



Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL



HHS OIG DATA BRIEF

**MEDICARE PAYMENTS FOR CLINICAL
DIAGNOSTIC LABORATORY TESTS IN
2015: YEAR 2 OF BASELINE DATA**

Suzanne Murrin
Deputy Inspector General for
Evaluation and Inspections

OEI-09-16-00040
SEPTEMBER 2016

BACKGROUND

Beginning January 1, 2018, the Centers for Medicare & Medicaid Services (CMS) will change the way it sets payment rates for clinical diagnostic laboratory (lab) tests. This is the first such reform in 3 decades, and is a result of the Protecting Access to Medicare Act of 2014 (PAMA). PAMA requires CMS to replace current payment rates, which are based on historical lab charges adjusted for inflation, with new rates based on current charges in the private health care market.¹ CMS estimates that the new payment system will save Medicare \$3.9 billion over 10 years.²

AT A GLANCE

- Medicare Part B paid \$7 billion for lab tests in 2015, a total that did not change from 2014
- The top 25 lab tests by Medicare payments totaled \$4.1 billion in 2015, slightly less than in 2014
- Medicare paid 19 percent more for all drug tests in 2015 than in 2014
- Medicare paid 44 percent less in 2015 than in 2014 for all molecular pathology tests
- New payment rates for lab tests will be based on data provided by a projected 5 percent of labs; these labs received 69 percent of Medicare payments in 2015
- Although Medicare payment rates are expected to decrease overall, rates for some tests will increase in certain locations under the new payment system
- Certain aspects of the new payment system that could limit savings warrant ongoing monitoring

PAMA also mandated that the Office of Inspector General (OIG) monitor Medicare payments for lab tests and the implementation and effect of the new payment system for lab tests.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 is one of a series of reports that OIG will issue as part of monitoring Medicare payments for lab tests. OIG is also issuing a companion report, *Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress* (OEI-09-16-00100), which examines CMS's progress toward implementing the new payment system.

THIS DATA BRIEF

- ✓ Provides an update to our data brief on Medicare lab payments in 2014 (OEI-09-15-00210) and is the second set of annual baseline analyses of the top 25 lab tests.⁴
- ✓ Presents key statistics and metrics that OIG will use for ongoing monitoring of the implementation and effect of the new payment system.
- ✓ The series builds on a body of prior OIG work regarding Medicare payments for lab tests.⁵

LAB TEST PAYMENT RATES: 1984–2017

The system that Medicare currently uses to determine lab test payment rates has remained largely unchanged since 1984. Each Medicare claims processing contractor established a local fee schedule of payment rates based on local charges to Medicare in 1984 and 1985.⁶ This created 57 local fee schedules, collectively known as the Clinical Laboratory Fee Schedule. Payment rates on the Clinical Laboratory Fee Schedule are adjusted annually to account for inflation.

To contain costs under this system, Congress established a national limitation amount that caps the local rates.⁷ Medicare pays the lowest of the following three amounts: the lab’s charge, the local fee schedule rate, or the national limitation amount.

For tests developed after 1984, CMS has based the Medicare payment rate on rates for similar tests or—if no similar tests exist—on a variety of data about the tests.

LAB TEST PAYMENT RATES: 2018 AND AFTER

Beginning in 2018, CMS will update the Clinical Laboratory Fee Schedule using rates paid by private payers—i.e., private health insurance companies, Medicaid managed care organizations, and Medicare Advantage plans.⁸ During the first 3 months of 2017, labs will submit information to CMS about the rates that private payers paid them for lab tests during the first half of 2016.⁹ Certain labs will be exempt from reporting their private payer data to CMS.¹⁰

For each test, Medicare will use the median of private payer rates, weighted by the test volume, to set a new payment rate. Medicare will update payment rates every 3 years using data reported by labs.¹¹ The payment rates will apply nationally. For the first 3 years, payment rates cannot be reduced by more than 10 percent each year. For the next 3 years, reductions cannot exceed 15 percent each year.¹²

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 Part B 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 either the current payment system or the new one.

How Will Medicare’s Payment System Change?

CURRENT <i>Implemented in 1984</i>	FUTURE <i>To be implemented in 2018</i>
Payment rates for existing tests are based on lab charges in 1984–1985 , adjusted annually for inflation	Payment rates for existing tests will be based on current rates from private payers , and updated every 3 years using current data
57 local fee schedules	Single national fee schedule
Same pricing schedule for all categories of lab tests on the fee schedule	Creates a new category of lab tests— advanced diagnostic laboratory tests —with a different pricing schedule

MEDICARE PART B PAID \$7 BILLION FOR LAB TESTS IN 2015, A TOTAL THAT DID NOT CHANGE FROM 2014

Medicare Part B payments for lab tests under the Clinical Laboratory Fee Schedule totaled \$7.0 billion in 2015, accounting for about 3 percent of all Part B payments in 2015.^{13, 14} Total payments remained relatively unchanged from 2014.¹⁵ This data brief does not include Medicare payments made under other payment systems, such as the Physician Fee Schedule, the Outpatient Prospective Payment System, or the payment system for critical access hospitals.

