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Data Brief

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Despite Savings on Many Lab Tests in 2019, Total Medicare Spending Increased Slightly Because of Increased Utilization for Certain High-Priced Tests

Key Results

In the second year of the new payment system, reduced payment rates for many lab tests resulted in savings for the Medicare program. However, total Medicare spending increased slightly because of increased utilization and spending on certain high-priced tests, such as genetic tests.

What OIG Found

Medicare Part B spent $7.68 billion on lab tests in 2019, a $93 million increase from 2018. For the top 25 tests by Medicare spending, expenditures also increased slightly, to $4.64 billion, up from $4.57 billion in 2018. Analysis of these top 25 tests illustrates 2 trends that led to these spending outcomes.

First, for the group of 17 tests (among the top 25) that had payment rate reductions, overall Medicare spending decreased in 2019. Most of these tests had the maximum 10-percent payment rate reduction allowed by the Protecting Access to Medicare Act of 2014 (PAMA). Despite increased utilization for some of these tests, overall Medicare spending decreased by $175 million for the group compared to 2018, demonstrating that—as expected—the PAMA requirements achieved savings for the Medicare program.

Second, for the group of eight tests with payment rates that did not change, overall Medicare spending increased in 2019 because of increases in utilization for many of these tests. Payment rates for these tests did not change for one of two reasons: (1) tests with payment rates that had already reached the rate required by PAMA did not require further reductions in 2019, or (2) tests that were new to the Clinical Laboratory Fee Schedule (CLFS) as of 2018 were not affected by PAMA rate reductions.

Why OIG Did This Review

PAMA changed the way the Medicare program sets payment rates for lab tests by aligning Medicare payment rates with private payment rates. Prior to PAMA, the Office of Inspector General (OIG) found that Medicare was paying significantly more than other payers for many lab tests. The Centers for Medicare & Medicaid Services (CMS) calculated new rates that took effect in 2018. As part of PAMA, Congress also mandated that OIG publicly release an annual analysis of the top 25 tests based on Medicare spending and conduct analyses that OIG determines appropriate. This data brief provides an analysis of Medicare payments for lab tests in 2019, the second year of the new payment system.

How OIG Did This Review

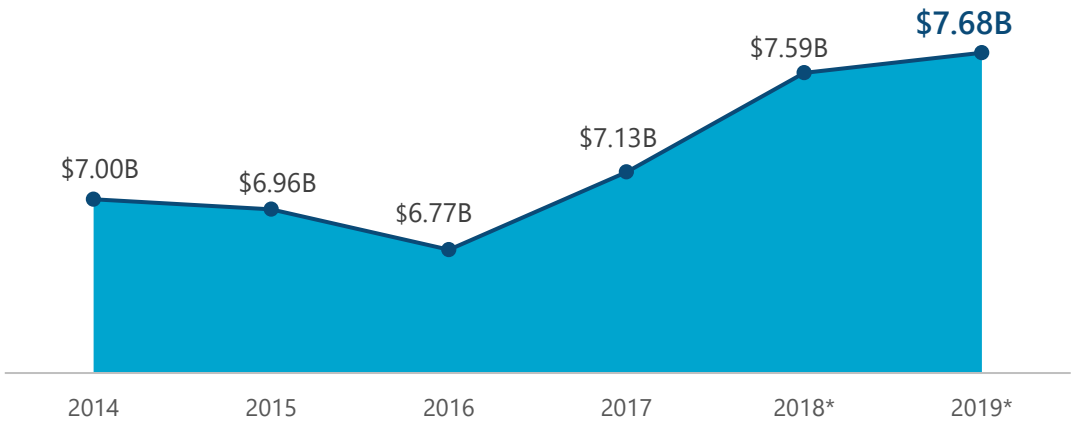
We analyzed claims data for lab tests performed in 2019 that CMS paid for under the CLFS. These tests are covered under Medicare Part B and do not include tests that Medicare paid for under other payment systems, such as the payment system for critical access hospitals or the Hospital Outpatient Prospective Payment System. We identified the top 25 lab tests based on Medicare spending for tests performed in 2019. We also identified key statistics and emerging trends, including Medicare spending by procedure code and test category.

