CHAPTER 9

Mandated report: Assessing the impact of recent changes to Medicare's clinical laboratory fee schedule payment rates

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Chapter summary

Before 2018, Medicare's clinical laboratory fee schedule (CLFS) payment rates were set based on local, historical charges and capped at certain amounts. CLFS payment rates were not always adjusted to reflect laboratories' improvements in efficiency, changes in technology, or market conditions over time. For example, CMS did not adjust payment rates for the fact that performing some laboratory tests had become faster and less expensive over time as automation reduced the need for manual interactions with laboratory technicians (Centers for Medicare & Medicaid Services 2016b). Because of how CLFS payment rates were set and updated over time, Medicare paid more for laboratory tests than other payers, with one estimate suggesting that Medicare paid between 18 percent and 30 percent more per test than other payers for 20 high-volume or high-expenditure laboratory tests.

In response to evidence of overpayments, the Protecting Access to Medicare Act of 2014 required CMS to establish CLFS payment rates based on the rates private payers paid for laboratory tests. Laboratories that meet certain requirements, such as receiving a minimum level of payments under the CLFS, are required to report their private-payer rates to CMS. After laboratories report their data, CMS sets the CLFS payment rate for each laboratory test at the volume-weighted median of all reported private-payer rates. These payment rates are not subject to any adjustments (e.g., geographic adjustments) or annual updates; they are updated only when CMS collects

In this chapter

another round of private-payer data. The first round of data reporting occurred in 2017, and CMS used those data to set CLFS payment rates beginning in 2018. The second round of data reporting was originally scheduled to take place in 2020. However, in the Further Consolidations Appropriations Act, 2020, the Congress delayed the second round of data reporting, which is now scheduled for 2022. As part of that legislation, the Congress also mandated the Commission to examine the methodology CMS used to set private payer–based CLFS payment rates and to report on the least burdensome data collection process that would result in a representative and statistically valid data sample of private market rates from all laboratory market segments, including independent, hospital, and physician-office laboratories.

In the first round of data reporting, CMS received private-payer data from laboratories that accounted for 51 percent of Medicare CLFS spending in 2016. However, reporting was not consistent across different types of laboratories. Independent laboratories were overrepresented in the data, and hospital outpatient and physician-office laboratories were underrepresented. Representatives of the laboratory industry have claimed that, compared with independent laboratories, hospital outpatient and physician-office laboratories receive higher private-payer rates, and thus their underrepresentation in the first round of data reporting artificially lowered Medicare's payment rates, which could create disruptions in access to laboratory tests.

The Commission's analysis found that using private-payer data substantially lowered Medicare payment rates for CLFS tests. We project that, relative to average 2017 rates, CLFS payment rates will decrease by an average of 24 percent once the private payer–based rates are fully phased in by 2025. However, we found that payment rate changes were not uniform across types of laboratory tests. The transition to private payer–based rates resulted in much larger payment reductions for low-cost, routine tests than for newer, more expensive tests. In fact, the transition to private payer–based rates led to rate increases for some tests, particularly for those that are newer and more expensive.

We found that overall utilization of CLFS laboratory tests remained relatively flat after CMS implemented private payer–based rates, suggesting stable access to CLFS laboratory tests among Medicare fee-for-service beneficiaries. In contrast to relatively flat utilization rates, aggregate Medicare CLFS spending increased after CMS implemented private payer–based rates. This spending increase was predominantly driven by newer, high-cost tests, such as genetic tests. While the field of genetic testing is still nascent and changing rapidly, the lower average payment

rate reductions (or payment rate increases) among such tests and their associated high rates of spending growth in recent years suggest that relying on private-payer rates alone will not control Medicare spending growth on these tests in the future.

The Commission worked with a third-party contractor, RTI International (RTI), to examine survey methodologies that could be used to collect private-payer data from a representative and statistically valid sample of laboratories. RTI found that collecting private-payer data using a survey could produce accurate estimates of payment rates for independent, hospital, and physician-office laboratories and reduce the number of laboratories that would be required to report private-payer data by up to 70 percent. However, this analysis should be considered a proof of concept; further analysis would be needed to more fully explore this alternative to CMS's current rate-setting process. CMS may also require additional legislative authority to implement such a data collection process.