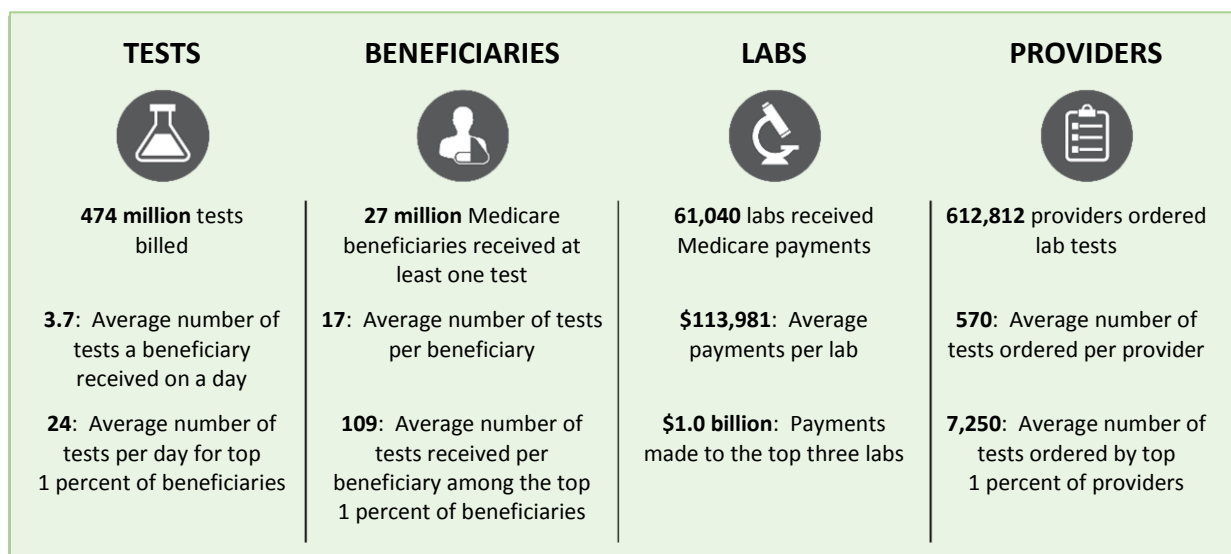
In 2015, Medicare paid for 474 million tests under 1,174 procedure codes from Medicare’s Clinical Laboratory Fee Schedule.¹⁶ These procedure codes include many categories of lab tests, from common chemistry tests (such as a test that determines a person’s magnesium level) to less common but more complex molecular pathology tests (such as a genetic test for hereditary breast or ovarian cancer). Medicare Part B also paid a total of \$238 million in 2015 for blood draws that are used in lab testing.

Labs billed tests for around half of all Medicare beneficiaries (27 million) under Part B in 2015.¹⁷ On average, labs billed for 17 tests for each of these beneficiaries during 2015 and, for 1 percent of these beneficiaries, labs billed for 109 or more tests.¹⁸ On days that tests were billed for beneficiaries, labs billed for an average of 3.7 tests per day for each beneficiary. For 1 percent of beneficiaries, labs billed for an average of 24 or more tests, all occurring on a single date of service.

Medicare Part B paid 61,040 different labs an average of \$113,981 each for lab tests that they performed in 2015. Three labs received a combined total of \$1.0 billion in 2015. Each of these 3 labs performed tests at multiple locations—1 lab performed tests at more than 100 locations—which may account for their high volume. In contrast, half of all labs received less than \$1,048 each. In 2015, independent labs accounted for 55 percent of Medicare Part B payments for lab tests, hospital labs accounted for 24 percent, and physician office labs accounted for the remaining 20 percent.¹⁹

Approximately 600,000 providers ordered lab tests for their patients in 2015. On average, each provider ordered a total of 570 of these tests during 2015. One percent of these providers each ordered at least 7,250 tests during 2015.

Figure 1. What Medicare’s \$7 Billion for Lab Tests Went Toward in 2015



Source: OIG analysis of Medicare Part B lab test payments, 2016.

THE TOP 25 LAB TESTS BY MEDICARE PAYMENTS TOTALED \$4.1 BILLION IN 2015, SLIGHTLY LESS THAN IN 2014

Medicare paid a total of \$4.1 billion for the top 25 lab tests, slightly less than the \$4.2 billion it paid for the top 25 tests in 2014. (Twenty-three of the top 25 tests in 2014 were also on the list of the top 25 in 2015.) This \$4.1 billion amount represents 59 percent of Medicare payments for all lab tests that were paid for under the Clinical Laboratory Fee Schedule in 2015. Changes in the Medicare payment rates for these 25 tests could have a significant impact on overall Medicare spending for lab tests when the new payment system for lab tests goes into effect in 2018. Table 1 on the next page lists the top 25 lab tests based on Medicare Part B payments in 2015 and presents key statistics for each test and changes from 2014.

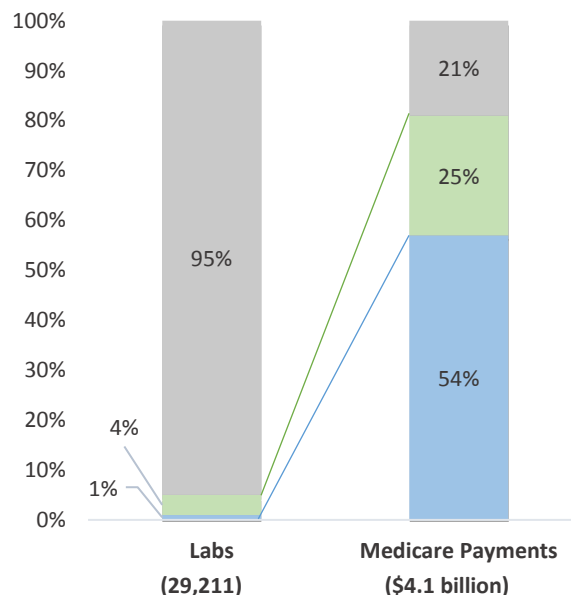
Medicare payments across the top 25 lab tests varied greatly. The top eight tests each accounted for more than \$200 million in Medicare payments during 2015. Combined, these eight tests totaled \$2.7 billion and accounted for about two-thirds of Medicare payments for the top 25 tests. The remaining 17 tests totaled \$1.4 billion and accounted for the remaining one-third of payments. Of the top 25 lab tests, the top three tests each accounted for more than \$400 million during 2015.