RESULTS

Although payment rates were lower for most Medicare lab tests in 2019, total spending increased slightly because of increased spending on certain high-priced tests

Medicare spent a total of $7.68 billion on clinical laboratory (lab) tests in 2019, a $93 million increase from 2018. Based on rate adjustments required by the Protecting Access to Medicare Act of 2014 (PAMA), payment rates in 2019 were lower for 73 percent of lab tests than they were in 2018. However, the savings that resulted from these lower rates were overtaken by increased spending on genetic tests and other high-priced lab tests. See Exhibit 1 for annual Medicare spending on lab tests since 2014, when OIG began this series of reports.

Exhibit 1: Medicare spending for lab tests continued an upward trend in 2019.

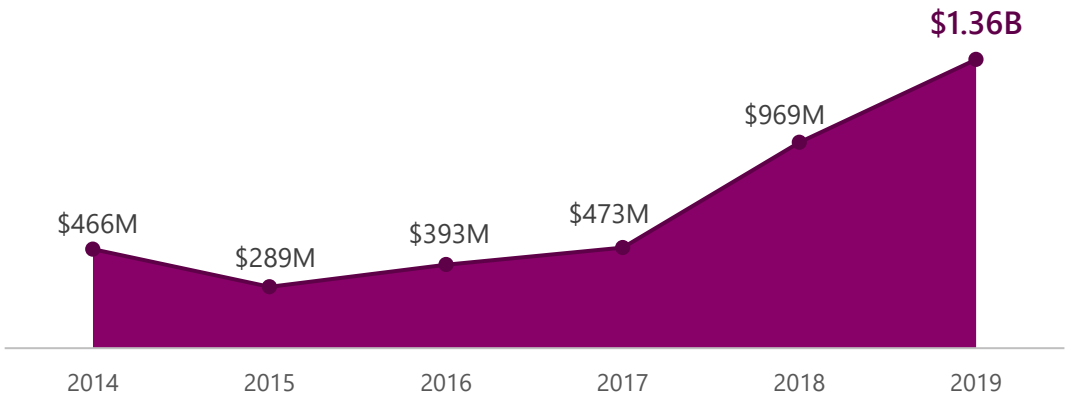


*In 2018 and 2019, lab payment rates were subject to the rate reductions required by PAMA.
Note: Medicare spending dollar values are rounded.
Source: OIG analysis of 2014–2019 spending on lab tests in Medicare Part B, in billions, 2020.

Medicare spending on genetic tests reached $1.36 billion in 2019

Medicare spending on genetic tests reached $1.36 billion in 2019, an increase of about $390 million from 2018, as shown in Exhibit 2 on the next page. The spending increase was largely driven by an increase in utilization of genetic tests. Medicare paid for about 2.22 million units of genetic tests in 2019, up from about 1.76 million units in 2018. See Appendix A for details about spending on three categories of genetic tests: molecular pathology, multianalyte algorithmic assays, and genomic sequencing procedures.

Exhibit 2: Medicare spending on genetic tests increased for the fourth year in a row and reached its highest point of $1.36 billion in 2019.



Source: OIG analysis of 2014–2019 spending on lab tests in Medicare Part B, 2020.

Total Medicare spending on the top 25 lab tests increased slightly in 2019

Similar to total Medicare Part B spending on lab tests, expenditures on the top 25 tests increased slightly in 2019. Medicare spent $4.64 billion on the top 25 tests in 2019, up from $4.57 billion in 2018. Payment rates were reduced for 17 of the top 25 tests, whereas the payment rates for the remaining 8 tests did not change in 2019. Exhibit 3 on the next page displays key statistics for the top 25 lab tests by Medicare spending.

For the group of 17 tests that had reduced payment rates, total spending decreased in 2019

Overall Medicare spending decreased for the group of 17 tests (among the top 25) that had reduced payment rates in 2019.[1] For all but one of these tests, the 2019 rates were reduced by 10 percent, the maximum rate reduction allowed by PAMA for tests in 2019 (see the "Rate Change from 2018" column in Exhibit 3).[2, 3] Because of these rate changes, total spending for the group of 17 tests decreased by $175 million in 2019, illustrating that—as expected—the lab payment rate changes required by PAMA achieved savings for some lab tests.

Notably, savings for some of these tests occurred despite increased utilization in 2019 compared to 2018. For example, Medicare spending for the comprehensive blood chemistry test (line 1 in Exhibit 3) decreased by about $45 million in 2019, despite an increase in utilization of about a half-million tests.