The Commission also examined the extent to which collecting data from a representative sample of independent, hospital, and physician-office laboratories would affect Medicare's CLFS spending by analyzing how hospital outpatient and physician-office laboratories' private-payer rates compared with those received by independent laboratories. Based on data reported to CMS, we found that, for the 100 Medicare CLFS tests with the highest spending in 2016, hospital outpatient and physician-office laboratories received private-payer rates that were, on average, 45 percent and 53 percent higher, respectively, than independent laboratories. Because of these substantially higher private-payer rates, full representation of hospital outpatient and physician-office laboratories in the first round of data reporting would have resulted in higher Medicare CLFS spending, although the magnitude of the increase would depend on assumptions made about the distribution of types of laboratories and the rates these laboratories were paid by private payers.

The Commission maintains that Medicare should set payment rates at a level that ensures beneficiary access to high-quality laboratory tests, while also providing incentives for laboratories to furnish care efficiently in order to make good use of taxpayers' and beneficiaries' resources. To do that, Medicare should ensure that payment rates are sufficient to cover the costs of relatively efficient laboratories but should not increase rates solely to accommodate laboratories that receive high private-payer rates. In setting CLFS payment rates, incorporating private-payer data from a representative sample of all types of laboratories would be imprudent for routine laboratory tests where higher private-payer rates likely reflect provider negotiating leverage rather than the costs of furnishing the tests.

For most routine tests, policymakers should consider setting laboratory payment rates based on private-payer data from certain types of laboratories (e.g., independent laboratories) while excluding the data from others (e.g., hospital outpatient laboratories). Through the first two years of setting Medicare rates based on private-payer data, lower Medicare payments appear to have had little impact on the use of routine laboratory tests among Medicare fee-for-service beneficiaries, suggesting that access to services can be maintained with lower rates. However, if access issues did arise, policymakers could consider implementing targeted payment adjustments instead of incorporating private-payer data from all laboratories that receive high private-payer rates. Targeted payment adjustments could help ensure access in particular circumstances without overpaying for all laboratory tests.

The Commission's analyses also suggest that using private-payer data to set Medicare payment rates for many new, high-cost tests is problematic. Determining appropriate payment rates for such laboratory tests may be challenging for private payers. Indeed, our analyses suggest that private payers may not be able to negotiate lower prices for such tests in the same manner as they do for more routine tests. In the future, the Commission will explore ways to improve how Medicare sets prices for new high-cost technologies, including certain pharmaceuticals, devices, and laboratory tests. ■

Statutory mandate: Public Law 116–94

(b) STUDY AND REPORT BY MEDPAC.

(1) IN GENERAL.—The Medicare Payment Advisory Commission (in this subsection referred to as the ''Commission'') shall conduct a study to review the methodology the Administrator of the Centers for Medicare & Medicaid Services has implemented for the private payor rate-based clinical laboratory fee schedule under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) SCOPE OF STUDY.—In carrying out the study described in paragraph (1), the Commission shall consider the following:

(A) How best to implement the least burdensome data collection process required under section 1834A(a)(1) of such Act (42 U.S.C. 1395m–1(a)(1)) that would—

(i) result in a representative and statistically valid data sample of private market rates from all laboratory market segments, including hospital outreach laboratories, physician-office laboratories, and independent laboratories; and

(ii) consider the variability of private payor payment rates across market segments.

(B) Appropriate statistical methods for estimating rates that are representative of the market.

(3) REPORT TO CONGRESS.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to the Administrator, the Committee on Finance of the Senate, and the Committees on Ways and Means and Energy and Commerce of the House of Representatives a report that includes—

(A) conclusions about the methodology described in paragraph (1); and

(B) any recommendations the Commission deems appropriate. ■

Background

In the Further Consolidated Appropriations Act, 2020, the Congress mandated that the Commission examine the methodology CMS uses to set private payer–based rates for laboratory tests paid under Medicare's clinical laboratory fee schedule (CLFS). The mandate requires the Commission to report, by June 2021, on the least burdensome data collection process that would result in a representative and statistically valid data sample of private market rates from all laboratory market segments (see text box for mandate).

In this report, we describe Medicare's laboratory payment system that was in effect through 2017 and describe the effects—on Medicare payment rates, spending, and utilization of laboratory tests—associated with setting Medicare's payment rates using information from private payers, which began in 2018. We also examine the methods by which CMS could collect representative private-payer data using a survey and discuss the potential consequences for Medicare spending.