A SMALL PROPORTION OF LABS ACCOUNTED FOR THE MAJORITY OF PAYMENTS FOR THE TOP 25 TESTS

As shown in Figure 2, 1 percent of labs (292 out of 29,101 labs) received 54 percent of all Medicare Part B payments for the top 25 lab tests in 2015. These labs each received an average of \$7.6 million in 2015.

After the top 1 percent of labs, the next 4 percent of labs accounted for 25 percent of Medicare payments for the top 25 lab tests. These labs each received an average of \$890,787 for these tests in 2015. The remaining 95 percent of labs accounted for just 21 percent of payments for the top 25 lab tests. These labs each received an average of \$31,105 in 2015.

Figure 2. Medicare Payments for the Top 25 Lab Tests Were Unevenly Distributed Among Labs in 2015



Source: OIG analysis of Medicare Part B lab test payments, 2016.

Table 1. Top 25 Lab Tests Based on Medicare Part B Payments in 2015

Test Description and Procedure Code*		National Limitation Amount	Number of Tests (Millions)	Medicare Payments (Millions)	Changes From 2014 Payments (Millions)
1.	Blood test, thyroid-stimulating hormone (TSH) (84443)	\$22.87	21.2	\$475	↓ \$3
2.	Blood test, comprehensive group of blood chemicals (80053)	\$14.37	40.6	\$458	↑ \$5
3.	Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	\$10.58	41.5	\$428	↓ \$3
4.	Blood test, lipids (cholesterol and triglycerides) (80061)	\$18.22	27.2	\$379	↓ \$8
5.	Vitamin D-3 level (82306)	\$40.29	8.7	\$337	↑ \$13
6.	Hemoglobin A1C level (83036)	\$13.21	18.6	\$241	↑ \$5
7.	Opiates (drug) measurement (G6056)	\$26.48	8.1	\$208	↑ \$35
8.	Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), per patient encounter (G0431)	\$98.96	2.3	\$208	↑ \$15
9.	Blood test, basic group of blood chemicals (80048)	\$11.51	13.8	\$134	↓ \$3
10.	Blood test, clotting time (85610)	\$5.35	21.9	\$117	↓ \$11
11.	Parathormone (parathyroid hormone) level (83970)	\$56.17	2.1	\$114	↑ \$4
12.	Cyanocobalamin (vitamin B-12) level (82607)	\$20.51	5.5	\$110	↑ \$3
13.	PSA (prostate specific antigen) measurement (84153)	\$25.03	4.2	\$103	↓ \$1
14.	Chemical analysis using chromatography technique (82542)	\$24.58	4.3	\$97	↓ \$24
15.	Thyroxine (thyroid chemical) measurement (84439)	\$12.27	6.8	\$81	↑ \$2
16.	Bacterial colony count, urine (87086)	\$10.99	7.4	\$80	↑ \$1
17.	Benzodiazepines level (G6031)	\$25.17	3.2	\$77	↑ \$10
18.	NEW TO TOP 25 Drug confirmation (G6058)	\$18.03	4.3	\$75	↑ \$63
19.	Natriuretic peptide (heart and blood vessel protein) level (83880)	\$46.19	1.5	\$68	↓ <\$1
20.	Ferritin (blood protein) level (82728)	\$18.54	3.5	\$64	↑ \$1
21.	Gene analysis (cytochrome P450, family 2, subfamily D, polypeptide 6) common variants (81226)	\$450.46	0.1	\$62	↓ \$105
22.	Complete blood cell count (red cells, white blood cell, platelets), automated test (85027)	\$8.81	6.8	\$58	↑ <\$1
23.	NEW TO TOP 25 Amphetamine or methamphetamine (G6042)	\$21.15	2.9	\$58	↑ \$13
24.	Folic acid level (82746)	\$20.01	2.8	\$55	↑ \$1
25.	Methadone level (G6053)	\$22.22	2.5	\$53	↑ \$1
Total Medicare Part B Payments: \$4.14 billion					

Sources: OIG analysis of Medicare Part B lab test payments, 2016. National limitation amounts are from the 2015 Clinical Laboratory Fee Schedule.

Note: Medicare payments do not sum to total because of rounding.

* See endnote 16 for the American Medical Association (AMA) copyright notice.

MEDICARE PAID 19 PERCENT MORE FOR ALL DRUG TESTS IN 2015 THAN IN 2014

Although total Medicare payments for lab tests overall were nearly unchanged from 2014 to 2015, payments for drug tests increased considerably. These tests gauge the presence or level of drugs in a person’s body. Some tests are for therapeutic drugs that have the potential for abuse, such as opiates. Other tests are for illicit drugs, such as methamphetamine. From 2014 to 2015, Medicare payments for drug tests increased 19 percent, going from \$910 million to \$1.1 billion. Medicare payments increased by at least \$1 million for each of 18 different drug tests.