Exhibit 3: Medicare Part B spending on the top 25 lab tests in 2019

	Test Description (Procedure Code)	2019 Payment Rate	Rate Change From 2018	2019 Test Volume (Millions)	2019 Test Spending (Millions)	Spending Change From 2018 (Millions)
1	Blood test, comprehensive group of blood chemicals (80053)	$11.74	-10%	42.17	**$491.62**	↓ -$45.48
2	Blood test, lipids (cholesterol and triglycerides) (80061)	$14.88	-10%	28.69	**$418.83**	↓ -$44.75
3	Blood test, thyroid stimulating hormone (TSH) (84443)	$18.67	-10%	21.37	**$391.45**	↓ -$43.26
4	Complete blood cell count (red cells, white blood cell, platelets), automated test (85025)	$8.63	-10%	41.24	**$354.14**	↓ -$36.95
5	Drug test(s), definitive, 22 or more drug class(es), including metabolite(s) if performed (G0483)	$246.92	0%	1.28	**$307.06**	↓ -$6.38
6	Genetic Test: Molecular pathology procedure level 9 (81408)	$2,000.00	0%	0.15	**$290.42**	↑ $172.50
7	Vitamin D-3 level (82306)	$32.89	-10%	8.92	**$286.13**	↓ -$32.81
8	Genetic Test: Gene analysis (colorectal cancer) (81528)	$508.87	0%	0.48	**$239.40**	↑ $71.73
9	Testing for presence of drug (80307)	$64.65	-10%	3.43	**$216.51**	↓ -$19.56
10	Hemoglobin A1C level (83036)	$10.79	-10%	20.11	**$213.78**	↓ -$18.54
11	Drug test(s), definitive, per day; 15–21 drug class(es), including metabolite(s) if performed (G0482)	$198.74	0%	0.82	**$158.19**	↓ -$1.13
12	Genetic Test: Gene analysis (breast cancer 1 and 2) full sequence and duplication or deletion variants (81162)	$2,027.64	-10%	0.06	**$119.55**	↑ $70.02
13	Blood test, basic group of blood chemicals (80048)	$9.40	-10%	12.54	**$118.44**	↓ -$14.08
14	Drug test(s), definitive, per day; 1–7 drug class(es), including metabolite(s) if performed (G0480)	$114.43	0%	1.07	**$116.95**	↑ $3.00
15	Parathormone (parathyroid hormone) level (83970)	$45.86	-10%	2.47	**$110.42**	↓ -$5.48
16	Detection test for organism (87798)	$38.99	-10%	2.72	**$102.98**	↑ $50.89
17	Cyanocobalamin (vitamin B-12) level (82607)	$16.75	-10%	5.84	**$95.68**	↓ -$6.85
18	Drug test(s), definitive, per day; 8–14 drug class(es), including metabolite(s) if performed (G0481)	$156.59	0%	0.63	**$95.31**	↓ -$1.28
19	PSA (prostate specific antigen) measurement (84153)	$20.44	-10%	4.38	**$87.75**	↓ -$7.83
20	Genetic Test: Test for detecting genes associated with breast cancer (81519)	$3,873.00	0%	0.02	**$83.24**	↑ $6.62
21	ADLT: Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes (0037U)	$3,500.00	0%	0.02	**$78.18**	↑ $45.40
22	Thyroxine (thyroid chemical) measurement (84439)	$10.02	-10%	7.39	**$72.91**	↓ -$6.51
23	Bacterial colony count, urine (87086)	$8.97	-10%	7.34	**$65.72**	↓ -$7.59
24	Natriuretic peptide (heart and blood vessel protein) level (83880)	$39.26	-6%	1.58	**$61.91**	↓ -$2.88
25	Ferritin (blood protein) level (82728)	$15.15	-10%	4.14	**$61.65**	↓ -$3.47
					Total Medicare spending on the top 25 tests: $4.64 billion	

Note: Tests **81162** (line 12 in Exhibit 3) and **0037U** (line 21 in Exhibit 3) entered the top 25 lab tests in 2019. Test **0037U** is an Advanced Diagnostic Lab Test (ADLT).

Sources: OIG analysis of 2018–2019 spending on lab tests in Medicare Part B, 2020. Payment rates are from the 2019 Clinical Laboratory Fee Schedule (CLFS). See endnote 4 for the American Medical Association (AMA) copyright notice.

