



**U.S. Department of Health and Human Services**  
**Office of Inspector General**

**HHS OIG DATA BRIEF**

**Medicare Payments for  
Clinical Diagnostic  
Laboratory Tests  
in 2016: Year 3  
of Baseline Data**

**OEI-09-17-00140**

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**Why OIG Did This Review**

Beginning in 2018, the Medicare program will change the way it sets payment rates for clinical diagnostic laboratory (lab) tests. The Centers for Medicare & Medicaid Services (CMS) will replace current payment rates with new rates based on current charges in the private health care market. This is the first reform in 3 decades to Medicare’s payment system for lab tests.

As part of the same legislation reforming Medicare’s payment system, Congress 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 those tests. This data brief provides the third set of annual baseline analyses of the top 25 lab tests.

**How OIG Did This Review**

We analyzed claims data for lab tests that CMS paid for under Medicare’s Clinical Laboratory Fee Schedule. These tests are covered under Medicare Part B, and do not include tests that Medicare paid for under other payment systems, such as the payment system for critical access hospitals or the Outpatient Prospective Payment System. We identified the top 25 tests based on Medicare payments in 2016. We also identified key statistics and emerging trends, including Medicare payments by procedure code, beneficiary, lab, ordering provider, and test category.

**Medicare Payments for Clinical Diagnostic Laboratory Tests: Year 3 of Baseline Data**

**What OIG Found**

Medicare paid \$6.8 billion under Part B for lab tests in 2016, a total that changed very little in the 3-year period from 2014 through 2016. Medicare payments were concentrated among a small number of tests and labs. The top 25 tests by Medicare payments totaled \$4.3 billion and represented 60 percent of all Medicare payments for lab tests in 2016. The top 6 tests, which remained consistent with the top 6 from the previous 2 years, totaled \$2.4 billion in 2016. More than half of payments for the top 25 tests went to 1 percent of labs.

Medicare payments for four categories of tests changed notably over time, despite little change in the total payments for all lab tests. In comparison to Medicare payments for other test categories, payments for two categories of tests—an emerging category of tests and microbiology tests—increased notably from 2015 to 2016. Drug tests and molecular pathology tests decreased notably during the same period.

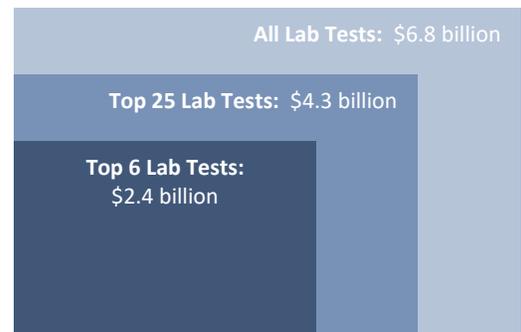
**What OIG Concludes**

Lab tests play a critical role in delivering health care for the millions of Medicare beneficiaries who receive tests each year. Although CMS paid for Medicare beneficiaries to receive over 1,000 different lab tests in 2016, 25 tests accounted for 60 percent of Medicare payments for all tests. 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. The information presented here will be useful in monitoring the effects of changes to Medicare’s payment system for lab tests. We will continue to monitor Medicare payments for lab tests and to identify emerging trends.

**Key Takeaway**

Total Medicare spending for lab tests in 2016 was concentrated among a small number of tests and labs. Changes in the Medicare payment rates for the top 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.

**More than 60 percent of Medicare lab test payments in 2016 were for 25 test codes**



Source: OIG analysis of Medicare Part B lab test payments, 2017.

## BACKGROUND

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.<sup>1</sup> In 2018, new rates based on rates paid by private payers will replace the current payment rates, which are based on lab charges from 1984 and 1985. The new payment system will establish a single national fee schedule, replacing 57 separate local fee schedules.

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. Specifically, PAMA requires OIG to publicly release an annual analysis of the top 25 tests, based on Medicare payments, and to conduct analyses that OIG determines appropriate regarding the implementation and effect of the new payment system.<sup>2</sup> This is the third annual analysis.<sup>3</sup>

This data brief analyzes claims data for lab tests that CMS paid for under Medicare’s Clinical Laboratory Fee Schedule. These tests are covered under Medicare Part B, and do not include tests that Medicare paid for under other payment systems such as the Physician Fee Schedule, the payment system for critical access hospitals, or the Outpatient Prospective Payment System.