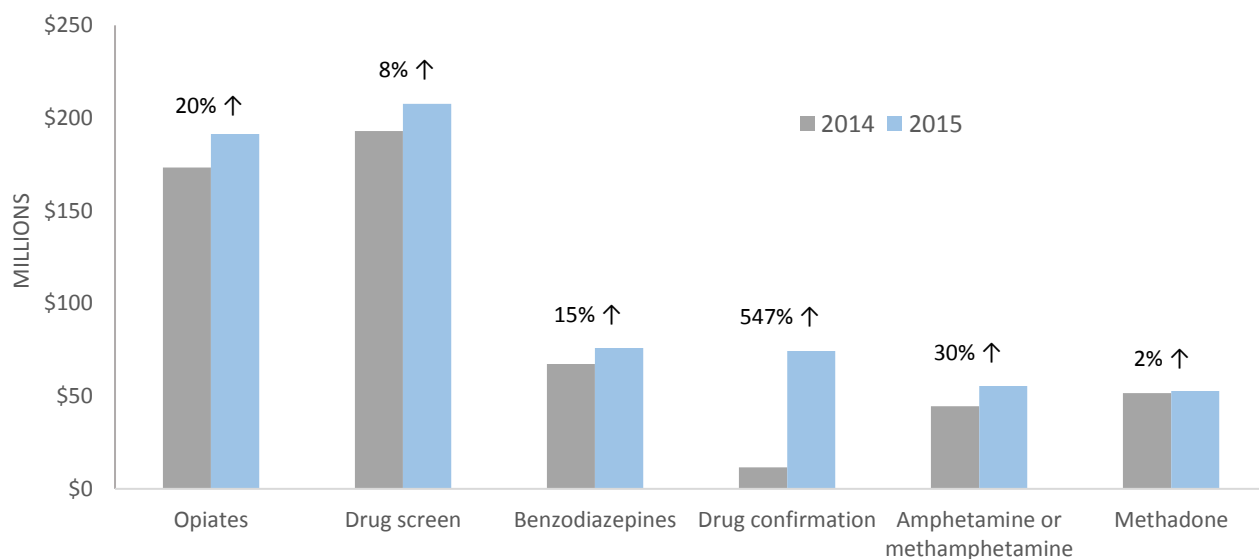
The increase in drug testing coincides with efforts to monitor drug abuse, but could also signal medically unnecessary drug testing. Prescription drug abuse is a growing problem nationwide. In 2011, the Centers for Disease Control and Prevention declared prescription drug abuse an epidemic.²⁰ Some of the increase in drug testing is likely legitimate efforts by physicians to monitor their patients’ drug use. However, the epidemic could provide a cover for labs that might seek to fraudulently bill Medicare for unnecessary drug testing. OIG has conducted a number of investigations into fraudulent and inappropriate drug testing. For example, one of the largest labs to conduct urine tests for drugs agreed in 2015 to pay \$256 million to resolve allegations that it billed Medicare and other Federal health programs for medically unnecessary drug and genetic tests.²¹

DRUG TESTS REPRESENTED A LARGER SHARE OF THE TOP 25 LAB TESTS IN 2015 THAN IN 2014

Six of the top 25 lab tests in 2015 were drug tests, compared to only 4 of the top 25 lab tests in 2014.²² Two of those tests were new to the top 25 in 2015: a test to confirm the beneficiary’s use of a specific drug (#18 on the list on page 6) and a test for amphetamine and methamphetamine (#23 on the list).

As shown in Figure 3, Medicare paid more in 2015 than in 2014 for each of the 6 drug tests in the top 25. Medicare Part B payments for a drug confirmation test (#18 on the list) grew by \$63 million, an increase of more than 500 percent in 1 year. This test can be used to confirm the presence and level of a number of different drugs. Medicare Part B payments for a test that confirms opiate use (#7 on the list) grew by \$35 million, an increase of 20 percent.

Figure 3. Medicare Payments for Drug Tests in the Top 25 Increased Between 2014 and 2015



Source: OIG analysis of Medicare Part B lab test payments, 2016.

MEDICARE PAID 44 PERCENT LESS IN 2015 THAN IN 2014 FOR ALL MOLECULAR PATHOLOGY TESTS

Although total Medicare payments for lab tests overall were nearly unchanged from 2014 to 2015, payments for molecular pathology tests decreased substantially. Molecular pathology tests analyze genetic material and often help doctors determine how their patients will respond to treatment. From 2014 to 2015, Medicare’s payments for these tests decreased from \$466 million to \$259 million. The decrease was largely concentrated in payments for three tests.

