



November 2018

MEDICARE LABORATORY TESTS

Implementation of New Rates May Lead to Billions in Excess Payments

Accessible Version

GAO Highlights

Highlights of [GAO-19-67](#), a report to congressional committees

Why GAO Did This Study

Medicare paid \$7.1 billion for 433 million laboratory tests in 2017. These tests help health care providers prevent, diagnose, and treat diseases.

PAMA included a provision for GAO to review CMS's implementation of new payment rates for these tests. This report addresses, among other objectives, (1) how CMS developed the new payment rates; (2) challenges CMS faced in setting accurate payment rates and what factors may have mitigated these challenges; and (3) the potential effect of the new payment rates on Medicare expenditures. GAO analyzed 2016 Medicare claims data (the most recent data available when GAO started its work and the year on which new payment rates were based) and private-payer data CMS collected. GAO also interviewed CMS and industry officials.

What GAO Recommends

GAO recommends that the Administrator of CMS (1) collect complete private-payer data from all laboratories required to report or address the estimated effects of incomplete data, (2) phase in payment-rate reductions that start from the actual payment rates rather than the maximum payment rates Medicare paid prior to 2018, and (3) use bundled rates for panel tests. HHS concurred with GAO's first recommendation, neither agreed nor disagreed with the other two, and has since issued guidance to help address the third. GAO believes CMS should fully address these recommendations to prevent Medicare from paying more than is necessary.

View [GAO-19-67](#). For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

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What GAO Found

The Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS) revised the Clinical Laboratory Fee Schedule (CLFS) for 2018, establishing new Medicare payment rates for laboratory services. Prior to 2018, these rates were based on historical laboratory fees and were typically higher than the rates paid by private payers. The Protecting Access to Medicare Act of 2014 (PAMA) required CMS to develop a national fee schedule for laboratory tests based on private-payer data. To revise the rates, CMS collected data on private-payer rates from approximately 2,000 laboratories and calculated median payment rates, weighted by volume. GAO found that the median private-payer rates were lower than Medicare's maximum payment rates in 2017 for 88 percent of tests. CMS is gradually phasing in reductions to Medicare payment rates, limited annually at 10 percent over a 3-year period (2018 through 2020), as outlined in PAMA.

CMS relied on laboratories to determine whether they met data reporting requirements, but agency officials told GAO that CMS did not receive data from all laboratories required to report. CMS did not estimate the amount of data it should have received from laboratories that were required to report but did not. CMS took steps to exclude inaccurate private-payer data and estimated how collecting certain types and amounts of additional private-payer data could affect Medicare expenditures. However, it is not known whether CMS's estimates reflect the actual risk of incomplete data resulting in inaccurate Medicare payment rates. GAO found that PAMA's phased in reductions to new Medicare payment rates likely mitigated this risk of inaccurate Medicare payment rates from 2018 through 2020. However, GAO found that collecting incomplete data could have a larger effect on the accuracy of Medicare payment rates in future years when PAMA allows for greater payment-rate reductions.

CMS's implementation of the new payment rates could lead Medicare to pay billions of dollars more than is necessary and result in CLFS expenditures increasing from what Medicare paid prior to 2018 for two reasons. First, CMS used the maximum Medicare payment rates in 2017 as a baseline to start the phase in of payment-rate reductions instead of using actual Medicare payment rates. This resulted in excess payments for some laboratory tests and, in some cases, higher payment rates than those Medicare previously paid, on average. GAO estimated that Medicare expenditures from 2018 through 2020 may be \$733 million more than if CMS had phased in payment-rate reductions based on the average payment rates in 2016. Second, CMS stopped paying a bundled payment rate for certain panel tests (groups of laboratory tests generally performed together), as was its practice prior to 2018, because CMS had not yet clarified its authority to do so under PAMA, according to officials. CMS is currently reviewing whether it has the authority to bundle payment rates for panel tests to reflect the efficiency of conducting a group of tests. GAO estimated that if the payment rate for each panel test were unbundled, Medicare expenditures could increase by as much as \$10.3 billion from 2018 through 2020 compared to estimated Medicare expenditures using lower bundled payment rates for panel tests.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
CLFS	Clinical Laboratory Fee Schedule
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
NPI	national provider identifier
PAMA	Protecting Access to Medicare Act of 2014

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November 30, 2018

Congressional Committees

Medicare is the single largest purchaser of laboratory tests in the United States.¹ In 2017, Medicare paid \$7.1 billion for 433 million laboratory tests that gave health care providers information they used in preventing, diagnosing, and treating disease.² Medicare—a federal health insurance program administered by the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS)—pays for laboratory tests under Medicare Part B using payment rates established under the Clinical Laboratory Fee Schedule (CLFS).³

On January 1, 2018, Medicare began paying for laboratory tests using rates established with a new payment rate-setting methodology (the 2018 CLFS), as required by the Protecting Access to Medicare Act of 2014 (PAMA).⁴ The 2018 CLFS reflects the first major change in payment methodology for laboratory tests in three decades. Prior to 2018, the CLFS was based on historical laboratory charges from the mid-1980s,

¹For this report, laboratory tests refer to clinical diagnostic laboratory tests or services.

²HHS, Office of Inspector General, *Data Brief Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017: Year 4 of Baseline Data*, OEI-09-18-00410 (Washington, D.C.: September 2018).

³Medicare Part B covers medically reasonable and necessary outpatient laboratory tests ordered by a qualified practitioner and provided in a laboratory that is certified by CMS. Medicare does not generally cover routine screening tests unless required by law. Laboratory tests performed as part of the services provided in the hospital outpatient setting are instead paid for under the Physician Fee Schedule.

⁴PAMA called for the implementation of new payment rates in January 2017. However, CMS delayed implementation of the new rates by one year. CMS made this decision in response to industry comments on the agency's proposed implementation schedule.

adjusted annually for inflation and other factors, and had remained relatively unchanged.⁵

PAMA directed CMS to develop new rates for the CLFS based on rates paid by certain private payers, creating a single, national fee schedule for laboratory tests.⁶ PAMA also called for a phase-in of the new payment rates by limiting any reductions to 10 percent per year for each of the first 3 years of implementation. PAMA continues phasing in the reductions in the second 3-year cycle after implementation, limiting any reductions to 15 percent per year. In 2015, CMS estimated that the changes in payment rates resulting from PAMA would reduce Medicare expenditures by \$360 million in the first year.⁷

PAMA included a provision for GAO to review CMS's implementation of the new payment rates for laboratory services in the revised CLFS. This report examines:

1. what is known about the payment rates laboratories receive from private payers;
2. how CMS developed the 2018 CLFS payment rates;
3. the challenges CMS faced in setting accurate Medicare payment rates based on complete and accurate private-payer data, and what factors may have mitigated these challenges; and
4. the potential effect of CMS's implementation of new payment rates on Medicare expenditures.

To describe what is known about the payment rates laboratories received from private payers, we reviewed market reports from industry analysts

⁵For laboratory tests dated on or after April 1, 2013, Medicare paid 2 percent less than the payment rate in accordance with the Balanced Budget and Emergency Deficit Control Act of 1985, as amended (codified as amended at 2 U.S.C. § 901a(6)) (i.e., sequestration). Congress mandated a 1.75 percent reduction in Medicare payments for laboratory tests under the CLFS in 2011-2015. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3401(l). 124 Stat. 119, 487 (2010) (codified at 42 U.S.C. § 1395l(h)(2)(A)(iv)).

⁶PAMA defines private payers as health insurance issuers and group health plans, Medicare Advantage Plans under Part C, or Medicaid managed care organizations. For this report, the term "private-payer rates" refers to rates paid by private payers as defined by PAMA.

⁷80 Fed. Reg. 59,386, 59,416 (Oct. 1, 2015).

and laboratory representatives that analyzed private-payer rates for laboratory tests. We identified these market reports by searching a database of industry analyses from 2014 through 2018.⁸ We also identified reports cited by laboratory industry representatives and reviewed information submitted to CMS by industry stakeholders during rate-setting processes.⁹ We did not independently verify the data in these reports. We also interviewed officials from three organizations representing the laboratory industry and laboratory companies that we identified. We selected these organizations because they represented a large and diverse group of laboratories and different perspectives in their support for the new payment rates initially proposed by CMS.¹⁰ We relied on market reports and interviews with industry officials because we were unable to identify a reliable and comprehensive source on private-payer rates for laboratory tests.

To describe how CMS developed the 2018 CLFS payment rates, we reviewed documents from CMS, such as guidance to industry and Medicare contractors, and the agency's proposed and final rulemaking that describes the process CMS established to collect data on private-payer rates that laboratories received.¹¹ We also reviewed documentation CMS published about its preliminary and final calculations of the 2018 CLFS.¹² In addition, we compared the median private-payer rates (weighted by volume) that CMS calculated to Medicare's 2017 national limitation amounts for laboratory tests (the maximum that CMS would pay

⁸This database was the Thomson's Embargoed Research Reports, which includes analyses of companies, industries, products, and markets.

⁹CMS released new, proposed rates in September 2017 and solicited industry comments before releasing the final rates in November 2017. For more information on key dates related to CMS's development of new payment rates, see appendix I.

¹⁰We also interviewed two additional industry organizations that requested meetings with us to discuss our work.

¹¹Although PAMA required CMS to complete additional tasks, such as establish an advisory panel and create a new payment system for a new category of tests called advanced diagnostic laboratory tests, this report focuses on CMS's efforts to develop the 2018 CLFS. As of August 2018, only one laboratory test met the criteria to be considered an advanced diagnostic laboratory test.

¹²CMS, *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System* (Baltimore, Md.: Sept. 22, 2017) and CMS, *Information Regarding the Final CY 2018 Private Payor Rate-Based Clinical Laboratory Fee Schedule (CLFS) Payment Rates* (Baltimore, Md.: Nov. 17, 2017).

for a laboratory test).¹³ We used this comparison to determine the percentage difference between the median payment rates and the 2017 national limitation amounts. We also interviewed CMS officials and representatives from the laboratory industry and laboratory companies.

To determine the challenges CMS faced in setting accurate Medicare rates based on complete private-payer data, and what factors may have mitigated these challenges, we conducted two types of analyses. First, we determined the share of Medicare payments in 2016 that reporting laboratories received to compare against the share that CMS estimated laboratories meeting reporting requirements would receive. We identified laboratories reporting data to CMS using the national provider identifier (NPI) they reported. We used the Medicare claims data to determine these laboratories' share of Medicare payments in 2016.¹⁴ We assessed the reliability of the claims data by testing for missing data and obvious outliers. On this basis, we determined that these data were sufficiently reliable for the purposes of our report.