### Lab test payment rates: 2018 and after

Beginning in 2018, CMS will update the Clinical Laboratory Fee Schedule using rates paid by private payers.<sup>4,5</sup> 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.<sup>6</sup>

During the first 3 months of 2017, labs submitted information to CMS about the rates that private payers paid them for lab tests during the first half of 2016.<sup>7</sup> Because labs reported difficulty in collecting the right payment information, CMS allowed 60 more days for labs to report without penalty.<sup>8</sup> Certain labs were exempt from reporting their private payer data to CMS.<sup>9</sup>

### Exhibit 1. How will Medicare’s payment system change in 2018?

CURRENT <i>Implemented in 1984</i>	FUTURE <i>To be implemented in 2018</i>
Payment rates for existing tests are based on <b>lab charges in 1984–1985</b> , adjusted annually for inflation	Payment rates for existing tests will be based on the weighted median of <b>current rates from private payers</b> , and updated every 3 years using current data
<b>57</b> local fee schedules	<b>Single</b> national fee schedule

Source: OIG analysis of Medicare’s new payment system for lab tests, 2017.

## 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 from one another?

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.

## MEDICARE PART B PAID \$6.8 BILLION FOR LAB TESTS IN 2016, A TOTAL THAT CHANGED VERY LITTLE OVER 3 YEARS

Medicare payments for lab tests under the Clinical Laboratory Fee Schedule totaled \$6.8 billion in 2016, accounting for about 2 percent of all Part B payments in 2016.<sup>10, 11</sup> Total payments for tests decreased slightly from the 2015 total (\$7.0 billion) and the 2014 total (also \$7.0 billion).<sup>12, 13</sup>

**Tests.** In 2016, Medicare paid for 437 million tests under 1,173 procedure codes from Medicare’s Clinical Laboratory Fee Schedule.<sup>14</sup> 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 genetic tests (such as a test that detects genes associated with breast cancer).

Test volume is based on the number of units for which labs billed. For most procedure codes, the number of units corresponds to the number of tests performed, but some procedure codes include multiple tests. For example, procedure code G0483 was newly effective in 2016 and includes testing for 22 or more drug classes. In 2015, a lab would have instead billed using a different procedure code for each drug class.

**Beneficiaries.** Labs billed for tests for around half (28 million) of all Medicare beneficiaries under Part B in 2016.<sup>15</sup> On average, labs billed for 16 individual tests for each of these beneficiaries during 2016 and, for 1 percent of these beneficiaries, labs billed for 86 or more tests. On days that tests were billed for beneficiaries, labs billed for an average of 3.4 tests per day for each beneficiary. For the top 1 percent of beneficiaries, labs billed for an average of 17 or more tests, all occurring on a single date of service.

**Labs.** Medicare paid 58,593 different labs an average of \$115,546 each for lab test that they performed in 2016. Three labs received a combined total of \$1.1 billion in 2016. Each of these 3 labs performed tests at multiple locations—1 lab performed tests at more than 150 locations—which may account for their high total payments. In contrast, half of all labs received less than \$1,055 each. In 2016, independent labs accounted for 55 percent of Medicare payments for lab tests. Hospital labs accounted for 26 percent of these payments, and physician office labs accounted for 18 percent of payments.<sup>16</sup>

**Providers.** In 2016, 635,773 providers ordered lab tests for their patients. On average, each provider ordered 485 individual tests during 2016. One percent of these providers each ordered at least 6,176 tests during 2016.