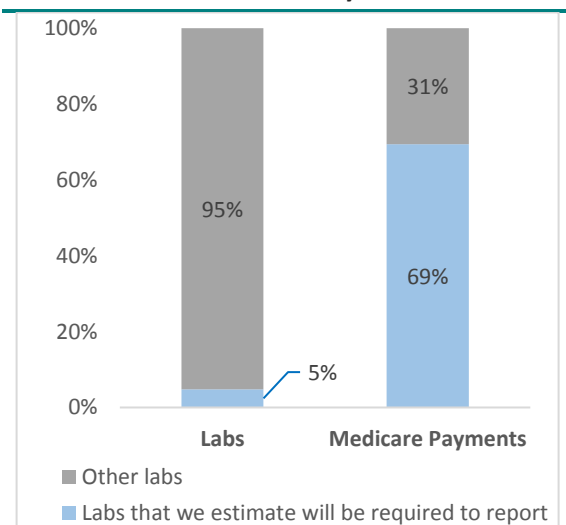
The decrease in billing for molecular pathology tests coincides with efforts to prevent medically unnecessary genetic testing. For example, CMS suspended payments in late 2014 to a company that performed medically unnecessary genetic tests of tissue taken from cheek swabs.²³

NEW PAYMENT RATES FOR LAB TESTS WILL BE BASED ON DATA PROVIDED BY A PROJECTED 5 PERCENT OF LABS; THESE LABS RECEIVED 69 PERCENT OF MEDICARE PAYMENTS IN 2015

As shown in Figure 4, we estimate using data from 2015 that 5 percent of labs (12,547 labs) will be required to report their private payer data to CMS.²⁴ CMS will use data reported by these labs to set new payment rates for lab tests. These labs accounted for 69 percent of Medicare payments for lab tests in 2015. The other 95 percent of all labs (248,977) accounted for the remaining 31 percent of Medicare payments in 2015.

The new Medicare payment rates may not reflect rates paid to labs that are exempt from reporting data. These labs account for a small portion of the volume of Medicare lab tests. Assuming that the volume of tests is distributed similarly among labs in the private market, the exemption of some labs will probably not affect the new payment rates, which will be based on the volume-weighted median of data from private payers.

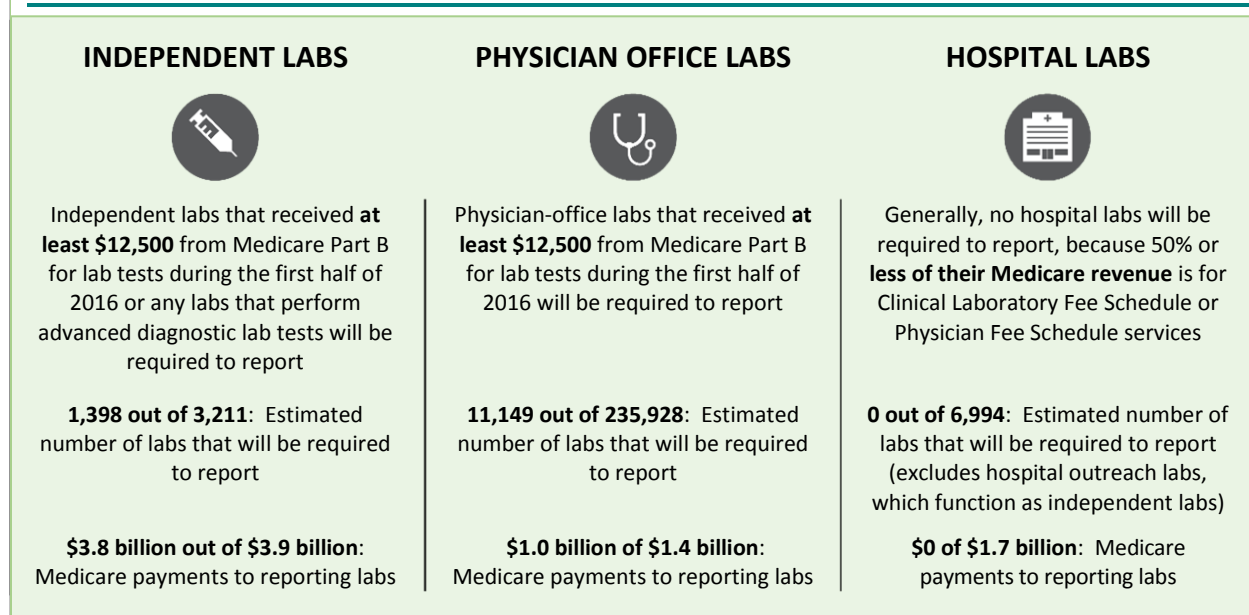
Figure 4. Labs That We Estimate Will Report Private Payer Data Represented More Than Two-Thirds of Medicare Payments in 2015



Source: OIG analysis of Medicare Part B lab test payments, 2016.

As shown in Figure 5, we estimate that about half of independent labs will be required to report their private payer data, whereas only a small portion of physician office labs and few hospital labs²⁵ will be required to their report data.²⁶ Thus, new payment rates will be based primarily on private payer data from independent labs.

Figure 5. Which Labs Will Be Required to Report Their Private Payer Data?



Source: OIG analysis of Medicare Part B lab test payments, 2016. See endnote 10 for more information about the criteria identifying applicable laboratories, i.e., laboratories that will be required to report.