For our second analysis related to collecting complete data, we estimated the potential effects that collecting data from additional laboratories could have had on Medicare payment rates and expenditures from 2018 through 2020.¹⁵ For this analysis we used the private-payer data that CMS collected to estimate what Medicare expenditures could be if CMS had received additional data. Specifically, we used the private-payer data CMS collected to identify median private-payer rates and payment rates at other percentiles. We then estimated the amounts of additional private-

¹³These median private-payer rates do not consider the 10-percent maximum reduction when phasing in the changes to Medicare rates. The national limitation amount was established in the Consolidated Omnibus Budget Reconciliation Act of 1985 and was initially set at 115 percent of the median rate across the different fee schedules. See Pub. L. No. 99-272, § 9303(b), 100 Stat. 82, 189 (1986) (codified as amended at 42 U.S.C. § 1395l(h)(4)(B)). Over time, the national limitation amount has been incrementally lowered. For laboratory tests performed after December 31, 1997, the national limitation amount was set at 74 percent of the median rate for each laboratory test across the 57 fee schedules. For new laboratory tests performed on or after January 1, 2001, and for which no limitation amount was previously established, the national limitation amount was set at 100 percent of the median rate across these 57 fee schedules.

¹⁴The latest year with complete data available on Medicare utilization and expenditures when GAO conducted this study was 2016.

¹⁵For this analysis, we assumed that Medicare would pay for the same number of each laboratory test as it did in 2016, similar to assumptions CMS made for comparable estimates.

payer data as well as the payment rates in these additional data that would be needed to shift median private-payer rates to these other percentiles. To estimate the amount that additional data could shift median private-payer rates, we assumed that all of the payment rates in additional data could shift these medians in the same direction, either up or down. For example, we estimated that collecting 20 percent more data with payment rates above the 60th percentile of payment rates in the data already collected could shift median rates to the 60th percentile, approximately. Conversely, we estimated that collecting 20 percent more data with payment rates below the 40th percentile of payment rates in the data already collected could shift median rates to the 40th percentile, approximately. We then estimated Medicare payment rates and expenditures using payment rates at these percentiles as median private-payer rates. See appendix II for our calculations at the different percentiles.

To determine the challenges CMS faced in setting accurate Medicare rates based on accurate private-payer data, we analyzed the effects on Medicare expenditures of including and excluding data that CMS identified as potentially inaccurate in calculating the payment rates, assuming that the same number of laboratory tests performed in 2016 was also performed in each year from 2018 through 2020. We also interviewed CMS officials about how they addressed the effect of inaccurate private-payer data on Medicare payment rates and their estimates of the potential effect of inaccurate data on Medicare expenditures, as well as the effect of incomplete private-payer data. We compared CMS's activities to relevant federal standards for internal control related to identifying, analyzing, and responding to risk.¹⁶

To examine the potential effect of CMS's implementation of new payment rates on Medicare expenditures, we estimated Medicare expenditures from 2018 through 2020, using CLFS rates CMS published and conducted two analyses related to panel tests, which are groups of tests performed together.¹⁷ The first analysis examined the effect of using 2017

¹⁶GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

¹⁷For each analysis, we assumed that Medicare would pay for the same number of each laboratory test as it did in 2016, similar to assumptions CMS made for comparable estimates.

national limitation amounts to phase in reductions to payment rates for panel tests, which Medicare commonly paid at lower rates. We estimated changes in Medicare expenditures if CMS had limited annual reductions to payment rates for panel tests based on the average amounts Medicare had allowed for payment in 2016 instead of on the national limitation amounts from 2017.¹⁸

For our second analysis of the potential effect of CMS's implementation of new payment rates on Medicare expenditures, we examined the effect of paying for panel tests as a group using bundled payments or separately as individual component tests using multiple, unbundled payments. We estimated potential changes in Medicare expenditures due to paying separately for each component test that makes up a panel test, in comparison with paying a bundled rate. For panel tests without billing codes, we used Medicare bundled payment rates from 2016 to compare with CMS's calculated payment rates for component tests from 2018 through 2020 because bundled payment rates are not available for these years.

We took additional steps to support or extend our analyses. We reviewed analyses conducted by CMS and reviewed information from a subcommittee to the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests regarding payment for panel tests. We interviewed CMS about its legal authority to use bundled payment rates and its actions to avoid paying more than necessary for laboratory tests. We compared CMS's actions to the relevant standards for internal control in the federal government related to using quality information and to designing and implementing control activities to respond to risks.¹⁹

We conducted this performance audit from July 2017 to November 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

¹⁸Before 2018, there were 57 jurisdictions that had their own fee schedules for laboratory services. The national limitation amount was set at 74 percent of the median rate for each laboratory test across the 57 fee schedules. Because so many of the payment rates were constrained by the national limitation amount, most laboratory tests were paid the same national rate. PAMA replaced the 57 fee schedules with a single national payment rate.

¹⁹[GAO-14-704G](#).

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Medicare Payment for Individual and Panel Tests before PAMA's Implementation in 2018

Medicare pays for laboratory tests that are performed individually or in a group. For individual tests, laboratories submit claims to Medicare for each test they perform that is on the CLFS; tests are identified using a billing code.²⁰ Prior to the implementation of PAMA in 2018, the payment rates on the CLFS were based on rates charged for laboratory tests in 1984 through 1985 adjusted for inflation. Additionally, 57 geographic jurisdictions had their own fee schedules for laboratory tests.²¹ CMS used the 57 separate fee schedules to calculate a national limitation amount, which served as the maximum payment for individual laboratory tests. Thus, the payment rate for an individual test was the lesser of the amount claimed by the laboratory, the local fee for a geographic area, or the national limitation amount for a particular test.

Medicare pays bundled payment rates for certain laboratory tests that are performed as a group, called panel tests.²² Panel tests can be divided into two categories—those without billing codes and those with billing codes. Panel tests without billing codes are composed of at least 2 of 23 distinct component tests. Additionally, there are 7 specific combinations of these 23 component tests that are commonly used and have their own billing

²⁰These billing codes are called Healthcare Common Procedure Coding System (HCPCS) codes and describe the laboratory test or testing method. A single code may refer to more than one testing method for a particular substance or more than one substance analyzed by a single testing method.

²¹For laboratory tests performed by a physician or laboratory, other than a qualified hospital laboratory, CMS was required to establish fee schedules on a regional, statewide, or carrier service area basis for tests furnished on or after July 1, 1984. See 42 U.S.C. § 1395l(h)(1)(B). The 57 jurisdictions included the 50 states, the District of Columbia, and Puerto Rico. California, Kansas, and Missouri were each divided into 2 jurisdictions; New York was divided into 3 jurisdictions.

²²These groups of tests are typically performed together because they are all related to the analysis of a specific organ's function, are standard for the diagnosis of particular diseases, or are commonly ordered together for multiple diagnostic purposes.

code. Prior to 2018, Medicare paid for both types of panel tests (those without or with a billing code) using a bundled rate based on the number of tests performed, with modest payment increases for each additional test conducted.²³ For example, in 2017, Medicare paid \$7.15 for panel tests with two component tests and \$9.12 for panel tests with 3 component tests, with a maximum bundled payment rate of \$16.64 for all 23 component tests. Prior to 2018, the Medicare Administrative Contractors would count the number of tests performed before determining the appropriate bundled payment rate.²⁴ For those panel tests with a billing code, the payment rate was the same if laboratories used the associated billing code for the panel test or listed each of the component tests separately.

Medicare Payment for Individual and Panel Tests after PAMA's Implementation in 2018

After PAMA's implementation in 2018, the 57 separate fee schedules for individual laboratory tests were replaced with a single national fee schedule. The payment rates for this single national fee schedule were based on private-payer rates for laboratory tests paid from January 1, 2016 through June 30, 2016. Specifically, the payment rate for an individual test was generally based on the median private-payer rates for a given test, weighted by test volume.

Payment for panel tests also changed in 2018. For panel tests without billing codes, Medicare Administrative Contractors no longer counted the number of component tests performed to determine the bundled payment rate; instead, Medicare paid the separate rate for each component test in the panel. For panel tests with a billing code, the payment rate depended on how the laboratory submitted the claim. If a laboratory used the billing code associated with the panel test, Medicare paid the bundled payment rate for that billing code. If a laboratory submitted a claim for the panel

²³Panel tests are performed using automated laboratory equipment that can perform multiple tests using a single specimen; thus, the cost of performing multiple tests is not significantly higher than the cost of performing a single test. National Academy of Sciences, *Medicare Laboratory Payment Policy: Now and in the Future* (Washington, D.C.: 2000).

²⁴CMS administers the Medicare program through contracts with private entities, such as Medicare Administrative Contractors. These contractors help CMS with the day-to-day operations of the Medicare program, in part, by processing and paying claims submitted by laboratories.

test, but listed each of the component tests separately instead of using the panel test’s billing code, Medicare paid the individual payment rate for each component test. Table 1 below summarizes the changes to payment rates before and after 2018.

Table 1: Key Changes to Medicare Payment Rates for Laboratory Tests before and after the 2018 Implementation of the Protecting Access to Medicare Act of 2014 (PAMA)

Before 2018	Beginning in 2018
Payment rates based on laboratory charges from the mid-1980s, adjusted annually for inflation.	Payment rates based on private-payer rates for laboratory tests paid from January 1, 2016 through June 30, 2016 and set as the median of private-payer rates, weighted by volume.
57 local fee schedules for laboratory tests.	Single national fee schedule for laboratory tests.
Panel tests both without and with billing codes: Medicare Administrative Contractors counted the number of component tests performed to determine the appropriate bundled payment rate for the panel ^a	Panel tests without billing codes: Medicare pays for each component test.
For panel tests only with a billing code: The payment rate was the same if laboratories used the associated billing code for the panel test or listed each of the component tests separately.	Panel tests with billing codes: If laboratories submit a claim using the billing code, Medicare pays the bundled rate associated with that code. If laboratories submit a claim listing each component test, Medicare pays for each component test.

Source: GAO analysis of information from the Centers for Medicare & Medicaid Services (CMS) and Department of Health and Human Services Office of Inspector General. | GAO-19-67

^aMedicare Administrative Contractors are private entities that assist CMS with the day-to-day operations of the Medicare program, such as processing and paying claims submitted by laboratories.

Types of Clinical Laboratories

Multiple types of laboratories receive payment under Medicare. The three laboratory types that received the most revenue from the CLFS in 2016 were independent laboratories, hospital-outreach laboratories, and physician-office laboratories.²⁵ (See table 2.)

²⁵Other types of laboratories that perform tests that are paid for by the CLFS include those in skilled nursing facilities and dialysis facilities.

Table 2: Medicare Laboratory Test Payments by Laboratory Type, 2016

Type of laboratory	Medicare payment (in millions)	Percentage of total Medicare laboratory test payments
Independent laboratory Laboratories that perform tests independent of an institution or a physician's office.	3,740	55
Hospital-outreach laboratory Laboratories that perform tests for individuals not receiving hospital inpatient or outpatient care. ^a	1,768 ^b	26 ^b
Physician-office laboratory Laboratories that are maintained by a physician or group of physicians performing diagnostic tests in connection with the physician practice.	1,224	18
Other Other laboratories that perform tests paid for by the CLFS, such as those in skilled nursing facilities and dialysis facilities.	68	1
Total	6,800	100

Source: GAO review of information from the Centers for Medicare & Medicaid Services and analysis of data from the Department of Health and Human Services (HHS) Office of Inspector General | GAO-19-67

^aLaboratory tests performed as part of the services provided in the hospital inpatient or outpatient setting are not paid based on Medicare's Clinical Laboratory Fee Schedule (CLFS). They are paid based on the inpatient prospective payment system, under Medicare Part A, and the outpatient prospective payment system, under Medicare Part B, respectively.