### Exhibit 2. What Medicare’s \$6.8 billion for lab tests went toward in 2016

TESTS	BENEFICIARIES	LABS	PROVIDERS
			
<b>437 million</b> tests billed	<b>28 million</b> Medicare beneficiaries received at least 1 test	<b>58,593</b> labs received Medicare payments	<b>635,773</b> providers ordered lab tests
<b>3.4:</b> Average number of tests a beneficiary received on a day	<b>16:</b> Average number of individual tests per beneficiary	<b>\$115,546:</b> Average payments per lab	<b>485:</b> Average number of tests ordered per provider
<b>17:</b> Average number of tests per day for top 1 percent of beneficiaries	<b>86:</b> Average number of tests in 2016 for the top 1 percent of beneficiaries	<b>\$1.1 billion:</b> Payments made to the top three labs	<b>6,176:</b> Average number of tests ordered by top 1 percent of providers

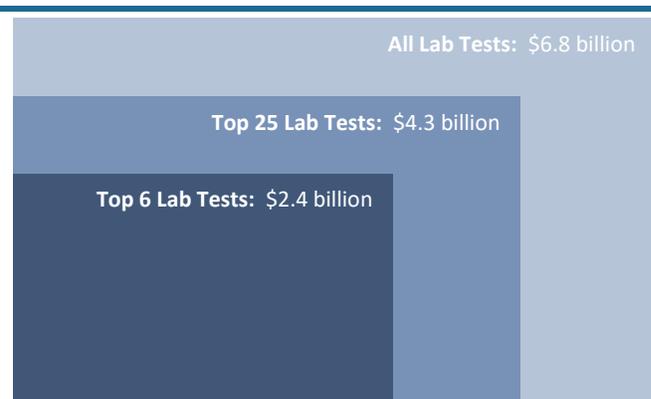
Source: OIG analysis of Medicare Part B lab test payments, 2017.

## MORE THAN 60 PERCENT OF MEDICARE PART B PAYMENTS FOR LAB TESTS IN 2016 WERE FOR 25 TESTS

Medicare paid a total of \$4.3 billion for the top 25 lab tests in 2016, representing 63 percent of Medicare payments for all lab tests paid for under the Clinical Laboratory Fee Schedule. The 2016 total is slightly higher than the \$4.1 billion that Medicare paid for the top 25 tests in 2015 and the \$4.2 billion it paid in 2014. Exhibit 5 lists the top 25 lab tests based on Medicare payments in 2016.

Seventeen lab tests have remained in the top 25 tests for the last 3 years, reflecting relative stability within this group of high-volume tests ordered each year by physicians treating the Medicare population. Of these, the top 6 lab tests have maintained their respective positions among the top 25 tests for the last 3 years and accounted for 35 percent (\$2.4 billion) of all payments for lab tests in 2016, as shown in Exhibit 3. These six tests include common blood tests and a test for Vitamin D<sub>3</sub> levels. Medicare payments for each of these tests increased over the last 3 years. From 2015 to 2016, payments for each test increased by at least \$2 million, with a maximum increase of \$32 million for a test measuring blood lipid levels, as shown in Exhibit 5 on the next page.

**Exhibit 3. More than one-third of Medicare payments were for six tests**

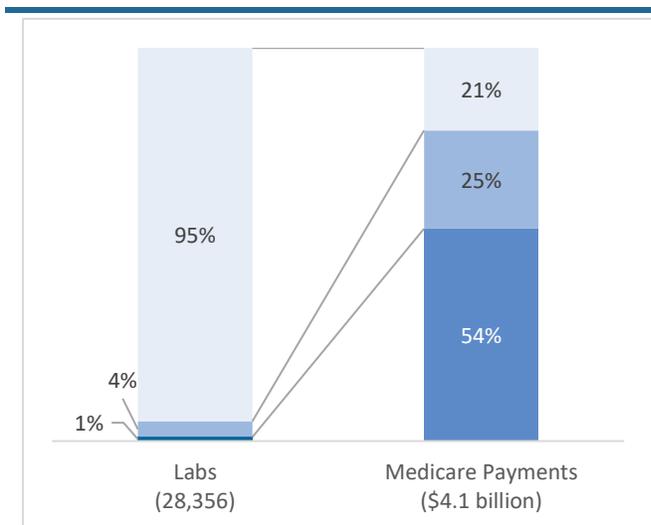


Source: OIG analysis of Medicare Part B lab test payments, 2017.

### More than half of Medicare payments for tests in the top 25 went to 1 percent of labs

One percent of labs (284 out of 28,356 labs) received 54 percent of all Medicare payments for the top 25 lab tests in 2016, as shown in Exhibit 4. These labs each received an average of \$8.2 million in 2016. 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 \$935,611 for these tests in 2016. 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 \$33,793 in 2016. Medicare payments were similarly concentrated among a small proportion of all labs in 2014 and 2015.