For the group of eight tests with payment rates that did not change, total spending increased in 2019

Overall Medicare spending increased for the group of 8 tests (among the top 25) with payment rates that did not change in 2019. The reason that payment rates for six tests in the group did not change is because they had already reached the rate required by PAMA—i.e., the volume-weighted median of lab-reported data.[5] The remaining two tests (lines 6 and 21 in Exhibit 3) entered the CLFS in 2018 (after Round 1 of the PAMA-required rate calculations), and their payment rates will not change until CMS establishes new rates based on more recent data from private payers.

Four of the eight tests (lines 6, 8, 14, and 20 in Exhibit 3) had higher Medicare spending as a result of an increase in utilization. Because each of these tests had relatively high payment rates, ranging from $114.43 to $3,783, even a small increase in utilization could result in a dramatic increase in spending. Three of the eight tests (lines 5, 11, and 18 in Exhibit 3) saw lower Medicare spending as a result of a decrease in the utilization.

The remaining test (line 21 in Exhibit 3) was not in the top 25 in 2018 and had total spending of over $78 million in 2019. The organ neoplasm DNA sequencing test is an ADLT that CMS recognized as a covered service effective May 18, 2018.[6, 7, 8, 9] The payment rate for this test is $3,500, and Medicare paid for 22,822 units of the test. See the box below for details on ADLTs.

Establishing Advanced Diagnostic Laboratory Tests

PAMA established a new class of tests: **Advanced Diagnostic Laboratory Tests (ADLTs).** ADLTs are subject to a distinct method of temporary pricing, and labs that perform these tests are required to submit data from private payers annually.

To be considered an ADLT, a test must be offered and furnished by a single lab and either:

- be cleared or approved by the Food and Drug Administration, or
- be a test that
  - is an analysis of multiple biomarkers of DNA, RNA, or proteins;
  - provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests;
  - when combined with an empirically derived algorithm, yields a result that predicts the probability a specific patient will develop a certain condition(s) or respond to a particular therapy(ies); and
  - may include other assays.

CONCLUSION

Our analysis of Medicare Part B spending on lab tests demonstrates that—as expected—the payment rate adjustments required by PAMA achieved savings for some lab tests that had payment rate reductions in 2019. Prior to PAMA, OIG reports and other research showed that Medicare was paying significantly more than private payers for many lab tests.[10] The new payment system implemented under PAMA more closely aligns Medicare payment rates with private payer rates. In the coming years, payment rate reductions for many lab tests that are on the CLFS are expected to result in further savings for the Medicare program.

However, not all tests on the CLFS had payment rate reductions in 2019. This occurred for one of two reasons: (1) tests with payment rates that had already reached the rate required by PAMA did not require further reductions, or (2) tests that were new to the CLFS as of 2018 were not affected by the 2019 rate reductions required by PAMA. Medicare spending increased for some of these tests that did not have payment rate reductions, including certain high-priced genetic tests, because of increased utilization of these tests. Further, because this group of tests had relatively high payment rates, the increased spending for this group overtook the savings achieved by the PAMA rate reductions in 2019.

Looking ahead, we anticipate that Medicare spending for lab tests in 2020 will be significantly affected by the COVID-19 pandemic, especially diagnostic testing for the novel coronavirus and other respiratory illnesses. OIG has a body of oversight activities underway regarding COVID-19-related lab testing. Additionally, OIG will continue to monitor the effect of the PAMA changes on Medicare spending.

METHODOLOGY

Data Analysis*:* We based this report on our analysis of Medicare claims data for lab tests performed in 2019 and reimbursed under the CLFS. Through our analysis, we identified key statistics and emerging trends for Medicare spending on lab tests. We analyzed Medicare spending and test volume by procedure code and category. Test volume is based on the number of units for which labs billed Medicare. We calculated total spending for 2019 and compared that to the results from 2014 to 2018.

- *Top 25 lab tests.* We identified the top 25 lab tests (based on total spending for each procedure code) in 2019 and calculated total spending for these tests. We calculated the differences in Medicare spending from 2018 to 2019 for tests within the top 25. We also examined spending patterns among two groups of tests: those that had PAMA-required reductions in payment rates and those that did not have payment rate reductions. For each group, we calculated overall Medicare spending in 2019.

- *Analysis by test category.* We used Current Procedural Terminology (CPT) categories for all tests on the CLFS. For Healthcare Common Procedure Coding System (HCPCS) Level II codes that are unique to the CLFS, we had CMS assign CPT categories to those codes. We used CPT category definitions to identify genetic tests, which includes molecular pathology, multianalyte algorithmic assays (MAAAs), and genomic sequencing procedures (GSPs).