Medicare's clinical laboratory fee schedule

Clinical laboratory tests analyze specimens from the body (e.g., blood or urine) to diagnose health conditions and help guide treatments. Clinical laboratory tests are valuable tools that help accurately diagnose and treat patients. Under Part B, Medicare covers medically reasonable and necessary laboratory tests that are ordered by a physician or a qualified nonphysician practitioner when they are provided in a laboratory that is certified by CMS under the Clinical Laboratory Improvement Amendments (CLIA).[1]

Laboratory tests are furnished in a variety of settings, and Medicare's payment mechanisms vary based on setting. In institutional settings, Medicare often bundles the

payment for laboratory tests together with other services provided to beneficiaries. For example, laboratory tests are generally bundled when provided as part of an inpatient hospital stay, an outpatient hospital service, or a skilled nursing facility stay. In addition, Medicare generally pays for laboratory tests that involve the work of a physician (e.g., anatomic pathology services) under the physician fee schedule. For laboratory tests that are not bundled or paid under the physician fee schedule, Medicare predominantly pays for tests under the CLFS.[2] (Unless explicitly noted otherwise, the rest of this report applies only to laboratory tests paid under the CLFS.)

The CLFS contains a heterogeneous mix of tests. Some tests are relatively routine and are provided by a wide variety of laboratories. These tests include organ- or disease-oriented panel tests, such as comprehensive metabolic panels (Healthcare Common Procedure Coding System (HCPCS) code 80053); chemistry tests, such as an assay of the thyroid-stimulating hormone (HCPCS code 84443); and hematology and coagulation tests, such as complete blood counts (HCPCS code 85025). Other tests are low-volume, complex tests that are often furnished by relatively few laboratories. This group includes molecular pathology tests, such as a test that analyzes a beneficiary's predisposition to hereditary breast and ovarian cancers (HCPCS code 81162); multianalyte assays with algorithmic analyses, such as a test to detect colorectal cancers (HCPCS code 81528); and proprietary laboratory analyses, such as a genomic profiling assay for solid tumors (HCPCS code 0037U).

In 2019, Medicare spent over $7.5 billion on 428 million Medicare CLFS laboratory tests. These tests were almost entirely furnished by three types of laboratories—independent laboratories, hospital outpatient laboratories, and physician-office laboratories. Policymakers and researchers often subdivide the hospital outpatient laboratory category into two groups—outreach and non-outreach laboratories. Hospital outreach laboratories are those that furnish laboratory tests for patients who are not admitted hospital inpatients or registered hospital outpatients—in essence, they serve as community laboratories. In 2019, independent laboratories billed for just under half of all CLFS tests (49 percent), while physician-office laboratories billed for 22 percent, hospital (non-outreach) laboratories billed for 18 percent, hospital outreach laboratories billed for 11 percent, and other laboratory types billed for 1 percent (Table 9-1).

Until recently, Medicare's CLFS payment rates were based on historical charges and likely were excessive

Before 2018, Medicare's CLFS payment rates were set based on local, historical laboratory charges and capped at certain amounts. Each Medicare claims processing contractor established its own fee schedule based on local laboratory charges in 1984 and 1985, resulting in 57 different fee schedules that were collectively known as the CLFS.

Beginning in 1986, the Congress established national limits on the local fee schedule rates, called national limitation amounts.[3] Medicare's payment rates for laboratory tests were also capped based on a laboratory's charges. The result was that Medicare's actual payment for a laboratory test was the lesser of the laboratory's charges, the local fee schedule amount, or the national limitation amount. Because laboratories' charges and local fee schedule amounts generally exceeded national limitation amounts, most (but not all) laboratory tests were paid based on national limitation amounts.[4]

For new laboratory tests, CMS established payment rates by one of two methods—crosswalking or gapfilling. CMS used the crosswalking method when a new test was comparable in terms of test methods and resources with an existing test. For crosswalked codes, CMS set payment rates using the rate for an existing test (or tests). If no comparable test existed, CMS used the gapfilling methodology, under which Medicare claims processing contractors set payment rates in their jurisdiction based on information such as laboratory charges, resources required to perform the test, and other payers' payment rates.[5] CMS then used these local payment rates to establish a national limitation amount.

CLFS payment rates were updated annually. Updates were generally based on the consumer price index for all urban consumers (CPI–U), CPI–U minus a certain amount (e.g., 0.5 percentage point) or were set directly by the Congress. For example, the Affordable Care Act of 2010 set CLFS payment rate updates at CPI–U minus a multifactor productivity update and directed CLFS payment rates to be reduced by 1.75 percent per year from 2011 to 2015.