^bAccording to the HHS Office of Inspector General, these data may also include payments that were made to independent laboratories or laboratories that mostly submit claims under Medicare's inpatient prospective payment system or the outpatient prospective payment system in addition to the CLFS.

Estimates of the size of the total U.S. laboratory market vary. For example, the Healthcare Fraud Prevention Partnership estimated that the laboratory industry received \$87 billion in revenue in 2017, while another market report estimated the laboratory industry received \$75 billion in revenue in 2016.²⁶ Similar to Medicare, the three laboratory types that generally receive the most revenue overall are independent laboratories, hospital-outreach laboratories, and physician-office laboratories, when

²⁶Healthcare Fraud Prevention Partnership, *Examining Clinical Laboratory Services* (Baltimore, Md.: May 2018) and Kaufman, Hall & Associates, LLC, *Industry Flash Report—Laboratory Services* (Skokie, Ill.: November 2016).

laboratory tests performed in hospital inpatient and outpatient settings were excluded.²⁷

Estimates of revenue received by these laboratories also vary. For example, in recent years, estimates of the share of laboratory industry revenue generated by independent laboratories ranged from 37 percent to 54 percent.²⁸ Additionally, estimates of revenue generated by hospital-outreach laboratories recently ranged from 21 to 35 percent, and physician-office laboratories ranged from 4 to 11 percent of total laboratory industry revenue.²⁹

Private-Payer Rates for Laboratory Tests Generally Vary by Laboratory Type and Other Characteristics

Private-payer rates for laboratory tests conducted by the three largest laboratory types generally vary by type and other characteristics, according to market reports and the laboratory industry officials we interviewed.

- **Independent laboratories.** These laboratories generally receive lower private-payer rates than other types of laboratories, according to industry officials we interviewed. Market reports we reviewed noted that about half of the independent laboratory market is dominated by two national laboratories and that these national laboratories provide more competitive pricing by performing a large volume of tests at one time.³⁰ Medicare

²⁷Credit Suisse, *Clinical Laboratory Update: 1Q Preview: Lab Traffic Tracker Update* (London, England: Apr. 13, 2018) and Kaufman, Hall & Associates, LLC, *Industry Flash Report*, 2.

²⁸Credit Suisse, *Clinical Laboratory Update*, 14 and Kaufman, Hall & Associates, LLC, *Industry Flash Report*, 2.

²⁹Credit Suisse, *Clinical Laboratory Update*, 14 and Kaufman, Hall & Associates, LLC, *Industry Flash Report*, 2. The estimates for physician-office laboratories include other types of laboratories, such those in skilled nursing facilities.

³⁰Credit Suisse, *Clinical Laboratory Update*, 14 and G2 Intelligence, *U.S. Clinical Laboratory and Pathology Testing 2013–2015: Market Analysis, Trends, and Forecasts* (New London, Conn.: 2015). These national laboratories are Laboratory Corporation of America (LabCorp) and Quest Diagnostics.

accounted for a smaller proportion of the revenue earned by these two national laboratories (12 percent), compared to other laboratories, according to another market report we reviewed.³¹ In contrast, a different market report noted that smaller, independent laboratories tend to earn more of their revenue from Medicare (34 percent).³²

- **Hospital-outreach laboratories.** These hospital-affiliated laboratories typically receive relatively higher private-payer rates, according to industry officials we interviewed. Although hospital-outreach laboratories perform tests similar to other laboratories, they can obtain above-average payment rates by leveraging the market power of their affiliated hospital when negotiating rates with private payers, according to industry officials and market reports.³³ Hospital-outreach laboratories generally receive about 25 to 30 percent of their revenue from the Medicare CLFS.³⁴
- **Physician-office laboratories.** Physician-office laboratories typically receive higher private-payer rates than independent laboratories, according to a recent analysis by a laboratory industry association.³⁵ This industry association also noted that the cost structure to operate in a setting such as a physician-office laboratory is different than in large independent laboratories, as the physician-office laboratory is unable to conduct a large number of tests at one time. Officials from another industry association we interviewed said that payment rates for these laboratories are generally dependent on the size of the physician

³¹“Hospital Labs at Greater Risk for PAMA CLFS Cuts,” *Laboratory Economics*, vol.12, no.3 (March 2017).

³²George Washington University School of Public Health and Health Services, Department of Health Policy, *Results from the National Survey of Independent and Community Clinical Laboratories* (Washington, D.C.: Nov. 14, 2012).

³³“The Outlook for Hospital Lab Outreach Testing,” *Laboratory Economics*, vol. 12, no.10 (October 2017) and Chi Solutions, Inc., *White Paper: The Top Five Outreach Industry Trends* (San Diego, Calif.: 2009).

³⁴“The Outlook for Hospital Lab Outreach Testing,” *Laboratory Economics*, 7. Laboratory tests performed as part of the services provided in the hospital inpatient or outpatient setting are not paid based on the Medicare CLFS. They are paid based on the inpatient prospective payment system, under Medicare Part A, and the outpatient prospective payment system, under Medicare Part B, respectively.

³⁵Point-of-Care-Testing Association, Letter to CMS on “Rate Setting Under Section 216 of the Protecting Access to Medicare Act” (Washington, D.C.: Oct. 23, 2017).

practice group. These same officials told us that larger physician groups (e.g., 10 or more physicians) typically negotiate higher rates from private payers than smaller physician groups. Most physician-office laboratories received less than \$25,000 in revenue per year from Medicare, according to CMS.

Additionally, in 2013, the Department of Health and Human Services Office of Inspector General found that Medicare's payment rates on the CLFS were higher than rates paid by some private health insurance plans. Specifically, it found that Medicare rates for laboratory tests were 18 percent to 30 percent higher than rates paid by certain insurers under health benefits plans for federal employees.³⁶

CMS Analyzed Private-Payer Data to Develop New Payment Rates

CMS analyzed private-payer data it collected from about 2,000 laboratories to develop new payment rates for individual laboratory tests on the CLFS. PAMA defined laboratories required to report private-payer data, called applicable laboratories, as laboratories that meet certain criteria. (See sidebar.) Applicable laboratories with their own specific billing number, the NPI, submitted these data to CMS.³⁷ If one organization operated multiple applicable laboratories, each with its own

Definition of Applicable Laboratories Required to Report Private-Payer Data to CMS

CMS defined applicable laboratories as those meeting four criteria: (1) they met the definition of laboratory under regulations implementing the Clinical Laboratory Improvement Amendments of 1988; (2) they billed Medicare Part B under their own Medicare billing number, also called the national provider identifier; (3) more than 50 percent of their total Medicare revenues

³⁶HHS, Office of Inspector General, *Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings*, OEI-07-11-00010 (Washington, D.C.: June 2013).

³⁷The NPI is the standard unique health identifier used by health care providers for billing Medicare and other payers.

came from the Clinical Laboratory Fee Schedule (CLFS) and/or the Physician Fee Schedule; and (4) they received at least \$12,500 in Medicare revenue from the CLFS from January 1, 2016, through June 30, 2016.

Source: Centers for Medicare & Medicaid Services. | GAO-19-67

NPI, then the organization could report data to CMS for multiple applicable laboratories. CMS collected data from applicable laboratories on payments they received from private payers during the first half of 2016. Specifically, CMS collected data on (1) the unique billing code associated with a laboratory test; (2) the private-payer rate for each laboratory test for which final payment was made during the data collection period (January 1, 2016, through June 30, 2016); and (3) the volume of tests performed for each unique billing code at that private-payer rate. For the data CMS collected between January 1, 2017, and May 30, 2017, CMS relied on the entities reporting to CMS to attest to the completeness and accuracy of the data they submitted.³⁸

CMS relied on each laboratory to identify whether or not it was an applicable laboratory and took steps to assist laboratories in meeting reporting requirements. According to CMS officials, they relied on laboratories to self-identify as applicable laboratories because they were unable to accurately identify the number of laboratories required to report.³⁹ To assist laboratories, CMS issued multiple guidance documents to the industry outlining the criteria for being an applicable laboratory and describing the type of data CMS intended to collect.⁴⁰ CMS also conducted educational calls when the proposed and final rules were issued and prior to the data collection period. CMS officials told us they conducted additional outreach activities, including holding conference calls with national laboratory associations and attending professional conferences. Officials said they used these outreach activities in addition

³⁸CMS initially required reporting entities to submit data on private-payer rates by March 31, 2017. However, on March 30, 2017, CMS announced a 60-day enforcement discretion period with respect to the potential assessment of civil monetary penalties for reporting entities that failed to meet reporting requirements. Thus, the data collection period was extended to May 30, 2017, allowing reporting entities to continue submitting data without incurring civil monetary penalties. CMS may assess civil monetary penalties on applicable laboratories that do not submit data to the agency as required by law.

³⁹According to CMS, several factors prevented them from determining an accurate estimate. For example, officials said the laboratory market is constantly changing because of mergers and acquisitions. Additionally, CMS officials told us that claims data did not enable CMS to determine whether or not a laboratory billed Medicare under its own NPI or the NPI of another entity in its organization.

⁴⁰For example, see CMS, *Frequently Asked Questions, CMS 1621 F, Medicare Program—Medical Clinical Diagnostic Laboratory Tests Payment System Final Rule* (Baltimore, Md.: March 9, 2017) and CMS, *MLN Matters, No. SE1619, Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payer Rate-Based Payment System* (Baltimore, Md.: Jan. 12, 2017).

to the guidance issued to inform laboratories of the reporting requirements for applicable laboratories, for example.

In addition, CMS established a revenue threshold of \$12,500 in an effort to reduce the reporting burden for entities that receive a relatively small amount of revenues under the CLFS. In its final rule, CMS noted that it expected that many of the laboratories that would be below this revenue threshold and, thus exempt from reporting data to CMS, would be physician-office laboratories.⁴¹ CMS also chose to use the NPI in its definition of applicable laboratory in the final rule to allow hospital-outreach laboratories that use their own NPI to submit data to the agency.⁴² In its proposed rule, CMS suggested using an alternative identification number to the NPI.⁴³ However, according to the final rule, CMS chose to use the NPI in its definition of applicable laboratory to allow those hospital-outreach laboratories billing using their own NPI to submit private-payer data to the agency.⁴⁴

According to CMS, at the end of the 5-month submission period, the agency had received data from approximately 2,000 applicable laboratories, representing a volume of almost 248 million laboratory tests; these data accounted for about \$31 billion in revenue from private payers. CMS reported that the data it collected included private-payer rates for 96

⁴¹81 Fed. Reg. 41,035, 41,044 (June 23, 2016). Also, on July 27, 2018, CMS requested public comments on reducing the low expenditure threshold to qualify as an applicable laboratory from \$12,500 to \$6,250. According to CMS, such a change might allow some physician-office laboratories and small, independent laboratories to meet the definition of applicable laboratory and report private-payer data to CMS. 83 Fed. Reg. 35,704, 35,849 (July 27, 2018).

