 25 lab tests

Just as they did for Medicare lab test payments overall, independent labs received the majority of Medicare payments for the top 25 lab tests in 2014. Specifically, they received 55 percent of Medicare lab test payments. Labs based in hospitals and labs based in physicians' offices accounted for the remaining payments (25 percent and 20 percent, respectively). Figure 5 shows how Medicare Part B payments

for the top 25 lab tests are distributed among the different types of settings.

Notably, several of the top 25 tests were performed primarily at independent labs. Independent labs accounted for 99 percent of two molecular pathology tests (procedure codes 81226 and 81225). They accounted for over 70 percent of 4 other tests in the top 25 (procedure codes 83925, 83840, 82542, and 80154). Three of those four tests (procedures codes 83840, 82542, and 80154) are tests for drugs with the potential for abuse.

84443 80053 85025 80061 82306 5. 83036 G0431 83925 9. 81226 80048 10. 11. 85610 12. 82542 Independent lab 13. 83970 14. 82607 ■ Hospital-based lab 15. 81225 ■ Physician-based lab 16. 84153 87086 84439 19. 83880 20. 80154 21. 82728 85027 82746 23. 83840 25. 87186 \$0 \$100 \$200 \$300 \$400 \$500 **Medicare Payments (Millions)**

Figure 5. Medicare Payments for the Top 25 Lab Tests by Setting in 2014

Source: OIG analysis of Medicare Part B lab test payments, 2015.

Note: The total payments also include \$19.1 million that Medicare paid for lab tests in the top 25 that were performed in other settings, such as skilled nursing facilities and dialysis facilities.

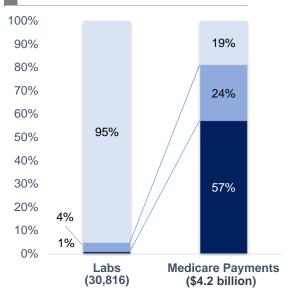
A small portion of labs accounted for the majority of Medicare Part B payments for the top 25 lab tests

Labs varied widely in terms of the total payments they received for performing the top 25 lab tests. As shown in Figure 6, 1 percent of labs (309 out of 30,816 labs) received 57 percent of all Medicare Part B payments for the top 25 lab tests in 2014. These labs each received an average of 7.8 million in 2014 for performing these tests. The next 4 percent of labs accounted for 24 percent of the payment for the top 25 lab tests. These labs each received an average of \$813,250 for these tests. The remaining 95 percent of labs accounted for the remaining 19 percent of payments for the top 25 lab tests. These labs each received an average of \$28,030 for these tests.

The top 25 lab tests fell into 7 categories, predominantly the chemistry category

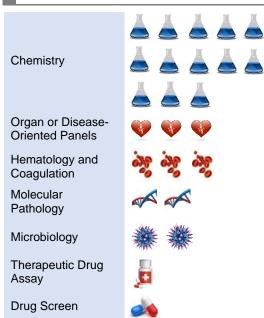
Thirteen of the top 25 lab tests were in the chemistry category. Medicare paid \$2.0 billion for these 13 tests in 2014. As shown in Figure 7, each of the other categories had no more than 3 tests in the top 25. Tests in the chemistry category measure the level of a specific substance such as a protein, hormone, or drug. Some of these substances can also be tested for by using tests in categories other than chemistry. For example, among the top 25 lab tests, *levels* of methadone can be measured using a test within the chemistry category, and the *presence* of methadone can be detected using a test within the drug-screen category.¹⁴

Figure 6. Concentration of Medicare Payments for Top 25 Lab Tests Among Labs in 2014



Source: OIG analysis of Medicare Part B lab test payments, 2015. Note: Includes only labs that performed any top 25 lab test.

Figure 7. Top 25 Lab Tests in 2014 by Category



Source: OIG analysis of Medicare Part B lab test payments,

Among the top 25 lab tests, molecular pathology tests cost the most per test

Two of the top 25 lab tests—procedures codes 81226 and 81225—were molecular pathology tests. Although these 2 tests were not billed for as often as other tests in the top 25—in 2014, Medicare Part B paid for fewer than 400,000 of each test—they were the most expensive on a per-test basis, with national

limitation amounts of \$452 and \$292, respectively. In contrast, the other 23 lab tests in the top 25 had national limitation amounts ranging from \$5 to \$99 per test (see Figure 4 on page 5).