**Exhibit 4. Fifty-four percent of Medicare payments went to fewer than 300 labs**



Source: OIG analysis of Medicare Part B lab test payments, 2017.

## Exhibit 5. Top 25 lab tests based on Medicare Part B payments in 2016

Test Description (Procedure Code)*	National Limitation Amount**	Number of Tests (Millions)	Medicare Payments (Millions)	Change From 2015 Payments (Millions)
1. Blood test, thyroid-stimulating hormone (TSH) (84443)	\$22.89	21.5	\$482	↑ \$7.4
2. Blood test, comprehensive group of blood chemicals (80053)	\$14.39	41.6	\$470	↑ \$11.7
3. Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	\$10.59	42.0	\$433	↑ \$5.5
4. Blood test, lipids (cholesterol and triglycerides) (80061)	-	29.0	\$411	↑ \$31.7
5. Vitamin D <sub>3</sub> level (82306)	\$40.33	9.0	\$350	↑ \$13.3
6. Hemoglobin A1C level (83036)	\$13.22	19.3	\$250	↑ \$9.8
7. Drug test(s), definitive, per day, 22 or more drug class(es), including metabolite(s) if performed (G0483)	\$215.23	1.2	\$241	<i>New code in 2016</i>
8. Drug test(s), presumptive, any number of drug classes, per date of service (G0479)	\$79.25	3.0	\$221	<i>New code in 2016</i>
9. Blood test, basic group of blood chemicals (80048)	\$11.52	13.7	\$133	↓ \$0.7
10. Drug test(s), definitive, per day, 15–21 drug class(es), including metabolite(s) if performed (G0482)	\$166.03	0.8	\$127	<i>New code in 2016</i>
11. Parathormone (parathyroid hormone) level (83970)	\$56.23	2.2	\$120	↑ \$6.2
12. Cyanocobalamin (vitamin B <sub>12</sub> ) level (82607)	\$20.54	5.6	\$113	↑ \$2.7
13. Blood test, clotting time (85610)	\$5.36	19.6	\$105	↓ \$11.5
14. PSA (prostate specific antigen) measurement (84153)	\$25.06	4.2	\$103	↓ \$0.1
15. Thyroxine (thyroid chemical) measurement (84439)	\$12.28	7.1	\$85	↑ \$3.7
16. Bacterial colony count, urine (87086)	\$11.00	7.6	\$82	↑ \$2.3
17. Drug test(s), definitive, per day, 8–14 drug class(es), including metabolite(s) if performed (G0481)	\$122.99	0.6	\$73	<i>New code in 2016</i>
18. Natriuretic peptide (heart and blood vessel protein) level (83880)	\$46.24	1.5	\$69	↑ \$1.3
19. Drug test(s), definitive, per day, 1–7 drug class(es), including metabolite(s) if performed (G0480)	\$79.94	1.0	\$69	<i>New code in 2016</i>
20. Ferritin (blood protein) level (82728)	\$18.57	3.7	\$67	↑ \$3.5
21. Gene analysis (colorectal cancer) (81528)	\$508.87	0.1	\$62	<i>New code in 2016</i>
22. Test for detecting genes associated with breast cancer (81519)	\$3,419.40	0.02	\$60	<i>New code in 2016</i>
23. Complete blood cell count (red cells, white blood cell, platelets), automated test (85027)	\$8.81	6.8	\$58	↓ \$0.3
24. Folic acid level (82746)	\$20.03	2.9	\$56	↑ \$0.7
25. Evaluation of antimicrobial drug (antibiotic, antifungal, antiviral) (87186)***	\$11.78	4.5	\$51	↑ \$0.6
<b>Total Medicare payments: \$4.29 billion</b>				

Sources: OIG analysis of Medicare Part B payments, 2017.

\* See endnote 10 for the American Medical Association (AMA) copyright notice.