⁴²Most hospital-outreach laboratories use the NPI associated with their affiliated hospital to submit claims for tests performed for individuals not receiving hospital inpatient or outpatient care. However, some hospital-outreach laboratories submit claims to CMS using their own NPI.

⁴³This alternative identification number was the Taxpayer Identification Number used by the Internal Revenue Service to administer tax law.

⁴⁴In the preamble to the final rule, CMS explained that it chose not to use the Taxpayer Identification Number, at least, in part, because this number is typically held by the hospital in which the laboratory operates, and it is unlikely a hospital would meet the criteria that more than 50 percent of its revenues come from the CLFS and/or Physician Fee Schedule.

percent of the 1,347 eligible billing codes on the CLFS.⁴⁵ CMS used these data to calculate a median, private-payer rate, weighted by volume and phased in this change by limiting payment-rate reductions to 10 percent per year. Beginning in 2018, these new payment rates served as the single, national payment rate for individual laboratory tests.⁴⁶ These payment rates were also used for the individual, component tests that make up panel tests and were used when laboratories billed Medicare for panel tests by listing the component tests separately.

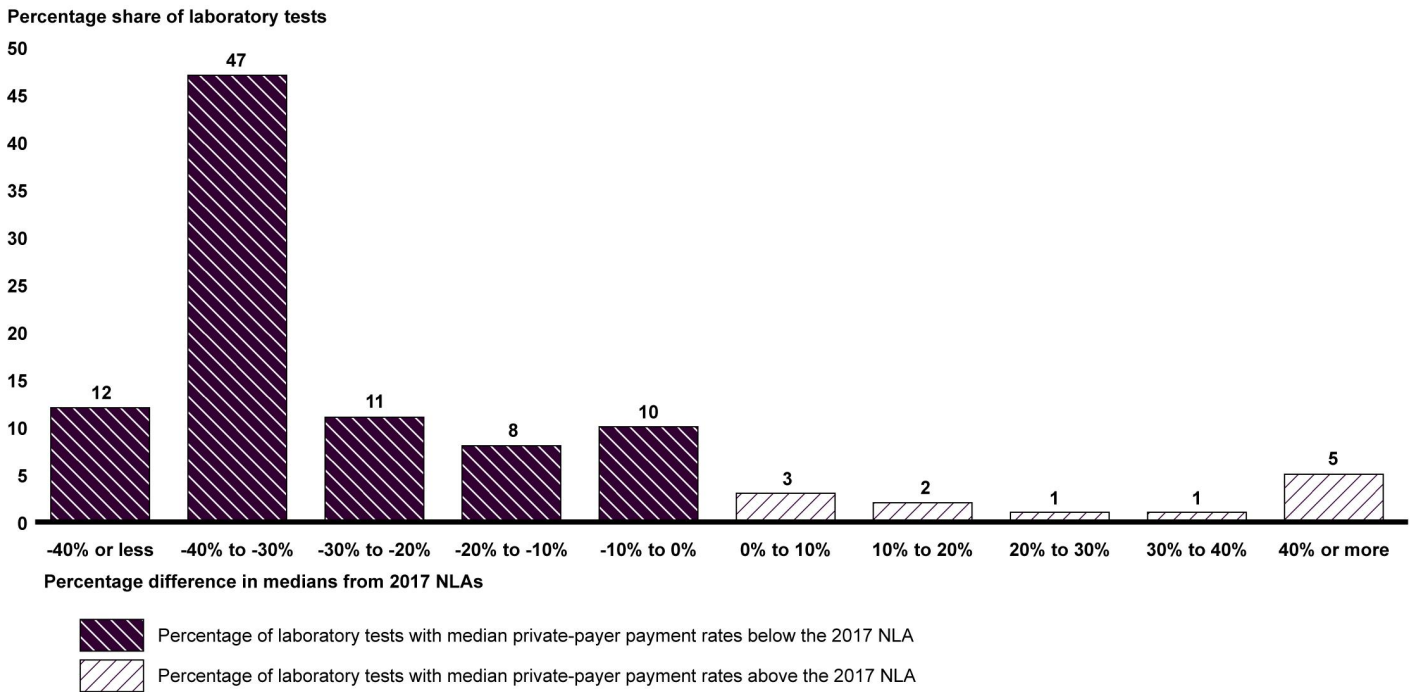
In general, the median payments rates, weighted for volume, that CMS calculated were lower than Medicare's previous payment rates for most laboratory tests.⁴⁷ According to our analysis, these median payment rates were lower than the corresponding 2017 CLFS national limitation amounts (the maximum that CMS would pay for laboratory tests) for approximately 88 percent of tests. Figure 1 below describes the percentage difference between these median payment rates and Medicare's 2017 national limitation amounts for laboratory tests.

⁴⁵For those codes for which CMS did not receive data, the agency used its crosswalking or gapfilling methodologies to set the rates for the 2018 CLFS. Crosswalking is used if it is determined that a new laboratory test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. Gapfilling is used when no comparable test is available.

⁴⁶Unlike the rates used before 2018, the new payment rates do not account for geographic variation.

⁴⁷These median private-payer rates do not consider the 10-percent maximum reduction when phasing in the changes to Medicare rates.

Figure 1: Percentage Difference between the Median Payment Rates and Medicare’s 2017 National Limitation Amount (NLA) for Laboratory Tests



Source: GAO analysis of data from the Centers for Medicare & Medicaid Services. | GAO-19-67

Note: These median payment rates were calculated using the private-payer data submitted to the Centers for Medicare & Medicaid Services (CMS) and do not consider the 10-percent maximum reduction when phasing-in the changes to Medicare rates. Also, the NLA is a national limit for payment for individual laboratory tests.

The final payment rates that CMS calculated, which included the 10-percent, phased in, payment-rate reductions, will remain in effect until December 31, 2020; PAMA requires CMS to calculate new payment rates for the CLFS every 3 years. Reporting entities will next be required to submit data on private-payer rates to CMS in early 2020, for final payments made from January 1, 2019 through June 30, 2019. PAMA capped any reductions for the second 3-year cycle after implementation to a maximum of 15 percent per year.⁴⁸

⁴⁸PAMA does not phase in payment-rate reductions following the conclusion of the second 3-year cycle after implementation. As implemented by CMS, this means that payment-rate reductions are not capped by a maximum percentage amount after 2023. Thus, beginning January 1, 2024, there will be no limitation on the amount payment rates for laboratory tests could decrease from the previous year.

PAMA's Provisions and CMS's Actions May Have Mitigated Some Challenges Related to Incomplete and Inaccurate Private-Payer Data, but Future Challenges Remain

Incomplete Data Likely Had a Limited Effect from 2018 through 2020 but Could Affect Future Rates

CMS did not collect private-payer data from all laboratories required to report this information and did not estimate how much data was not reported by these laboratories, according to agency officials. CMS relied on laboratories to determine whether they met data reporting requirements and submit data accordingly. CMS emphasized the importance of receiving data from all laboratories required to report by stating that it is critical that CMS collect complete data on private-payer rates in order to set accurate Medicare rates.⁴⁹ However, agency officials told us that CMS did not receive data from all laboratories required to report. They also told us that CMS did not have the information available to estimate how much data was missing because not all laboratories reported or the extent to which the data collected were representative of all of the data that laboratories were required to report.

Prior to collecting private-payer data, CMS estimated that laboratories subject to reporting requirements would receive more than 90 percent of CLFS expenditures to physician-office laboratories and independent laboratories. Specifically, based on its analysis of 2013 Medicare expenditures, CMS estimated that reporting requirements would apply to the laboratories that received 92 percent of CLFS payments to physician-office laboratories and 99 percent of CLFS payments to independent laboratories.⁵⁰

After laboratories reported private-payer data, we analyzed the share of CLFS expenditures received by the laboratories that reported. Our analysis found that CMS collected data from laboratories that received the majority of CLFS payments to physician-office, independent, and

⁴⁹81 Fed. Reg. 41,036, 41,069 (June 23, 2016).

⁵⁰81 Fed. Reg. 41,036, 41,095 (June 23, 2016).

other non-hospital laboratories in 2016. However, the laboratories that reported private-payer data received less than 70 percent of CLFS expenditures to physician-office, independent, and other non-hospital laboratories. Specifically, using Medicare claims data, we calculated that CMS collected data from laboratories that received 68 percent of 2016 CLFS payments to physician-office, independent, and other non-hospital laboratories.⁵¹

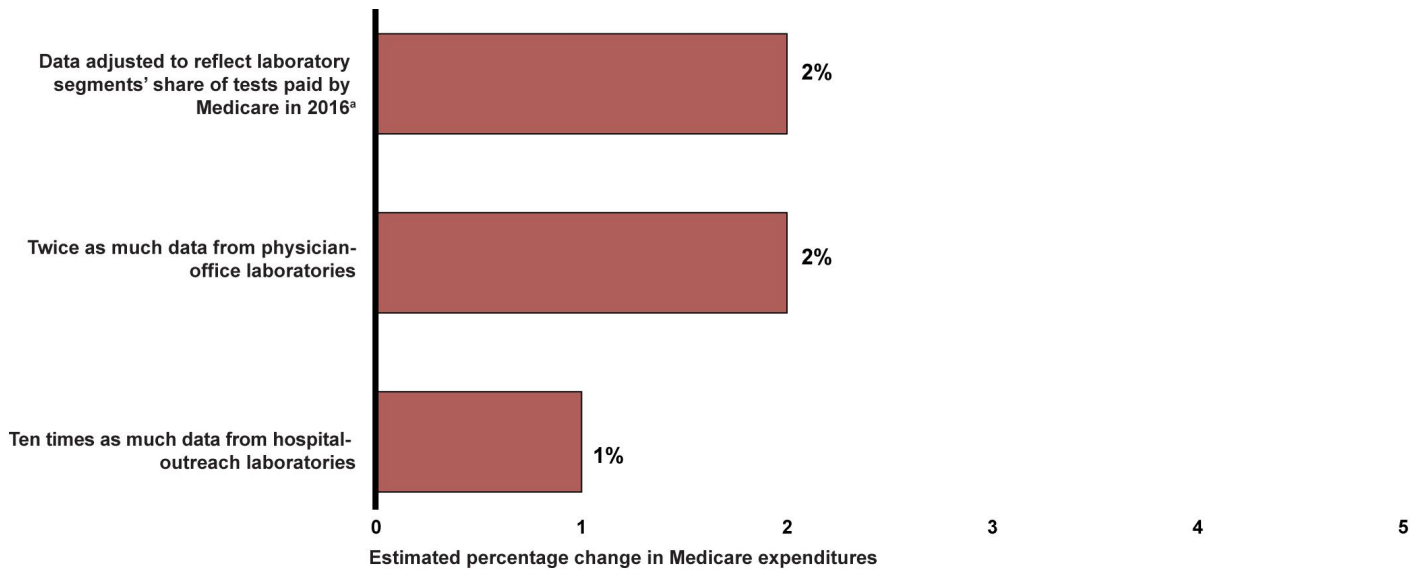
Although it did not collect complete data, CMS concluded that it collected sufficient private-payer data to set Medicare payment rates and that collecting more data from additional laboratories that were required to report would not significantly affect Medicare expenditures.⁵² This conclusion was based, in part, on a sensitivity analyses that CMS conducted of the effects that collecting certain types and amounts of additional data would have on weighted median private-payer rates and the effects those rates could have on Medicare payment rates and, thus, expenditures.⁵³ Results from these analyses showed that Medicare expenditures based on the CLFS would have changed by 2 percent or less after collecting more data from the various types of laboratories. For example, CMS estimated that doubling the amount of private-payer data from physician-office laboratories would increase expenditures by 2 percent and collecting ten times as much data from hospital outreach laboratories would increase expenditures by 1 percent. (See fig. 2.)