CONCLUSION

Lab tests are integral to the provision of health care for millions of Medicare beneficiaries, as physicians rely on these tests to help prevent, diagnose, and treat disease. In 2014, more than half of all Medicare beneficiaries received lab tests paid under the Clinical Laboratory Fee Schedule, costing \$7.0 billion in Medicare Part B payments.

Key Dates in the Implementation of the New Payment System

April 2014: Congress passes PAMA

January 2016: Applicable laboratories must begin reporting payment rates for private payers

January 2016: CMS must assign a unique procedure code to existing advanced diagnostic lab tests (ADLTs)

January 2017: Market-based payment system for lab tests takes effect

The new system of payment required by PAMA calls for a major undertaking by CMS, with significant implications for the lab industry. Implementing the new market-based approach will require CMS to collect data from labs about the rates paid by private payers for all lab tests. We found that in 2014, Medicare paid 63,730 different labs for lab tests billed under 1,146 procedure codes; however, not all labs will be required to report private-payer payment rates to CMS.

This data brief provides baseline analyses of the top 25 lab tests for 2014, 3 years before the new payment system goes into effect. As required by PAMA, in addition to issuing an annual analysis of the top 25 lab tests, we will conduct analyses that we determine appropriate regarding the new payment system's implementation and effect.

METHODOLOGY

We based this data brief on our analysis of Medicare's claims data for lab tests performed in 2014 and reimbursed under the Clinical Laboratory Fee Schedule. The claims data were from the National Claims History Physician/Supplier Part B claims files and National Claims History Outpatient files. The Physician/Supplier Part B files primarily include lab test claims from independent labs and labs based in physicians' offices. The Outpatient files primarily include lab test claims from hospital-based labs.

Our analysis included only lab tests paid under Medicare's Clinical Laboratory Fee Schedule. We did not include lab tests paid under other payment systems, such as the Outpatient Prospective Payment System or the Critical Access Hospital payment system.¹⁵ We also did not include claims for physicians' interpretations of tests.

We analyzed the claims data to identify key statistics for Medicare Part B payments for lab tests. We analyzed the claims data by procedure code, beneficiary, lab, setting, and category. We identified the top 25 lab tests on the basis of total payments for each procedure code in 2014, and then performed a similar analysis for each of the top 25 tests.

Analysis by lab. We used different variables to identify individual labs that billed Medicare. For lab tests in the Physician/Supplier Part B claims files, we identified a unique lab based on the Tax Identification Number (TIN). We chose the TIN because each TIN represents all locations for a lab. For tests in the Outpatient claims files, we identified a unique lab based on the organization's CMS Certification Number. The Outpatient claims files do not include a variable for a provider's TIN.

Analysis by setting. We identified the setting for a lab test using either the place of service or the type of bill. For lab tests in the Physician/Supplier Part B claims files, we identified the setting according to the "place of service variable." For lab tests in the Outpatient claims files, we identified setting according to the "type of bill variable," which indicates the type of facility and service.

Analysis by category. We categorized a lab test according to its subsection within the CPT (2014 edition). Each lab test that has a Level I HCPCS code is assigned to a CPT subsection. One lab test in the top 25—procedure code G0431—is billed using a Level II HCPCS code; we used this test's description to assign it to a "drug screen" category.

Standards

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

ACKNOWLEDGMENTS

This report was prepared under the direction of Blaine Collins, Regional Inspector General for Evaluation and Inspections in the San Francisco regional office, and Michael Henry, Deputy Regional Inspector General.

Sarah Ambrose and China Tantameng served as the team leaders for this study. Other Office of Evaluation and Inspections staff who provided support include Mandy Brooks, Berivan Demir Neubert, Evan Godfrey, David Graf, Joyce Greenleaf, Althea Hosein, and Christine Moritz.