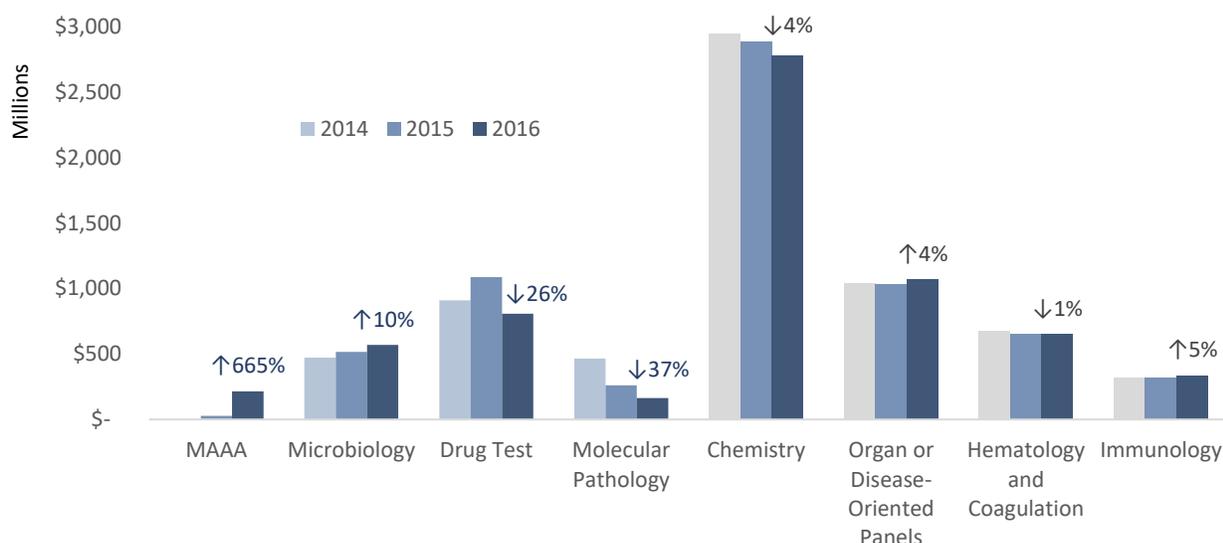
\*\* The national limitation amount is a capped rate established by Congress to contain costs. The national limitation amounts listed in this column are from the 2016 Clinical Laboratory Fee Schedule. Medicare pays the lowest of the following three amounts: the lab's charge, the local fee schedule rate, or the national limitation amount.

\*\*\* Procedure code 87186 ranked as Test 25 in 2014 and ranked as Test 26 in 2015, by Medicare payments.

## MEDICARE PART B PAYMENTS FOR FOUR TEST CATEGORIES CHANGED NOTABLY OVER 3 YEARS

Compared with changes in other test categories from 2014 to 2016, Medicare payments changed notably for four test categories. Payments for an emerging category of tests—multianalyte assays with algorithmic analyses (MAAAs)—increased by 665 percent from 2015 to 2016. Payments for microbiology tests increased by 10 percent from 2015 to 2016. Payments for drug tests and molecular pathology tests decreased by 26 percent and 37 percent, respectively, from 2015 to 2016. Exhibit 6 shows changes in Medicare payments over a 3-year timeframe among the eight test categories for which Medicare paid the most. Although payments in four of these categories changed notably, the other four categories changed by no more than 5 percent from one year to the next.

**Exhibit 6. Changes in Medicare payments over 3 years among eight test categories were notable for four categories of lab tests, with the greatest change in MAAAs**



Note: The percentage differences represent changes from 2015 to 2016.

Source: OIG analysis (2017) of Medicare Part B lab test payments for the test categories for which Medicare paid the most in 2016.

**Multianalyte assays with algorithmic analyses (MAAAs).** Payments for MAAAs increased considerably from 2015 to 2016. MAAAs are an emerging category of tests that combine multiple test results with other patient information to yield a predictive score, such as the risk of a cancer’s recurrence or a drug response. These tests are typically offered only by the lab companies that developed the tests.

In 2015, Medicare included the first MAAA—a colorectal cancer screening test—on the Clinical Laboratory Fee Schedule. Medicare payments for this test more than doubled between 2015 and 2016, from \$28 million to \$62 million.<sup>17</sup> In 2016, Medicare began paying for 10 new tests in the MAAA category and paid a total of \$216 million for MAAAs. On average, Medicare paid \$890 per MAAA test, making this the most expensive category on the Clinical Laboratory Fee Schedule in terms of payment per test. Two of these 10 tests appear in the top 25 in 2016: a genetic colorectal cancer screening test that is paid for at \$509 per test (Test 21 in Exhibit 5), and a test detecting genes associated with breast cancer that is paid for at \$3,419 per test (Test 22 in Exhibit 5).