⁵¹Other non-hospital laboratories received 1 percent of CLFS payments in 2016, while independent and physician-office laboratories received 55 and 18 percent of these payments, respectively. (See table 2.)

⁵²CMS, *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule*.

⁵³CMS's sensitivity analyses projected CLFS expenditures for 2018 but do not account for PAMA's 10-percent annual limit on payment-rate reductions. Instead, for purposes of these analyses, CMS set Medicare payment rates equal to median private-payer rates.

Figure 2: Centers for Medicare & Medicaid Services (CMS) Estimates of Effects on Medicare Expenditures of Collecting Different Amounts of Laboratory Payment Rate Data



Source: GAO analysis of data from the Centers for Medicare & Medicaid Services. | GAO-19-67

Notes: CMS's estimates assume additional data from various types of laboratories would have the same characteristics of data already received from these types of laboratories. Estimated effects do not consider the limits on payment-rate reductions required under the Protecting Access to Medicare Act of 2014. Percentage change in Medicare expenditures are for expenditures based on the Clinical Laboratory Fee Schedule (CLFS) only.

^aCMS adjusted the relative proportions of data from hospital-outreach, physician-office, and independent laboratories to match the share of payments based on the Medicare CLFS that each of these types of laboratories received.

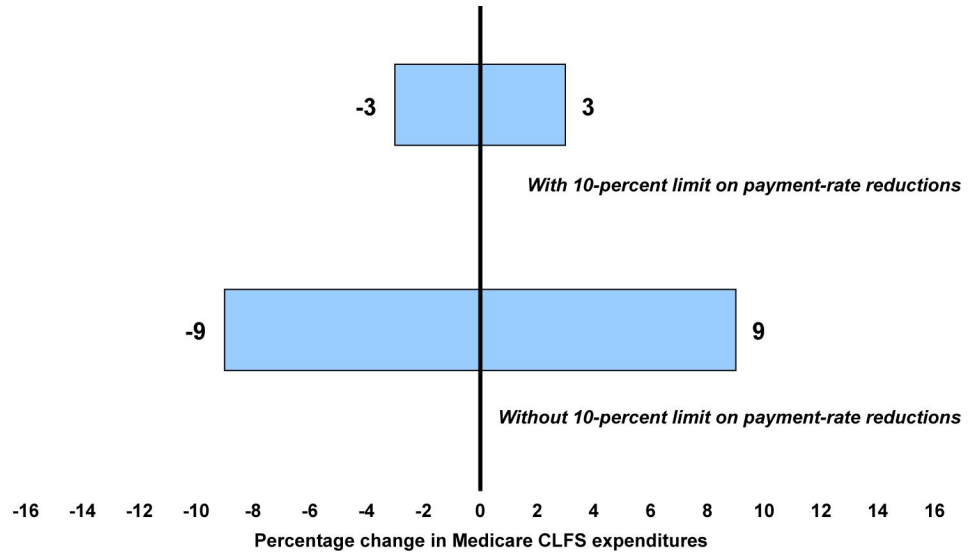
PAMA's 10-percent limit on annual payment-rate reductions likely reduced the effect that incomplete private-payer data could have on the CLFS because this limit applied to most Medicare payment rates for laboratory tests. As demonstrated in figure 1, while 59 percent of tests had median private-payer rates that were at least 30 percent less than their respective 2017 national limitation amounts, CMS published Medicare rates for these tests for 2018 through 2020 that were reduced by only 10 percent per year as a result of this limit. For example, a hypothetical laboratory test with a 2017 CLFS national limitation amount of \$10.00 and a median private-payer rate of \$7.00 would result in CLFS rates of \$9.00 in 2018, \$8.10 in 2019, and \$7.29 in 2020. Changes to median private-payer rates due to collecting more complete data or eliminating inaccurate data would have no effect on Medicare payment rates from 2018 through 2020 for this hypothetical test if they resulted in new median rates of \$7.29 or less.

Our analysis of the potential effects that collecting data from additional laboratories could have had on Medicare payment rates and expenditures found that the effect of CMS not collecting complete data would likely have been greater absent PAMA's limits on annual reductions to Medicare payment rates. As a result, CMS may face challenges setting accurate Medicare rates if it does not collect complete data from all laboratories required to report in the future when PAMA allows for greater annual payment-rate reductions.⁵⁴ To conduct this analysis, we used the private-payer data CMS collected to analyze the range of effects that collecting additional data could have on Medicare expenditures, assuming 2016 utilization rates remain constant. The extent of these effects depends on the amount of additional data CMS would need to collect to obtain complete data and whether the payment rates in these additional data would have been greater or less than the medians of the rates reported.⁵⁵ For example, we estimated that if CMS needed to collect 20 percent more data for its collection to be complete, doing so could increase Medicare CLFS expenditures from 2018 through 2020 by as much as 3 percent or reduce them by as much as 3 percent depending on the payment rates in these additional data. However, if annual limits to Medicare payment-rate reductions were not applied, collecting these additional data could increase CLFS expenditures by as much as 9 percent or reduce them by as much as 9 percent. (See fig. 3 and app. II for additional information about these estimates.)

⁵⁴Similarly, the HHS Office of Inspector General found that collecting incomplete private-payer data remains a risk in future data reporting periods. See HHS, Office of Inspector General, *Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies To Ensure Data Quality*, OEI-09-17-00050 (July 2018).

⁵⁵We analyzed the potential effects of collecting additional data with payment rates that ranged from greater than the 70th percentile to lower than the 30th percentile of payment rates in the data CMS collected. (See app. II.)

Figure 3: Estimated Range of Possible Changes in Medicare Expenditures Based on the Clinical Laboratory Fee Schedule (CLFS) if the Centers for Medicare & Medicaid (CMS) Had Collected 20 Percent More Data on Private-Payer Rates, 2018-2020



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-19-67

Notes: We estimated changes in Medicare expenditures based on what the median rates would have been if CMS had collected 20 percent more data and if the payment rates in this additional data would have been either below the 40th percentile rates or above the 60th percentile rates in the data CMS collected. We assumed that the same number of laboratory tests performed in 2016 would be performed in each year from 2018 through 2020.

As demonstrated in figure 2, CMS did analyze how collecting certain types and amounts of data from additional laboratories would affect Medicare expenditures. However, without valid estimates of how much more data these additional laboratories were required to report and how much these data would change median payment rates, it remains unknown whether CMS’s analyses estimate the actual risk of setting Medicare payment rates that do not reflect private-payer rates from all applicable laboratories, as mandated by PAMA.⁵⁶ CMS could have compared the data it collected with independent information on the payment rates laboratories were required to report, for example. The independent information could be estimated by auditing a random sample of laboratories or could be estimated using data from third-party vendors, if these vendors could supply relevant and reliable information.

⁵⁶In addition, federal internal control standards for risk assessment require agencies to analyze risks to program objectives. [GAO-14-704G](#).

CMS Mitigated Challenges of Setting Accurate Medicare Payment Rates by Identifying and Excluding Inaccurate Private-Payer Data that Could Have Led to Paying More than Necessary

We found that CMS mitigated challenges to setting accurate Medicare payment rates by identifying, analyzing, and responding to potentially inaccurate private-payer data. CMS addressed potentially inaccurate private-payer data and other data that CMS determined did not meet reporting requirements.

- CMS removed or replaced data from four reporting entities that appeared to have or confirmed having reported revenue—which is the payment rate multiplied by the volume of tests paid at that rate—instead of payment rates. We estimated that if CMS had included these data that CLFS expenditures from 2018 through 2020 would have increased by 7 percent.
- CMS removed data it determined were reported in error including duplicate submissions and submissions with payment rates of \$0.00. We estimated that removing these data will change CLFS expenditures from 2018 through 2020 by less than one percent.

CMS identified four other types of potentially inaccurate data that it determined would not significantly impact Medicare payment rates or expenditures and did not exclude them from calculations of median private-payer rates. CMS considered the following potentially inaccurate data to have met its reporting requirements:

1. data from 57 entities that reported particularly high rates in at least 60 percent of their data,
2. data from 12 entities that reported particularly low rates in at least 50 percent of their data,
3. data with payment rates that were 10 times greater than the 2017 national limitation amounts or 10 times less than these amounts, and
4. data from laboratories that may not have met the \$12,500 low-expenditure threshold or that reported data from a hospital NPI instead of a laboratory NPI.⁵⁷

⁵⁷CMS, *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule*.

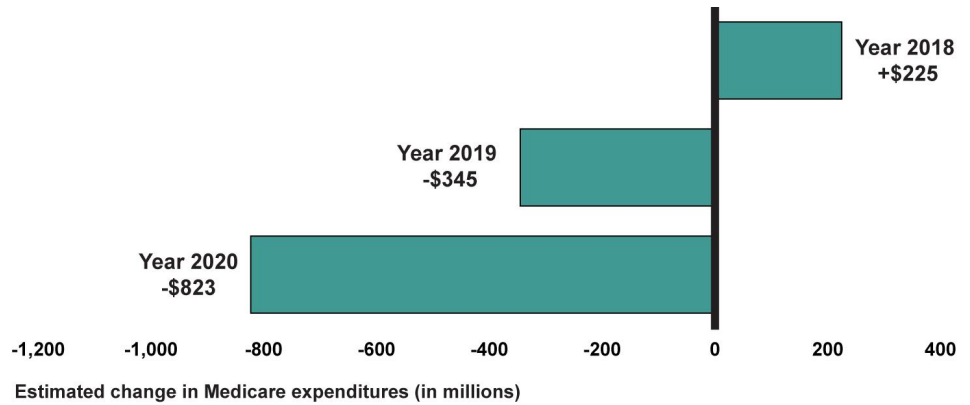
We found that each of these four types of potentially inaccurate data would have changed estimated Medicare CLFS expenditures from 2018 through 2020 by 1 percent or less if CMS had instead excluded the data. To conduct this analysis, we recalculated Medicare rates after excluding each type of data and estimated Medicare expenditures assuming 2016 rates of utilization.