CLFS payment rates were not adjusted to reflect laboratories' improvements in efficiency, changes in technology, or market conditions. For example, CMS did

TABLE 9–1 **Independent laboratories billed for about half of CLFS tests, 2019**

Type of laboratory		Definition	Share of: Medicare CLFS volume 2019	Share of: Medicare CLFS spending 2019
Independent		Perform tests independent of an institution or physician's office. Comprise a wide variety of laboratories, including large national laboratories (e.g., LabCorp and Quest), regional laboratories, and laboratories that specialize in genetic testing.	49%	63%
Physician office		Maintained by a physician or group of physicians performing diagnostic tests in connection with the physician practice.	22	16
Hospital outpatient	Non-outreach	Furnish laboratory tests only for hospital inpatients and registered hospital outpatients.	18	13
	Outreach	Furnish laboratory tests for patients who are not admitted hospital inpatients or registered hospital outpatients.	11	8
Other		Located in other settings such as nursing facilities or end-stage renal disease facilities.	1	1

Note: CLFS (clinical laboratory fee schedule). Numbers do not sum to 100 due to rounding. Table includes tests paid under Medicare's CLFS and excludes other tests, such as those bundled into the payment for hospital inpatient and outpatient services and those paid on a cost basis through critical access hospitals. Laboratory type is based on the place of service in the carrier file and the type of bill in the outpatient file. Hospital outreach laboratories are identified using type of bill 14x; hospital (non-outreach) laboratories are identified using bill types 12x and 13x.

Source: MedPAC summary of CMS regulations and Acumen LLC analysis of Medicare CLFS claims for MedPAC.

not adjust payment rates for the fact that performing some laboratory tests had become faster and less expensive over time because automation reduced the need for manual interactions with laboratory technicians.

Research suggested that Medicare's payment rates were excessive because of how CLFS payment rates were set and updated over time. A 2013 report from the Health and Human Services Office of Inspector General (OIG) found that Medicare paid between 18 percent and 30 percent more than other insurers for 20 high-volume or high-expenditure laboratory tests (Office of Inspector General 2013).

Beginning in 2018, Medicare's CLFS payment rates are based on private-payer data

The Protecting Access to Medicare Act of 2014 (PAMA) required CMS to shift the basis for CLFS payment rates from historical laboratory charges to current private-payer rates. This shift was expected to save the Medicare program $2.5 billion over 10 years because Medicare's laboratory payment rates generally exceeded private-payer rates at the time (Congressional Budget Office 2014). Despite this expected reduction, representatives of the laboratory industry supported the shift to private payer–based rates outlined in PAMA (American Clinical Laboratory Association 2014). In their view, the legislation provided predictable reimbursements and would allow the laboratory industry to avoid further across-the-board cuts.[6]

Process of establishing private payer–based CLFS rates

PAMA requires laboratories to report the payment rates they receive from private payers so that CMS can establish the new CLFS rates. Laboratories must report their private-payer rates for claims paid during a six-month period, referred to as the "data collection period." Laboratories then have six months to review and analyze their private-payer data. Following the review period, laboratories have

Setting payment rates for advanced diagnostic laboratory tests

In addition to changing the way Medicare sets payment rates for laboratory tests, the Protecting Access to Medicare Act of 2014 also established a new subcategory of laboratory tests, referred to as "advanced diagnostic laboratory tests" (ADLTs). An ADLT is a clinical diagnostic laboratory test covered under Medicare Part B that is offered and furnished only by a single laboratory and meets one of the following two criteria:

Criterion A—The test:

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

Criterion B—The test is cleared or approved by the Food and Drug Administration.

ADLTs have separate reporting and payment requirements from other laboratory tests. Medicare's payment rate for a new ADLT is equal to the product's actual list charge for three calendar quarters.[7] After this period, the payment rate for an ADLT is set at the weighted median of private-payer rates, but unlike the payment rates for other laboratory tests, CMS collects new private-payer data and establishes a new payment rate for ADLTs every year instead of every three years (Centers for Medicare & Medicaid Services 2018).

As of January 2021, CMS has approved nine ADLTs. Medicare's payment rates for these tests during the new ADLT period range from $1,950 to $7,193 (Table 9-2) (Centers for Medicare & Medicaid Services 2021). ■

(continued next page)

three months to report the data to CMS, referred to as the "data reporting period." CLFS payment rates are based on the reported data in the next calendar year. CMS used the following schedule to establish private payer–based rates:

- January through June 2016—data collection period
- July through December 2016—laboratory review of private-payer data
- January through March 2017—data reporting period
- In January 2018—CMS began paying for CLFS tests using the new private payer–based rates

PAMA requires laboratories to report their private-payer rates every three years so CMS can periodically recalculate CLFS rates. The Congress has delayed the second round of data reporting, so data from the first data collection period (January through June 2016) will be used to set CLFS rates until January 1, 2023. (The rate-setting process described in this section applies to laboratory tests that are not considered advanced diagnostic laboratory tests. See text box for more information on how Medicare sets payment rates for advanced diagnostic laboratory tests.)