**Microbiology tests.** Payments for microbiology tests increased consistently from 2014 to 2016, going from \$472 million in 2014 to \$517 million in 2015 and then to \$570 million in 2016. These tests detect and identify microorganisms that may cause serious infections. Two of these tests appear in the top 25 in 2016: a test measuring bacterial count in urine that is paid for at \$11.00 per test (Test 16 in Exhibit 5) and a test evaluating antimicrobial drugs that is paid for at \$11.78 per test (Test 25 in Exhibit 5).

**Drug tests.** Payments for drug tests decreased from 2015 to 2016, reversing the increase from 2014 to 2015. Drug 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. Medicare payments for drug tests increased from \$910 million in 2014 to \$1.1 billion in 2015 before dropping to \$808 million in 2016.

The decrease in Medicare payments for drug tests coincided with CMS's use of a new payment approach for these tests. In 2015, CMS paid separately for each drug class for which the patient was tested. In 2016, CMS paid a set amount for multiple tests, regardless of which drugs were being tested. Because of the new payment approach, it is unknown how often tests for specific drug classes—such as opioids—were conducted in 2016. Of the 7 new drug test codes, 5 (Tests 7, 8, 10, 17, and 19 in Exhibit 5) appear in the top 25 tests in 2016. Medicare paid for these tests at rates ranging from \$79 to \$215 per test.

**Molecular pathology tests.** Payments for molecular pathology tests decreased consistently from 2014 to 2016. Molecular pathology tests detect variants in genetic material and often help doctors determine how their patients will respond to treatment. Medicare payments for molecular pathology tests decreased from \$466 million in 2014 to \$260 million in 2015.<sup>18</sup> In 2016, total payments for these tests dropped further, to \$165 million. The number of molecular pathology tests appearing in the top 25 has also fallen, from 2 tests in 2014, to 1 test in 2015, and no tests in the top 25 in 2016.

The decrease in billing for molecular pathology tests coincided with efforts by CMS, the Department of Justice, and OIG to prevent and reduce medically unnecessary genetic testing. For example, in late 2015 a company agreed to pay \$10 million to resolve allegations that it had submitted claims for genetic testing that was performed routinely and without an individualized assessment of need, and entered a corporate integrity agreement with OIG.<sup>19</sup>

## CONCLUSION

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Lab tests play a critical role in delivering health care for the millions of Medicare beneficiaries who receive tests each year. Forthcoming payment reforms could have significant implications for Medicare spending and for the lab industry. In 2016, Medicare paid \$6.8 billion for tests; the top 25 tests accounted for 60 percent of this amount. More than one-third of all lab test payments were for six tests. Changes in the Medicare payment rates for these tests could have a significant impact on Medicare spending when the new payment system for lab tests goes into effect in 2018.

The information presented here will be useful in monitoring the effects of changes to Medicare's payment system for lab tests. CMS projects that forthcoming payment reforms could save \$3.9 billion over 10 years.<sup>20</sup> Statistics from this and past OIG data briefs will serve as baselines that OIG will use to measure the effects of changes to the payment system. We will continue to monitor Medicare payments for lab tests and to identify emerging trends and vulnerabilities to potential Medicare cost savings.

## METHODOLOGY

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We based this data brief on our analysis of Medicare’s claims data for lab tests performed in 2016 and reimbursed under the Clinical Laboratory Fee Schedule. For comparison, we also reviewed the same claims data from 2014 and 2015. As a result of when we accessed claims data, our analysis in 2016 used a set of claims that was slightly more complete (i.e., by less than 1 percent) than the sets used for our 2014 and 2015 reports. The totals we report for 2016 are thus marginally higher, when compared with those reported for 2014 and 2015. 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 payment system for critical access hospitals or the Outpatient Prospective Payment System.<sup>21</sup> We also did not include claims for physicians’ interpretations of tests.