CMS's Implementation of New Payment Rates Could Lead to Medicare Paying Billions More than Necessary for Some Tests

CMS's Approach to Phase In Reductions to Payment Rates Temporarily Increased Some Rates and Contributed to Estimated Increases in Medicare Expenditures for Certain Laboratory Tests

Although weighted median private-payer rates were lower than Medicare's 2017 national limitation amounts for 88 percent of tests, we estimated the total Medicare expenditures based on the 2018 CLFS would likely increase by 3 percent (\$225 million overall) compared to 2016 expenditures, assuming test utilization remained at 2016 levels. This increase in estimated expenditures is due, in part, to CMS's use of above-average payment rates as a baseline to calculate payment rates for those laboratory tests affected by PAMA's annual payment-rate reduction limit of 10 percent. (See fig. 4.)

Figure 4: Estimated Change in Medicare Clinical Laboratory Fee Schedule (CLFS) Expenditures in Comparison to 2016 CLFS Expenditures, 2018-2020



Source: GAO analysis of data from the Centers for Medicare & Medicaid Services. | GAO-19-67

When applying the 10-percent payment-rate reduction limit, CMS used as its starting point the 2017 national limitation amounts in order to set a single, national payment rate for each laboratory test. Thus, the Medicare payment rate for a test in 2018 could not be less than 90 percent of the test’s 2017 national limitation amount.⁵⁸ However, prior to 2018, some payment rates were commonly lower than the national limitation amounts because they were based on the lesser of (1) the amount billed on claims, (2) the local fee for a geographic area, or (3) a national limitation amount, and because panel tests had different bundled payment rates. As a result, by reducing payment rates from national limitation amounts, CMS did not always reduce rates from what Medicare actually paid.

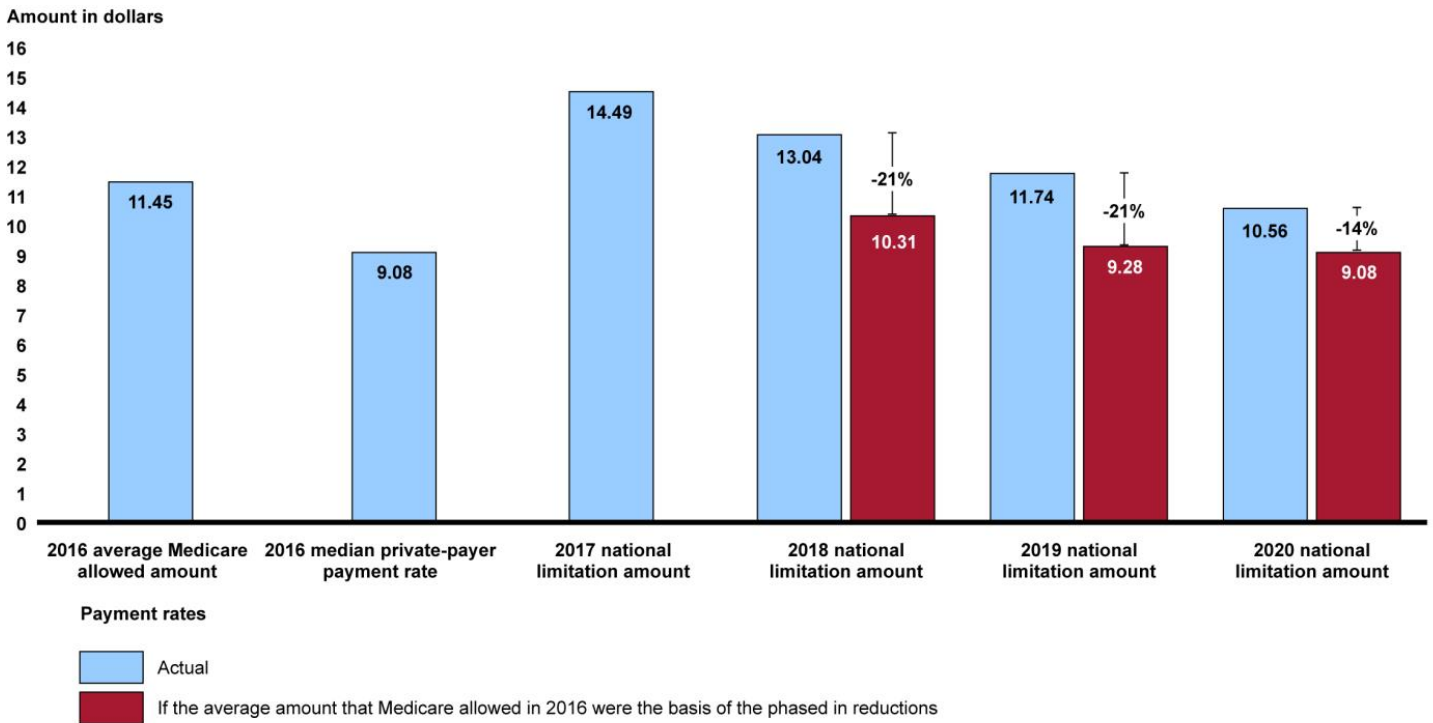
Panel tests, in particular, frequently received bundled payment rates that differed substantially from national limitation amounts associated with their billing codes prior to 2018. We compared national limitation amounts, which represent maximum Medicare payment rates for tests, with the average amounts Medicare allowed for payment in 2016, which reflect actual Medicare payment rates.⁵⁹ For example, figure 5 below shows that the 2017 national limitation amount for comprehensive

⁵⁸CMS calculated national limitation amounts for tests that did not have them to be able to establish a baseline for 10-percent reductions to Medicare payment rates.

⁵⁹The allowable amounts for these tests include Medicare payments and any cost-sharing payments made by beneficiaries, such as coinsurance and deductible payments, or payments by other insurers.

metabolic panel tests (\$14.49) was substantially higher than both the average amount Medicare allowed for payment in 2016 (\$11.45) and the median payment rate laboratories reported receiving from private payers (\$9.08). As a result, using the 2017 national limitation amount as a basis for payment reductions caused Medicare’s payment rate to increase from an average allowed amount of \$11.45 in 2016, to a payment rate of \$13.04 in 2018, instead of decreasing towards a lower median private-payer rate of \$9.08. By increasing average payment rates rather than phasing in reductions to rates, CMS’s implementation may lead to paying more than necessary for some tests.

Figure 5: Example of a Panel with an Increased Payment Rate Resulting from Phased In Payment-Rate Reductions (Comprehensive Metabolic Panel Test)



Source: GAO analysis of data from the Centers for Medicare & Medicaid Services. | GAO-19-67

Federal standards for internal control for information and communications require agency management to use quality information to achieve its objectives.⁶⁰ Basing reductions on national limitation amounts rather than

⁶⁰GAO-14-704G.

more relevant information on how much Medicare actually paid—such as the average allowable amounts in 2016, for example—could result in Medicare paying more than necessary by \$733 million from 2018 through 2020, according to our estimates.⁶¹

CMS's Changes to Payment Rates for Panel Tests Could Lead Medicare to Pay Billions of Dollars More than Is Necessary

In implementing PAMA, CMS eliminated bundled rates for panel tests that lack billing codes and started paying separately for each component test instead. CMS also implemented the 2018 CLFS in a manner that could lead to unbundling payment rates for panel tests with billing codes. If payment rates for all panel tests were unbundled, we estimated that Medicare expenditures could increase by \$218 million for panel tests that lack billing codes and by as much as \$10.1 billion for panel tests with billing codes from 2018 through 2020.⁶² CMS also estimated that there could be significant risks of paying more than necessary associated with unbundling and has taken initial steps to monitor these risks and explore possible responses, but had not yet responded to these risks as of July 2018.

CMS Unbundled Payment Rates for Panel Tests without Billing Codes

Beginning in 2018, CMS no longer uses bundled payment rates for panel tests without billing codes and instead pays laboratories individual payments for each component test that comprises these panel tests. However, CMS staff and members of its advisory panel discussed concerns with this approach. At an advisory panel meeting in 2016, CMS staff relayed concerns from stakeholders that CMS would not be able to collect valid data on private-payer rates for these panel tests. According

⁶¹This estimate considers the effect on expenditures for the 23 component tests that can comprise panel tests without billing codes and the 7 panel tests with billing codes. Other tests had 2017 national limitation amounts that exceeded the average amount Medicare paid for these tests based on the 2016 CLFS, but the percentage difference between these two amounts tended to be smaller.

⁶²These additional estimated expenditures are distinct from the \$733 million more that we estimated Medicare will pay due to phasing in payment-rate reductions based on national limitation amounts. However, as described below, addressing the cause of one estimated increase can change the magnitude of others.

to agency staff, stakeholders had informed CMS that private payers commonly use bundled payment rates for these panel tests, but laboratories would only be able to report unbundled payment rates for individual component tests.

We estimated that unbundling these payment rates would increase Medicare expenditures from 2018 through 2020 by \$218 million in comparison to the estimated Medicare expenditures over the same time period based on Medicare's 2016 utilization and allowable amounts. For example, under the 2016 CLFS, Medicare paid approximately 435,000 claims for panel tests that included the laboratory tests assay of creatinine (HCPCS code 82565) and assay of urea nitrogen (HCPCS code 84520) at an average bundled payment rate of \$6.82. In contrast, under the 2018 CLFS, these two component tests are reimbursed individually at \$6.33 and \$4.88, respectively, or \$11.21 combined—a 63 percent increase.

Despite concerns about the validity of available private-payer data on component tests for panel tests without billing codes, CMS used these data to set payment rates for component tests.⁶³ CMS officials told us that they stopped using bundled payment rates for these panel tests because it is not clear that CMS has the authority to combine the individual component tests into groups for bundled payment as it did before 2018 due to PAMA's reference to payments for each test.⁶⁴ However, in July 2018, CMS officials told us the agency was reviewing its authority regarding this issue. CMS officials told us they are exploring alternative approaches that could limit increases to Medicare expenditures but had not yet determined what additional legal authority would be needed, if any, and did not know when CMS would make this determination. Agency officials told us that CMS has taken initial steps to monitor unbundling and explore possible responses, including the following:

⁶³Standards for internal control in the federal government for information and communication require agency management to use quality information to achieve its objectives. [GAO-14-704G](#).

⁶⁴Prior to 2018, Medicare paid for panel tests using bundled payment rates that were set based on how many of 23 component tests were performed in the panel. CMS officials referred to PAMA's requirements that laboratories report the payment rate that was paid by each private payer for a given test and that the Medicare payment rate for each test be equal to the weighted median determined for each test.

- **Monitoring unbundling:** CMS has begun monitoring changes in panel test utilization, payment rates, and expenditures associated with its implementation of PAMA, according to officials. For example, CMS officials told us that preliminary data indicated that Medicare payments for individual component tests of panel tests has increased substantially in 2018, but, as of July 2018, it was too early to draw conclusions from these data because laboratories have up to one year to submit claims for tests.
- **Collecting input on alternatives:** In 2016, a subcommittee of an advisory panel that CMS established reviewed Medicare's use of bundled payment rates for panel tests and published different approaches for CMS to consider implementing in combination with other changes to implement PAMA.