Data Source: The claims data were from the National Claims History Physician/Supplier Part B claim files and National Claims History Outpatient files. The Physician/Supplier Part B files primarily include claims from independent labs and physician office labs. The Outpatient files primarily include claims from hospital labs. We did not include tests paid for under other payment systems, such as the payment system for critical access hospitals or the Hospital Outpatient Prospective Payment System.[11] We did not include claims for physician interpretation of tests.

Limitations: In 2014, 2015, 2018, and 2019, we analyzed the 16-month file, and in 2016 and 2017, we analyzed the 17-month file. As a result, analysis for 2016 and 2017 used a set of claims that was marginally more complete than sets used for other reports and thus the totals for 2016 and 2017 are marginally higher than those reported for other years.

Standards

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

APPENDIX A

Medicare lab spending on genetic tests in 2019, by category

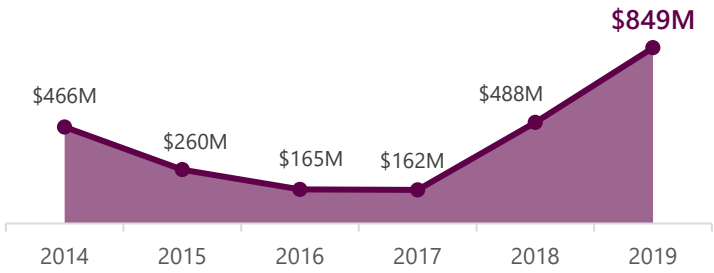
Molecular Pathology

Molecular pathology tests detect variants in genetic material and help doctors determine how patients will respond to certain treatments. This category entered the CLFS in 2014 and has the greatest number of tests compared to other categories of genetic tests.

Molecular pathology tests accounted for 62 percent of total Medicare spending on genetic tests in 2019.

- Spending **increased by 74 percent** in 2019, a **$360 million increase** from 2018.
- Volume **increased by 345,000 units,** from 1.2 million in 2018 to about 1.6 million in 2019.
- The number of test codes that Medicare paid for **increased from 149 in 2018 to 174 in 2019.**
- **Two tests** (lines 6 and 12 in Exhibit 3) were among the top 25 lab tests in 2019.

Spending on molecular pathology tests reached its highest point in 2019.



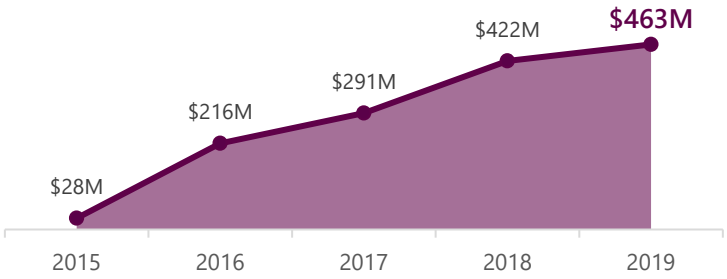
Multianalyte Algorithmic Assays

Multianalyte algorithmic assays (MAAAs) combine multiple test results with patient information to yield a predictive score, such as recurrence of a cancer or a treatment response. MAAAs entered the CLFS in 2015.

Medicare saw a slight increase in spending on MAAAs in 2019.

- Spending **increased by 10 percent** in 2019, a **$41 million increase** from 2018.
- Volume **increased by 108,000 units**, from 484,000 units in 2018 to 592,000 units in 2019.
- The number of test codes that Medicare paid for **increased from 24 in 2018 to 30 in 2019.**
- **Two tests** (lines 8 and 20 in Exhibit 2) were among the top 25 lab tests in 2019.

Total spending on MAAAs continued to increase in 2019.



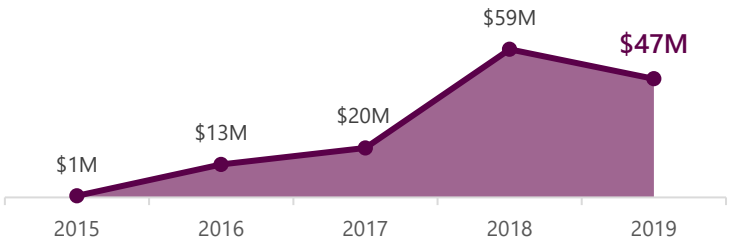
Genomic Sequencing Procedures

Genomic sequencing procedures (GSPs) identify structural changes in genetic material and are often used to diagnose or manage inherited diseases. GSPs entered the CLFS in 2015.