We analyzed the claims data to identify key statistics and emerging trends for Medicare Part B payments for lab tests. We analyzed Medicare payments and test volume by procedure code, beneficiary, lab, lab type, ordering provider, and test category. Test volume is based on the number of units for which labs billed. We identified the top 25 lab tests based on total payments for each procedure code in 2016, and we calculated total payments for these tests and analyzed payments by lab.

**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 the TIN is the highest level identifier in the claims data and includes multiple 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 2016 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 2016 Clinical Laboratory Fee Schedule that have Level II HCPCS codes, we asked CMS to assign test categories for the purpose of our analysis.

### 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**

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## ENDNOTES

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

<sup>2</sup> PAMA, § 216(c)(2).

<sup>3</sup> The first two annual analyses are: *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data* (OEI-09-15-00210), September 2015, and *Medicare Payments for Clinical Laboratory Tests in 2015: Year 2 of Baseline Data* (OEI-09-16-00040), September 2016. We also reported on CMS's implementation of the new payment system for lab tests; see *Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress* (OEI-09-16-00100), September 2016.

<sup>4</sup> Private payer rates include those paid by private health insurance companies, Medicaid managed care organizations, and Medicare Advantage plans.

<sup>5</sup> 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. 41036, 41037 (June 23, 2016).

<sup>6</sup> 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).

<sup>7</sup> 81 Fed. Reg. 41066 and 41098 (June 23, 2016). See also 42 CFR § 414.502 (defining “data collection period,” “data reporting period,” and “private payor”).

<sup>8</sup> *CMS Announces 60-Day Period of Enforcement Discretion for Reporting Applicable Information Under the Medicare Clinical Laboratory Fee Schedule*, available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf>.

<sup>9</sup> Both PAMA and the final rule implementing PAMA exempt certain labs from reporting their private payer data to CMS. Labs that do not receive the majority (i.e., more than 50 percent) of their Medicare revenue from the Clinical Laboratory Fee Schedule 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 Clinical Laboratory Fee Schedule 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 (June 23, 2016). See also 42 CFR § 414.502 (defining “applicable laboratory”).

<sup>10</sup> U.S. Department of Health and Human Services, *2016 CMS Statistics*, p. 25. Accessed at [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/2016\\_CMS\\_Stats.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/2016_CMS_Stats.pdf) on August 7, 2017. According to this source, total payments under the Medicare Part B benefit were projected to be \$294.4 billion for fiscal year 2016.

<sup>11</sup> 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).

<sup>12</sup> 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).

<sup>13</sup> Medicare paid an additional \$236 million in 2016 for specimen collection and validation.

<sup>14</sup> 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. 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**

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**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.

<sup>15</sup> U.S. Department of Health and Human Services, *2016 CMS Statistics*, p. 2. The projected enrollment in fee-for-service Medicare in 2016 was 56.6 million beneficiaries.

<sup>16</sup> In addition, 1 percent of tests were performed in other settings, such as skilled nursing facilities and dialysis facilities.

<sup>17</sup> Although the colorectal cancer screening test (procedure code G0464) was not on the 2014 Clinical Laboratory Fee Schedule, CMS recognized it as a covered service effective October 2014. CMS Transmittal 183, Change Request 9115. In 2014, CMS paid \$1.2 million for the test.

<sup>18</sup> The \$260 million in 2015 Medicare payments for molecular pathology tests reported in this report includes payments for codes that were uncategorized in 2015 but categorized as molecular pathology tests in 2016. Because of these additional codes, the \$259 million for molecular pathology tests reported in our 2015 report increased to a rounded total of \$260 million in this report.

<sup>19</sup> Department of Justice, “Millennium Health Agrees to Pay \$256 Million to Resolve Allegations of Unnecessary Drug and Genetic Testing and Illegal Remuneration to Physicians.” Accessed at <https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic> on August 28, 2017.

<sup>20</sup> 81 Fed. Reg. 41097 (June 23, 2016).

<sup>21</sup> Many of the lab tests performed in outpatient settings (such as hospitals, skilled nursing facilities, and dialysis facilities) are paid for under Medicare payment systems other than the Clinical Laboratory Fee Schedule. As we have noted, our analysis included only lab tests paid for under Medicare’s Clinical Laboratory Fee Schedule.