CMS's Implementation of PAMA May Have Allowed Unbundling of Payment Rates for Panel Tests with Billing Codes

Beginning in 2018, laboratories that submit claims for any of the seven panel tests with billing codes by using the billing codes for the individual component tests now receive the payment rate for each component test, rather than the bundled rate. Prior to 2018, laboratories could submit claims for these panel tests either by using the specific codes for panel tests or by billing separately for each of the component tests, and, regardless of how laboratories submitted claims, Medicare Administrative Contractors would pay bundled payment rates based on how many of the 23 component tests were conducted. However, CMS instructed Medicare Administrative Contractors to stop bundling payment rates for tests that are billed individually on claims rather than billed on claims using codes for panel tests, beginning in 2018.⁶⁵ CMS did so because it was not clear that CMS had the authority to combine the individual component tests into groups for bundled payment as it did before 2018 due to PAMA's reference to payments for individual tests, according to agency officials. This change could potentially have a large effect on Medicare spending. For example, if a laboratory submitted a claim individually for the 14 component tests that comprise a comprehensive metabolic panel it would receive a payment of \$81.91, a 528 percent increase from the 2018 Medicare bundled payment rate of \$13.04 for this panel test. (See fig. 6.)

⁶⁵See, CMS, *CMS Manual System Pub 100-04 Medicare Claims Processing Transmittal 3653 Change Request 9837* (Baltimore, Md.: Nov. 10, 2016).

Figure 6: Example of Payment Rate Difference Resulting from Unbundling a Payment Rate for a Panel Test with a Billing Code



Source: GAO analysis of information from the Centers for Medicare & Medicaid Services. | GAO-19-67

Improving how reductions to payment rates for panel tests are phased in could mitigate, but not completely counteract, the effect of unbundling these payment rates. For example, for the comprehensive metabolic panel test described in figure 6, basing maximum reductions on 2016

average allowable amounts would result in a 2018 Medicare bundled payment rate of \$10.31 instead of \$13.04 and individual payment rates for the 14 component tests that total \$56.06—a 32 percent decrease from \$81.91 that Medicare would otherwise pay.

If the payment rate for each panel test with a billing code were unbundled, we estimated that Medicare expenditures for these tests from 2018 through 2020 could reach \$13.5 billion, a \$10.1 billion increase from the \$3.3 billion we estimated Medicare would spend using the bundled payment rates in the CLFS. Similarly, prior to implementing PAMA, CMS estimated that Medicare expenditures to physician-office, independent, and other non-hospital laboratories could potentially increase as much as \$2.5 billion in 2018, alone if it paid for the same number of panel tests with billing codes as it did in 2016 but paid for each component test individually.⁶⁶ These estimates represent an upper limit on the increased expenditures that could occur if every laboratory stopped using panel test billing codes and instead used the billing codes for individual component tests. We do not know the extent to which laboratories will stop filing claims using panel test billing codes.

CMS officials also told us that they were aware of the risks associated with paying for the individual component tests instead of the bundled payment rate for a panel test with a billing code.⁶⁷ However, CMS guidance, which was effective in 2018, continued to allow laboratories to use the billing codes for individual component tests rather than the billing code for the panel.⁶⁸ CMS officials explained that this was due to PAMA's reference to payments for individual tests, similar to CMS's decision to stop paying bundled rates for panel tests without billing codes. At the time

⁶⁶CMS's estimate was based on an analysis of carrier claims, which generally exclude payments to hospital-outreach laboratories, and, for purposes of this analysis, CMS set 2018 Medicare payment rates equal to median private-payer rates. Our estimate includes all Medicare payments based on the CLFS for 2018 through 2020.

⁶⁷The U.S. House of Representatives Committee on Appropriations also recognized this risk in a report accompanying the Committee's bill making appropriations for HHS for fiscal year 2019. The report encouraged the Administrator of CMS to develop and issue a policy that ensures Medicare does not pay more for a group of individual laboratory tests than it would for a comparable panel test. H.R. Rep. No. 115-862, at 91 (2018). In addition, standards for internal control in the federal government require agency management to design and implement control activities to respond to risks. [GAO-14-704G](#).

⁶⁸See, for example, CMS, *General Correct Coding Policies for National Correct Coding Initiative Policy Manual for Medicare Services* (Baltimore, Md.: Jan. 1, 2018).

we did our work, CMS had not implemented a response to these risks but had taken some initial steps to monitor unbundling and consider alternative approaches to Medicare payment rates for these tests. HHS provided additional information on planned activities to address these risks in its written comments on a draft of this report. (See app. III.)

Conclusions

CMS collected data on private-payer rates from laboratories that were required to report these data, but not all laboratories complied with the reporting requirement, and the extent of noncompliance remains unclear. PAMA's provision directing CMS to phase in payment-rate reductions to Medicare payment rates likely moderates the potential adverse effects of incomplete private-payer data. However, in the future, failing to collect complete data could substantially affect Medicare payment rates because private-payer rates alone will determine Medicare payment rates. In addition, we estimated that Medicare expenditures on laboratory tests will be \$733 million higher from 2018 through 2020, because CMS started phasing in payment-rate reductions from national limitation amounts instead of more relevant data on actual payment rates, such as average allowable amounts. Finally, changes to payment rates, billing practices, and testing practices could increase Medicare expenditures by as much as \$10.3 billion from 2018 through 2020, if CMS does not address the risks associated with unbundling payment rates for panel tests. Agency officials indicated that it was unclear if PAMA limited CMS's ability to combine individual component tests into groups for bundled payment, and, as of July 2018, CMS was reviewing this matter but did not know when it would make a determination.

Recommendations for Executive Action

We are making the following three recommendations to CMS:

- The Administrator of CMS should take steps to collect all of the data from all laboratories that are required to report. If only partial data can be collected, CMS should estimate how incomplete data would affect Medicare payment rates and address any significant challenges to setting accurate Medicare rates. (Recommendation 1)
- The Administrator of CMS should phase in payment-rate reductions that start from the actual payment rates Medicare paid

Agency Comments and Our Evaluation

prior to 2018 rather than the national limitation amounts. CMS should revise these rates as soon as practicable to prevent paying more than necessary. (Recommendation 2)

- The Administrator of CMS should use bundled rates for panel tests, consistent with its practice prior to 2018, rather than paying for them individually; if necessary, the Administrator of CMS should seek legislative authority to do so. (Recommendation 3)

We provided a draft of this report to HHS for review and comment. HHS provided written comments, which are reproduced in appendix III. HHS also provided technical comments, which we incorporated as appropriate.

- HHS concurred with our first recommendation to take steps to collect all data from laboratories required to report and commented that it is evaluating ways to increase reporting. In particular, in a November 2018 final rule, HHS changed the definition of an applicable laboratory, which it expects will increase the number of laboratories required to report data on private-payer rates to the agency.
- HHS neither agreed nor disagreed with our second recommendation to phase in payment-rate reductions that start from the actual payment rates Medicare paid prior to 2018. HHS noted that any changes to the phasing in of payment-rate reductions would need to be implemented through rulemaking. We estimated that by using the national limitation amounts as a starting point for these reductions, Medicare expenditures would increase by \$733 million from 2018 through 2020. For this reason, we continue to believe CMS should revise these rates as soon as practicable and through whatever mechanism CMS determines appropriate.
- HHS neither agreed nor disagreed with our third recommendation to use bundled rates for panel tests. However, HHS commented that it is taking steps to address this issue. More specifically, for panel tests with billing codes, HHS is working to implement an automated process to identify claims for panel tests that should receive bundled payments, similar to the process used to bundle payment rates for these panel tests prior to PAMA's implementation and anticipates implementing this change by the summer of 2019. In addition, HHS posted guidance on November 14, 2018, stating that the panel tests with billing codes,

laboratories should submit claims using the corresponding code rather than the codes for the separate component tests beginning in 2019.⁶⁹ To reduce the potential of paying more than necessary, we believe it is important that CMS implement its proposed automated process to allow for these payments as soon as possible.

In contrast, for panel tests without billing codes, HHS commented that it is continuing to review its authority and considering other approaches to payment for these panel tests, such as adding codes to the CLFS. We estimate that unbundling the payment for these panel tests could increase Medicare expenditures by \$218 million from 2018 through 2020 compared to expenditures based on Medicare's 2016 utilization, and the actual amount could be higher if utilization increases. For this reason, we believe CMS should implement bundled payment rates for these panel tests to avoid excess payments.

We are sending copies of this report to the appropriate congressional committees and the Administrator of CMS. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>. If you or your staff have any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.



James C. Cosgrove
Director, Health Care

⁶⁹CMS, General Correct Coding Policies for National Correct Coding Initiative Policy Manual for Medicare Services (Baltimore, Md.: Jan. 1, 2019).

Congressional Committees

The Honorable Orrin G. Hatch
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Greg Walden
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy & Commerce
House of Representatives

The Honorable Kevin Brady
Chairman
The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: Table of Key Dates Related to Developing the New Payment Rates for the 2018 Clinical Laboratory Fee Schedule

Table 3: Key Dates Related to Developing the New Payment Rates for the 2018 Clinical Laboratory Fee Schedule (CLFS)

Date	Event
October 1, 2015	Centers for Medicare and Medicaid Services (CMS) issued the CLFS proposed rule.
October 13, 2015	CMS issued responses to frequently asked questions regarding the CLFS proposed rule.
June 23, 2016	CMS issued the CLFS final rule.
June 23, 2016–March 9, 2017	CMS issued responses to frequently asked questions regarding the CLFS final rule.
July 18, 2016	CMS held the joint Annual Laboratory Public Meeting and Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests meeting.
August 3, 2016	CMS issued laboratory billing codes subject to data collection and reporting.
August 8, 2016	CMS issued guidance to laboratories for collecting and reporting data.
September 12, 2016	CMS held a Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests meeting.
November 3, 2016	CMS issued the CLFS data reporting template.
January 1, 2017–May 30, 2017 ^a	CMS collected data on (1) the billing code associated with a laboratory test; (2) the private-payer rate for each laboratory test for which final payment was made during the data collection period (i.e., January 1, 2016, through June 30, 2016); and (3) the volume of tests performed for each billing code at that private-payer rate.
January 4, 2017	CMS issued additional guidance for laboratories as the data collection period began.
January 9, 2017	CMS issued the CLFS fee-for-service data collection user's manual.
January 12, 2017	CMS issued revised guidance to laboratories for collecting and reporting data.
July 31, 2017–August 1, 2017	CMS held a Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests meeting.
September 22, 2017	CMS released the proposed CLFS rates.
September 25, 2017	CMS held a Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests meeting.
October 23, 2017	Deadline for stakeholders to submit comments on the proposed CLFS rates to CMS.
November 17, 2017	CMS issued the final CLFS rates.
January 1, 2018	New CLFS rates became effective.

Source: GAO summary of information from the Centers for Medicare & Medicaid Services (CMS). | GAO-19-67

**Appendix I: Table of Key Dates Related to
Developing the New Payment Rates for the
2018 Clinical Laboratory Fee Schedule**

^aCMS initially required reporting entities to submit data on private-payer rates by March 31, 2017. However, on March 30, 2017, CMS announced a 60-day enforcement discretion period with respect to the potential assessment of civil monetary penalties for reporting entities that failed to meet reporting requirements. Thus, the data collection period was extended to May 30, 2017, allowing reporting entities to continue submitting data without incurring civil monetary penalties. CMS may assess civil monetary penalties upon applicable laboratories that do not submit data to the agency as required by law.