Medicare spending on GSPs decreased in 2019.

- Spending **decreased by 20 percent** in 2019, a **$12 million decrease** from 2018.
- Volume **increased by about 8,800 units**, from 61,000 units in 2018 to 70,000 units in 2019.
- Medicare paid for **26 test codes in 2019, as it did in 2018.**
- GSPs **did not** appear in the top 25 lab tests in 2019.

Total spending on GSPs decreased for the first time in 2019.



Source: OIG analysis of 2014–2019 spending on lab tests in Medicare Part B, 2020.

APPENDIX B

Prior Office of Inspector General Reports on Medicare Spending and Payment Rates for Lab Tests

Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions	OEI-09-19-00100	August 2020
Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017: Year 4 of Baseline Data	OEI-09-18-00410	September 2018
Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies To Ensure Data Quality	OEI-09-17-00050	July 2018
Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data	OEI-09-17-00140	September 2017
Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress	OEI-09-16-00100	September 2016
Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data	OEI-09-16-00040	September 2016
Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data	OEI-09-15-00210	September 2015
Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings	OEI-07-11-00010	June 2013
Variation in the Clinical Laboratory Fee Schedule	OEI-05-08-00400	July 2009

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

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ENDNOTES

[1] Of the 17 tests with payment rate reductions, 16 tests were among the top 25 lab tests in 2018. The remaining test is a high-priced genetic test (line 12 in Exhibit 3) that entered the top 25 lab tests in 2019.

[2] Originally, SSA § 1834A(b)(3)(A) and (B), 42 U.S.C. 1395m-1(b)(3)(A) and (B), as set forth in PAMA, P.L. No. 113-93, § 216(a)), provided that clinical diagnostic laboratory test payment shall not result in payment reduction greater than the applicable percent within the first 6 years. See also 81 Fed. Reg. 41036, 41079–80, and 41100 (June 23, 2016) (changing the phasing in of the payment reductions timetable to reflect the revised January 1, 2018, implementation date and memorializing the change at 42 CFR 414.507(d)).

[3] Since 2018, Congress amended SSA §1834A(b)(3), 42 U.S.C. 1395m-1(b)(3), twice to delay the limits to payment rate reductions—most recently by Coronavirus Aid, Relief, and Economic Security Act, P.L. No. 116-136, § 3718(b), and earlier by Further Consolidated Appropriations Act, 2020, P.L. No. 116-94, Division N, § 105(a)(2).

[4] Labs bill for each test on the CLFS using an 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 CPT codes. **The five character codes and descriptions included in this study are obtained from Current Procedural Terminology (CPT®), copyright 2018 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.

[5] Payment rates for these tests did not change in 2019 because the rates were equal to the volume-weighted median. The volume-weighed median is calculated by taking the median value of all private payer rates, weighted by test volume. See 81 Fed. Reg. 41076–77.

[6] This ADLT is a genomic sequencing analysis test that performs a comprehensive gene analysis on solid tumors and provides clinically actionable information for medical providers and beneficiaries. Foundation Medicine, *FoundationOne CDX*, https://www.foundationmedicine.com/test/foundationone-cdx. Accessed on September 7, 2020.

[7] Foundation Medicine's test (0037U) was approved under Criterion B, FDA cleared and approved, as stated in Section 1834A(d)(5)(B). Additionally, this test is covered under the National Coverage Determination (NCD) for Next Generation Sequencing (NGS). CMS Manual System, *Pub 100-3 Medicare National Coverage Determinations*, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R215NCD.pdf. Accessed on December 2, 2020.

[8] This test is part of a new category of tests known as the proprietary lab analyses (PLAs) tests, which includes a range of lab tests, including but not limited to genetic tests and some ADLTs. This category of test codes was established by the American Medical Association (AMA) in response to PAMA.

[9] CMS, *Advanced Diagnostic Laboratory Tests Under the Medicare CLFS*. Accessed at https://www.cms.gov/files/document/advanced-diagnostic-laboratory-tests-under-medicare-clfs.pdf on October 6, 2020.

[10] OIG, *Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial* Savings (OEI-07-11-00010), June 2013. See also OIG, *Variation in The Clinical Laboratory Fee Schedule* (OEI-05-08-00400), July 2009.

[11] 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 CLFS. As we have noted, our analysis included only lab tests paid for under Medicare's CLFS.