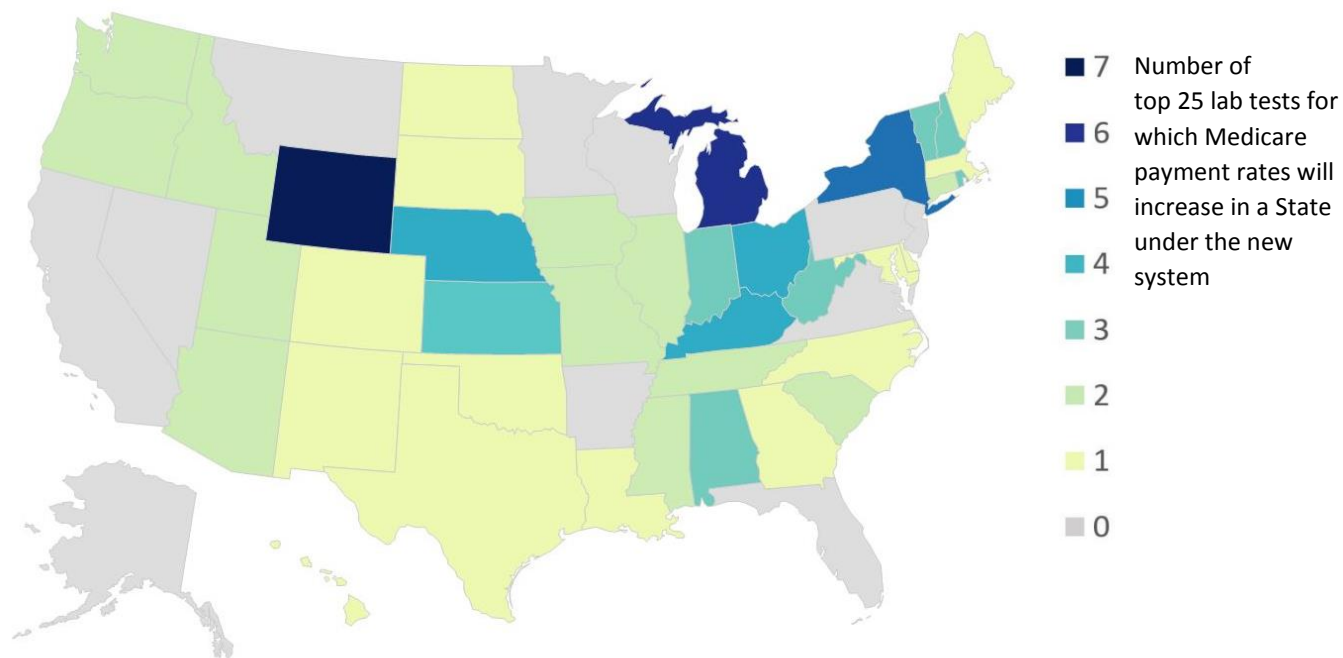
Note: Figures regarding how many labs will be required to report are estimates. We assumed that all independent labs and physician office labs will receive more than 50 percent of their Medicare revenue from the Clinical Lab Fee Schedule or Physician Fee Schedule.

ALTHOUGH MEDICARE PAYMENT RATES ARE EXPECTED TO DECREASE OVERALL, RATES FOR SOME TESTS WILL INCREASE IN CERTAIN LOCATIONS UNDER THE NEW PAYMENT SYSTEM

Medicare pays the National Limitation Amount (NLA) for a lab test unless the local fee schedule rate is lower. In areas that currently have rates less than the NLA, the change to a single national rate will cause the rates to increase in those areas under the new payment system.²⁷ For example, in 2015 Medicare paid \$58.79 for a given drug test in Ohio, whereas in most areas it paid the NLA of \$98.96. Under the new payment system, Medicare’s rate for this test in 2018 can decrease by no more than 10 percent from the 2015 NLA of \$98.96—i.e., to \$89.06. When CMS implements the single fee schedule in 2018, Medicare will pay at least 51 percent more in Ohio for this drug test than it does under the 2015 rate in the current payment system (an increase from \$58.79 to \$89.06—potentially more).

Under the new payment system, Medicare payment rates will increase in some areas of the country for 22 of the top 25 lab tests. In 38 States, Medicare payment rates for at least 1 of the top 25 tests will increase. As shown in Figure 6, in some States the Medicare payment rates will increase for as many as 7 of the top 25 tests. The amounts of these increases cover a wide range, from \$0.02 to \$30.27 per test.

Figure 6. Medicare Payment Rates For As Many As 7 of the Top 25 Lab Tests Will Increase in 38 States Under the New System



Source: OIG analysis of Medicare’s 2015 Clinical Laboratory Fee Schedule.

Note: New York has three local fee schedules, and California, Kansas, and Missouri each have two local fee schedules. For States with more than one fee schedule, the number shown is an average for the State’s fee schedules.

CERTAIN ASPECTS OF THE NEW PAYMENT SYSTEM THAT COULD LIMIT SAVINGS WARRANT ONGOING MONITORING

Although changes required by PAMA hold promise to lower Medicare payments, certain aspects of the new payment system could limit potential savings. As the January 2018 implementation date approaches, we identified three aspects of the new payment system that particularly warrant monitoring going forward.

First, Medicare could pay more for certain lab tests when it switches to a single national fee schedule. Despite expectations that the new payment system will result in lower national rates for most tests, the new rates will nonetheless cause payments to increase in locations where Medicare currently pays rates that are lower than the new national rate for that test. Further, the median pricing in the private market could be higher than Medicare’s current rate for some tests, resulting in new Medicare payment rates for those tests that are higher in *all* geographic areas.

Second, Medicare may pay more for specific sets of lab tests because under the new payment system, it will no longer be able to pay using “bundled” rates for those sets. CMS currently limits its payments for specific sets of blood tests—called “profiles”²⁸—to the lower of the profile rate or the total of the rates of all the individual tests.²⁹ Under the new payment system, Medicare payment rates will be based on

the weighted median of private payer rates, and CMS will no longer be able to pay a single bundled rate for a set of tests. In September 2016, CMS consulted with a Federal advisory panel (the one that PAMA required CMS to establish regarding the new payment system) about how to mitigate this concern.