Appendix II: Estimated Effects on Medicare Expenditures from Collecting Additional Data

Table 4 below demonstrates the challenges the Centers for Medicare & Medicaid Services (CMS) faces in setting accurate Medicare payment rates to the extent it does not collect complete data from laboratories on private-payer rates. Specifically, the table shows the potential effect that collecting additional data for each laboratory test could have on Medicare expenditures and how this effect could vary depending on (1) the amount of additional data collected, (2) payment rates in the additional data, and (3) limits to annual reductions in Medicare payment rates. These limits are in place from 2018 through 2023 to phase in changes to payment rates.

Table 4: Estimated Effects on Medicare Expenditures Based on the Clinical Laboratory Fee Schedule of Collecting Additional Data from Laboratories on Private-Payers’ Payment Rates, 2018 through 2020

n/a		n/a		Percentage difference in estimated Medicare expenditures caused by additional data, 2018 through 2020	
Percentage of additional data	Payment rates in additional data in comparison to those in data already collected	Percentage of additional data	Payment rates in additional data in comparison to those in data already collected		
40	Greater than 70th percentile	11		27	
30	Greater than 65th percentile	7		18	
20	Greater than 60th percentile	3		9	
10	Greater than 55th percentile	1		3	
10	Less than 45th percentile	-2		-5	
20	Less than 40th percentile	-3		-9	
30	Less than 35th percentile	-3		-14	
40	Less than 30th percentile	-3		-20	

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-19-67

Notes: We estimated changes in Medicare expenditures based on what the median rates would have been if the Centers for Medicare & Medicaid Services (CMS) had collected various amounts of additional data for each laboratory test and if all of the payment rates in this additional data would have been either above or below certain percentile rates in the data CMS collected. These

**Appendix II: Estimated Effects on Medicare
Expenditures from Collecting Additional Data**

percentiles correspond to estimates of what new median payment rates would be after including the additional data. We assumed that the same number of laboratory tests performed in 2016 would be performed in each year from 2018 through 2020.

Appendix III: Comments from the Department of Health and Human Services

Appendix III: Comments from the Department
of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 07 2018

James Cosgrove
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payments*" (GAO-19-67).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in blue ink, appearing to read "Matthew D. Bassett".

Matthew D. Bassett
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - MEDICARE LABORATORY TESTS: IMPLEMENTATION OF NEW RATES MAY LEAD TO BILLIONS IN EXCESS PAYMENTS (GAO-19-67)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report. HHS is committed to providing Medicare beneficiaries with access to high quality health care while protecting taxpayer dollars.

Section 216(a) of the Protecting Access to Medicare Act of 2014 added section 1834A to the Social Security Act which significantly revised the Medicare payment methodology for certain clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule. Beginning on January 1, 2018, Medicare began using certain private payor rate information reported by applicable laboratories to calculate Medicare payment rates for most laboratory tests paid under the Clinical Laboratory Fee Schedule. The use of market data to establish Clinical Laboratory Fee Schedule payment rates strengthens Medicare by paying more appropriately for laboratory services while maintaining beneficiaries' access to high quality laboratory services.

HHS appreciates the GAO's review in this area and will consider findings from this report as we continue to evaluate ways to improve the clinical laboratory payment system.

Recommendation 1

The Administrator of CMS should take steps to collect all of the data from all laboratories that are required to report. If only partial data can be collected, CMS should estimate how incomplete data would affect Medicare payment rates and address any significant challenges to setting accurate Medicare rates.

HHS Response

HHS concurs with taking steps to increase outreach to laboratories so that applicable laboratories report their data. HHS worked closely with stakeholders to establish parameters for the collection of the applicable information in the least burdensome manner possible. As a result of these efforts, the data reported to HHS captures over 96 percent of laboratory tests on the Clinical Laboratory Fee Schedule, representing over 96 percent of Medicare's spending on Clinical Laboratory Fee Schedule tests in Calendar Year 2016. Laboratories from every state, the District of Columbia, and Puerto Rico reported data.

HHS modeled three additional reporting scenarios to estimate the impact of increasing data reporting. HHS determined that additional reporting did not seem likely to significantly change payment amounts for this collection period, irrespective of how many additional laboratories reported. HHS will continue to analyze the effect of additional data when setting Medicare payment rates in the future. HHS believes it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a clinical diagnostic laboratory test while minimizing the reporting burden for entities.

On November 1, 2018, CMS released the Revisions to Payment Policies under the Physician Fee Schedule and other Revisions to Part B for Calendar Year 2019 (CMS-1693-F) final rule, which makes two changes to the definition of an applicable laboratory. Specifically, the final rule excludes Medicare Advantage plan payments from the total Medicare revenues and includes hospital outreach laboratories that bill Medicare Part B using the CMS-1450 14X Type of Bill in

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - MEDICARE LABORATORY TESTS: IMPLEMENTATION OF NEW RATES MAY LEAD TO BILLIONS IN EXCESS PAYMENTS (GAO-19-67)

the definition of applicable laboratory. We believe these changes will lead to an even more robust data collection from which to calculate payment rates for the next Clinical Laboratory Fee Schedule update.

HHS is continuing to evaluate ways to increase data reporting, including targeted outreach and auditing of laboratories that may meet the definition of an applicable laboratory. HHS is reviewing its authority under section 1834A(a)(9) of the Social Security Act to impose civil monetary penalties if it is determined that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting its data. Laboratories, or other stakeholders, that have questions or concerns regarding their status as an applicable laboratory or the status of a data submission are encouraged to contact HHS.

Recommendation 2

The Administrator of CMS should phase in payment rate reductions that start from the actual payment rates Medicare paid prior to 2018 rather than the national limitation amounts. CMS should revise these rates as soon as practicable to prevent paying more than necessary.

HHS Response

The requirements to phase-in payment rate reductions from the national limitation amounts were finalized after notice and comment rulemaking in the Medicare Clinical Diagnostic Laboratory Tests Payment System final rule (81 FR 41036) and codified in 42 C.F.R. § 414.507(d). Any changes to these requirements would need to be implemented through rulemaking.

Recommendation 3

The Administrator of CMS should use bundled rates for these tests, consistent with its practice prior to 2018, rather than paying for them individually; if necessary, the Administrator of CMS should seek legislative authority to do so.

HHS Response

Prior to implementation of the Protecting Access to Medicare Act of 2014, automated test panels without a current procedural terminology (CPT) code were paid at a bundled rate using a payment algorithm developed by HHS. However, section 216(a) of the Protecting Access to Medicare Act of 2014 established section 1834A of the Act, which generally requires that the Medicare payment rates for each clinical diagnostic laboratory test under the Clinical Laboratory Fee Schedule be an amount that is equal to the weighted median of the private payor rates for the test, based on the applicable information reported by applicable laboratories. Therefore, HHS discontinued the use of these automated test panel payment algorithms that bundled component CPT codes. HHS will revisit this determination regarding our authority, and HHS is considering other approaches to payment for these tests consistent with section 1834A of the Social Security Act such as adding codes to the Clinical Laboratory Fee Schedule for this purpose.

With regard to panel tests that have their own CPT code, whether the laboratory bills for the CPT panel code or component tests, per HHS policy the laboratory should be paid the CPT panel code amount when applicable. HHS is working to update the claims processing system to detect these claims in an automated fashion. This edit will be similar to one that had been implemented in earlier versions of the Clinical Laboratory Fee Schedule payment system until a change related to

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN
SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT
REPORT ENTITLED - MEDICARE LABORATORY TESTS: IMPLEMENTATION OF
NEW RATES MAY LEAD TO BILLIONS IN EXCESS PAYMENTS (GAO-19-67)**

an instruction issued in 2016. This update is targeted to be operational no later than summer 2019. In addition, HHS plans to release updated subregulatory guidance by the end of 2018.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

James C. Cosgrove, (202) 512-7114, cosgrovej@gao.gov

Staff Acknowledgments

In addition to the contact named above, Martin T. Gahart, Assistant Director; Gay Hee Lee, Analyst-in-Charge; Kaitlin Farquharson, Sandra George, Dan Lee, Elizabeth T. Morrison, Laurie Pachter, Vikki Porter, and Russell Voth made key contributions to this report.

Appendix V: Accessible Data

Data Tables

Accessible Data for Figure 1: Percentage Difference between the Median Payment Rates and Medicare's 2017 National Limitation Amount (NLA) for Laboratory Tests

Category	Percentage	Percentage difference in medians from 2017 NLAs
<i>Percentage of laboratory tests with median private-payer payment rates below the 2017 NLA`</i>	-40% or less	12
	-40% to -30%	47
	-30% to -20%	11
	-20% to -10%	8
	-10% to 0%	10
<i>Percentage of laboratory tests with median private-payer payment rates above the 2017 NLA</i>	0% to 10%	3
	10% to 20%	2
	20% to 30%	1
	30% to 40%	1
	40% or more	5

Accessible Data for Figure 2: Centers for Medicare & Medicaid Services (CMS) Estimates of Effects on Medicare Expenditures of Collecting Different Amounts of Laboratory Payment Rate Data

Category	Estimated percentage change in Medicare expenditures
Data adjusted to reflect laboratory segments' share of tests paid by Medicare in 2016a	+\$225
Twice as much data from physician-office laboratories	-\$345
Ten times as much data from hospital-outreach laboratories	-\$823

Accessible Data for Figure 3: Estimated Range of Possible Changes in Medicare Expenditures Based on the Clinical Laboratory Fee Schedule (CLFS) if the Centers for Medicare & Medicaid (CMS) Had Collected 20 Percent More Data on Private-Payer Rates, 2018-2020

n/a Category	Percentage change in Medicare CLFS expenditures	
	Low	High
With 10-percent limit on payment-rate reductions	-3	3
Without 10-percent limit on payment-rate reductions	-9	9

Accessible Data for Figure 4: Estimated Change in Medicare Clinical Laboratory Fee Schedule (CLFS) Expenditures in Comparison to 2016 CLFS Expenditures, 2018-2020

Year	Estimated change in Medicare expenditures (in millions)
Year 2018	+\$225
Year 2019	-\$345
Year 2020	-\$823

Accessible Data for Figure 5: Example of a Panel with an Increased Payment Rate Resulting from Phased In Payment-Rate Reductions (Comprehensive Metabolic Panel Test)

n/a Category	Payment rates	
	Actual	If the average amount that Medicare allowed in 2016 were the basis of phased in reductions
2016 average Medicare allowed amount	11.45	n/a
2016 median private-payer payment rate	9.08	n/a
2017 national limitation amount	14.49	n/a
2018 national limitation amount	13.04	10.31 (-21%)
2019 national limitation amount	11.74	9.28 (-21%)
2020 national limitation amount	10.56	9.08 (-14%)

Agency Comment Letter

Accessible Text for Appendix III Comments from the Department of Health and Human Services

Page 1

NOV 07 2018

James Cosgrove

Director, Health Care

U.S. Government Accountability Office

441 G Street NW

Washington, DC 20548

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