ENDNOTES

- ¹ The Protecting Access to Medicare Act of 2014 (PAMA), P.L. No. 113-93, § 216(a).
- ² The estimate is for total savings between fiscal years 2014 and 2024. Congressional Budget Office, *Cost Estimate for the Protecting Access to Medicare Act of 2014*, March 26, 2014, p. 2.
- ³ PAMA, § 216(c)(2).
- ⁴ See: OIG, *Questionable Billing for Medicare Part B Clinical Laboratory Services*, OEI-03-11-00730, August 2014; OIG, *Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings*, OEI-07-11-00010, June 2013; OIG, *Coverage and Payment for Genetic Laboratory Tests*, OEI-07-11-00011, June 2012; and OIG, *Variation in the Clinical Laboratory Fee Schedule*, OEI-05-08-00400, July 2009.
- ⁵ The Deficit Reduction Act of 1984, P.L. No. 98-369 § 2303(d).
- ⁶ Social Security Act, § 1833(h)(4)(B)(viii), 42 U.S.C. § 1395l(h)(4)(B)(viii). For new tests performed on or after January 1, 2001, for which no limitation amount has been established, the limit is 100 percent of the median. ⁷ PAMA, § 216(a)(1).
- ⁸ In the case of advanced diagnostic lab tests (ADLTs), Medicare will update the payment rates annually. PAMA established advanced diagnostic lab tests as a new category of test. The category includes tests that are performed by a single lab and either (1) analyze multiple biomarkers combined with a unique algorithm to yield a single patient-specific result, (2) are cleared or approved by the Food and Drug Administration, or (3) meet other similar criteria established by the Secretary of Health and Human Services.
- ⁹ U.S. Department of Health and Human Services, *2014 CMS Statistics*, page 6. Available online at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/CMS Stats 2014 final.pdf. The average projected enrollment in fee-for-service Medicare in 2014 was 53.6 million beneficiaries.
- ¹⁰ Ibid., p. 29. According to this source, Medicare Part B benefit payments are projected to be \$256.2 billion for fiscal year 2014.
- ¹¹ For lab tests and other Medicare fee-for-service claims dated on or after April 1, 2013, Medicare paid 2 percent less than the payment rate in accordance with the Budget Control Act of 2011, P.L. No. 112-25, Section 302, and the American Taxpayer Relief Act of 2012, P.L. No. 112-240, Section 901 (i.e., sequestration).
- ¹² Labs bill for each test on the Clinical Laboratory Fee Schedule using a Healthcare Common Procedure Coding System (HCPCS) code, which we refer to as a "procedure code." The HCPCS is divided into two subsystems, referred to as Level I and Level II of the HCPCS. Level I HCPCS codes are comprised of Current Procedural Terminology codes. The five character codes and descriptions included in this study are obtained from Current Procedural Terminology (CPT®), copyright 2014 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures.

Any use of CPT outside of this study should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply. Level II HCPCS codes are established by CMS primarily for items, supplies, and nonphysician services not covered by CPT codes.

- ¹³ Medicare pays for most lab tests furnished to hospital inpatients under the hospital inpatient prospective payment system (IPPS) or as reasonable costs under Part A to hospitals excluded from IPPS. CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 3, § 10.4. In 2014, Medicare began to pay for most lab tests performed in outpatient hospitals under the Outpatient Prospective Payment System (OPPS). Therefore, the amount that Medicare paid for lab tests performed in outpatient hospitals decreased in 2014. For more information about the limited circumstances under which Medicare pays for outpatient lab tests under the Clinical Laboratory Fee Schedule rather than the OPPS, see 78 Fed. Reg. 74826, 74942 (Dec. 10, 2013).
- ¹⁴ These tests are procedure codes 83840 and G0431, respectively.
- ¹⁵ In 2014, many of the lab tests performed in outpatient settings (such as hospitals, skilled nursing facilities, and dialysis facilities) were paid under Medicare payment systems other than the Clinical Laboratory Fee Schedule. As we have noted, our analysis included only lab tests paid under Medicare's Clinical Laboratory Fee Schedule.