Finally, the absence of certain private payer pricing data from the data that CMS will receive could limit decreases in Medicare lab test rates. As previously noted, certain labs will not be required to report their private payer data to CMS. This includes about half of independent labs, most physician office labs, and virtually all hospitals. Further, labs are not required to report payments that are not associated with a specific test procedure code—for example, when an insurance company makes a single payment for a test and other medical services that a patient received.³⁰ If the data that are not reported are systematically lower than the data that CMS will use to set new payment rates, the decreases in Medicare payment rates under the new payment system could be limited.

CONCLUSION

This data brief provides baseline analyses of Medicare Part B payments for lab tests in 2015, 3 years before Medicare's new payment system for lab tests is scheduled to go into effect. Although total Medicare payments for lab tests did not change from 2014 to 2015, payments for two categories of tests changed significantly—specifically, Medicare payments for drug tests increased by 19 percent in 1 year and payments for molecular pathology tests decreased by 44 percent. We also identified several aspects of the new payment system that may limit cost savings and, therefore, warrant monitoring.

We will continue to monitor Medicare lab test payments and CMS's reform of the payment system in the years leading up to, and after, the new rates go into effect. We are also issuing a companion report, *Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress* (OEI-09-16-00100), that examines CMS's progress toward implementing the new payment system.

METHODOLOGY

We based this data brief on our analysis of Medicare’s claims data for lab tests performed in 2015 and reimbursed under the Clinical Laboratory Fee Schedule. For comparison, we also reviewed the same claims data from 2014. 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 physician office labs. The Outpatient files primarily include lab test claims from hospital labs. We did not include lab tests that were paid for under other payment systems, such as the Critical Access Hospital or Outpatient Prospective Payment System.³¹ 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, lab type, ordering provider, category of lab test, and the lab’s reporting status (i.e., whether it would qualify as an “applicable lab” and thus be required to report its data). We identified the top 25 lab tests on the basis of total payments for each procedure code in 2015, and we then performed a similar analysis for the top 25 tests.

Analysis by beneficiary. We identified the beneficiary using the Health Insurance Claim Number on the claim. We used the date of service to determine the number of tests that beneficiaries received per day.

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 used a lab’s Tax Identification Number (TIN) to identify a unique lab. 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 lab type. We used each claim’s place of service or type of bill to identify the type of lab (independent lab, physician office lab, or hospital lab) that performed the test. For tests in the Physician/Supplier Part B claims files, we identified the lab type according to the “place of service” variable. For tests in the Outpatient claims files, we identified lab type according to the “type of bill” variable, which indicates the type of facility and service. We identified a lab’s type according to the majority of its claims for lab tests.

Analysis by ordering provider. We used the ordering provider’s National Provider Identifier (NPI) reported on the claim to identify the physician who ordered the lab test. Because the ordering provider’s NPI is reported only for claims from the Physician/Supplier claims file, our analysis is limited to claims in that file and does not include claims from the Outpatient claims file for lab tests performed by hospital labs.

Analysis by category. We determined a test’s category (drug test, molecular pathology, etc.) according to its subsection within the 2015 edition of Current Procedural Terminology (CPT). Each lab test that has a Level I Healthcare Common Procedure Coding System (HCPCS) code is assigned to a CPT subsection. For lab tests on the 2015 Clinical Laboratory Fee Schedule that have Level II HCPCS codes, we asked CMS to identify the test’s category.

Analysis by labs’ reporting status. To be consistent with CMS’s definition of “applicable lab” (i.e., a lab that will be required to report its private payer data to CMS), we used a lab’s National Provider Identifier in our determination of whether a lab will be required to report. We estimated that a lab will be required to report if it was an independent lab or physician office lab that received more than \$25,000 in lab test revenues under Medicare Part B during calendar year 2015. This approach is based

on CMS’s “low-expenditure threshold” of \$12,500 during the first half of calendar year 2016, which exempts labs under that threshold from reporting, except for any ADLTs they may perform. We assumed that all independent labs and physician office labs will receive more than 50 percent of their Medicare revenue from the Clinical Lab Fee Schedule or Physician Fee Schedule.

Fee schedule rate analysis. We analyzed Medicare’s 2015 Clinical Laboratory Fee Schedule to identify the extent of variation in the local payment rates for the top 25 tests.

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. Chelsea Samuel from the San Francisco regional office also conducted the study. Other Office of Evaluation and Inspections staff who provided support include Joe Chiarenzelli, Berivan Demir Neubert, Evan Godfrey, Althea Hosein, and Christine Moritz.

ENDNOTES

¹ PAMA, P. L. No. 113-93, § 216(a) (adding Social Security Act, § 1834A, 42 U.S.C. §1395m-1).

² 81 Fed. Reg. 41036, 41097 (June 23, 2016) (final rule implementing PAMA, § 216(a)).

³ PAMA, § 216(c)(2).

⁴ OIG, *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data*, OEI-09-15-00210.

⁵ See 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.

⁶ The Deficit Reduction Act of 1984, P.L. No. 98-369 § 2303(d).

⁷ Since 1998, the national limitation amount has been set at 74 percent of the median of the 57 fee schedule rates. 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. Social Security Act, § 1833(h)(4)(B)(viii), 42 U.S.C. § 1395l(h)(4)(B)(viii).

⁸ SSA § 1834A(b)(1)(A), 42 U.S.C. § 1395m-1(b)(1)(A), requires CMS to implement the new payment system beginning January 1, 2017; however, CMS moved the implementation date to January 1, 2018. 81 Fed. Reg. 41037.

⁹ 81 Fed. Reg. 41066 and 41098. See also 42 CFR § 414.502 (defining “data collection period,” “data reporting period,” and “private payor”).

¹⁰ Both PAMA and the final rule implementing PAMA exempt certain labs from reporting their private payer data to CMS. These labs are not considered to be “applicable laboratories.” Labs that do not receive the majority (i.e., more than 50 percent) of their Medicare revenue from the Clinical Lab Fee Schedule (CLFS) or Physician Fee Schedule will not have to report, nor will labs that receive less than \$12,500—the “low-expenditure threshold”—in lab test revenues from the CLFS during a data collection period. Out of consideration for the administrative burden that reporting would impose, CMS exempted labs under the low-expenditure threshold from reporting. The low-expenditure threshold does not apply to single labs with respect to ADLTs they offer and furnish. SSA § 1834A(a)(2), 42 U.S.C. § 1395m-1(a)(2). 81 Fed. Reg. 41041–51 and 41098. See also 42 CFR § 414.502 (including the low-expenditure threshold in the definition of “applicable laboratory”).

¹¹ 42 CFR § 414.504(a). 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. SSA § 1834A(d)(5), 42 U.S.C. § 1395m-1(d)(5).

¹² SSA § 1834A(b)(3), 42 U.S.C. § 1395m-1(b)(3).

¹³ U.S. Department of Health and Human Services, *2015 CMS Statistics*, p. 29. Accessed at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/2015CMSSStatistics.pdf> on August 31, 2016. According to this source, Medicare Part B benefit payments were projected to be \$272.9 billion for fiscal year 2015.

¹⁴ 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).

¹⁵ Congress mandated a 1.75-percent reduction in Medicare payments for lab tests under the Clinical Laboratory Fee Schedule in 2011–2015. Patient Protection and Affordable Care Act, P. L. No. 111-148, § 3401(l).

¹⁶ Labs bill for each test on the CLFS 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. Level I HCPCS codes are composed 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.

¹⁷ U.S. Department of Health and Human Services, *2015 CMS Statistics*, p. 6. The projected enrollment in fee-for-service Medicare in 2015 was 55.3 million beneficiaries.

¹⁸ In our analysis of lab tests paid for by Medicare Part B in 2014, we reported these figures in terms of claim lines rather than units. In 2014, the average number of lab test claim lines per beneficiary was 17; in 2015, the average was 16. In 2014, 1 percent of beneficiaries were each associated with at least 95 lab test claim lines; in 2015, the average was also 95.

¹⁹ In addition, 1 percent of tests were performed in other settings, such as skilled nursing facilities and dialysis facilities.

²⁰ CDC, *Prescription Painkiller Overdoses at Epidemic Levels*, November 1, 2011. Accessed at http://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html on August 31, 2016.

²¹ Department of Justice, *Millennium Health Agrees to Pay \$256 Million to Resolve Allegations of Unnecessary Drug and Genetic Testing and Illegal Remuneration to Physicians*, October 19, 2015. Accessed at <https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic> on August 31, 2016.

²² G codes replaced CPT codes for these six drug tests. CMS created the G codes in response to AMA's plan to replace the CPT codes for these six tests with a greater number of CPT codes. CMS was concerned about the potential for overpayment caused by the increase in the number of drug test codes. CMS, *Clinical Laboratory Fee Schedule (CLFS) Final Determinations*. Accessed at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallabfeesched/downloads/cy2015-clfs-codes-final-determinations.pdf> on August 31, 2016.

²³ Reed Abelson and Julie Creswell, "Pursuit of Cash Taints Promise of Gene Tests." *The New York Times*, June 24, 2014. Accessed at http://www.nytimes.com/2015/06/25/technology/genetic-testing-case-highlights-the-fields-hope-and-hype.html?_r=0 on August 31, 2016.

²⁴ The number of labs in this finding exceeds the number of labs discussed elsewhere in this data brief. For this finding, we identified labs at the National Provider Identifier (NPI) level, consistent with how CMS defines a lab that is required to report. 81 Fed. Reg. 41046. We identified 261,524 unique NPIs that Medicare paid for laboratory services in 2015.

²⁵ Only a hospital outreach lab that obtains a unique NPI—separate from the hospital's NPI—could potentially qualify as an applicable lab. However, such labs would appear in CMS claims data—and therefore, in our analysis—as independent labs.

²⁶ We estimate that in addition to the labs described in Figure 5, 15,391 labs will not be required to report. Of these, 15,113 are labs of types different than the main three types (for example, labs in skilled nursing facilities or labs in dialysis facilities). For the remaining 278 labs, we could not determine the type of lab (that is, a single type of lab test did not account for more than half the lab's claims).

²⁷ Past work by OIG has shown that the local fee schedule rates do not vary according to the cost of living. OIG, *Variation in the Clinical Laboratory Fee Schedule* (OEI-05-08-00400), July 2009.

²⁸ Profiles are specific sets of blood tests that enable physicians to more accurately diagnose their patients' medical problems.

²⁹ CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 16, § 90.1.1.

³⁰ 81 Fed. Reg. 41037–41038, 41054 (June 23, 2016).

³¹ In 2014, many of the lab tests performed in outpatient settings (such as hospitals, skilled nursing facilities, and dialysis facilities) were paid for under Medicare payment systems other than the CLFS. As we have noted, our analysis included only lab tests paid for under Medicare's CLFS.