Not all laboratories are required to report their private-payer rates to CMS. Instead, PAMA mandated that only "applicable laboratories" report. For the first data reporting period, CMS defined an applicable laboratory as one that:

- is certified under the Clinical Laboratory Improvement Amendments,
- bills Medicare under its own national provider identifier (NPI),

Setting payment rates for advanced diagnostic laboratory tests (cont.)

TABLE 9–2

CMS has approved nine ADLTs as of January 2021

HCPCS code	Laboratory name	Test name	Approval date	New ADLT period	Medicare payment amount during new ADLT period
0239U	Foundation Medicine	FoundationOne Liquid CDx	1/25/2021	4/1/21 to 12/31/21	$3,500
81554	Veracyte	Envisia Genomic Classifier	9/17/2020	10/1/20 to 6/30/21	$5,500
0172U	Myriad	myChoice CDx	12/11/2019	1/1/20 to 9/30/20	$4,040
0090U	Myriad	myPath Melanoma	9/6/2019	10/1/19 to 6/30/20	$1,950
0080U	Biodesix	BDX-XL2	5/17/2019	7/1/19 to 3/31/20	$3,520
81529	Castle Biosciences	DecisionDx-Melanoma	5/17/2019	7/1/19 to 3/31/20	$7,193
81552	Castle Biosciences	DecisionDx-UM	5/17/2019	N/A	N/A
81538	Biodesix	Veristrat	12/21/2018	N/A	N/A
0037U	Foundation Medicine	FoundationOne CDx	05/18/2018	7/1/18 to 3/31/19	$3,500

Note: ADLT (advanced diagnostic laboratory test), HCPCS (Healthcare Common Procedure Coding System), N/A (not applicable). HCPCS codes 81552 and 81538 were existing ADLTs.

Source: CMS.

- meets the "majority of Medicare revenues" threshold, and
- meets the low-expenditure threshold.

To meet the majority of Medicare revenues threshold, a laboratory must receive more than 50 percent of its total Medicare payments from the CLFS or the physician fee schedule. To calculate the share of Medicare revenues that comes from the CLFS or physician fee schedule, a laboratory (defined at the NPI level) sums all the payments it received from those two payment systems and divides that figure by its total Medicare revenues. For the first data reporting period, total Medicare revenues included all fee-for-service (FFS) payments under Medicare Part A and Part B, prescription drug payments under Part D, Medicare Advantage payments under Part C, and any associated beneficiary deductibles or coinsurance.

PAMA gave CMS the authority to establish a low-expenditure threshold, which CMS set at $12,500.[8] If a laboratory receives less than $12,500 in CLFS payments during the data reporting period (e.g., January through June 2016), it is exempted from reporting its private-payer rates to CMS. CMS estimated that the low-expenditure threshold would exempt about 95 percent of physician-office laboratories and 55 percent of independent laboratories from reporting. However, even after excluding those laboratories, CMS estimated that the agency would still collect data associated with 92 percent of CLFS spending for physician-office laboratories and 99 percent of CLFS spending associated with independent laboratories (Centers for Medicare & Medicaid Services 2016b). Thus, CMS's goal was to reduce the administrative burden on many small laboratories,

particularly physician-office laboratories, while still collecting sufficient data to set payment rates.

Laboratories not exempt from reporting must report "applicable information" to CMS, which consists of:

- the HCPCS code associated with each test the laboratory performed,
- the private-payer rate for each test for which final payment was made during the data collection period,[9] and
- the associated private-payer volume for each test.

Private-payer rates include the final amount paid for laboratory tests after all discounts, rebates, coupons, and other price concessions are applied. Private-payer rates include payments from secondary payers and any patient cost sharing. In general, laboratories should not report information in situations where payments cannot be directly attributed to a specific laboratory test. For example, payments made on a capitated, bundled, or encounter basis are generally excluded from reporting.

After laboratories report their data, CMS sets the CLFS payment rate for each laboratory test at the volume-weighted median of all reported private-payer rates.[10] PAMA required CMS to set rates using a weighted median instead of other measures of central tendency (e.g., geometric mean). The use of medians limits the effect of outlier values on CLFS rates, and weighting based on volume means that high-volume laboratories substantially influence CLFS rates.

PAMA stipulated that private payer–based CLFS payment rates are not subject to any adjustments, including geographic adjustments, budget-neutrality adjustments, or annual updates. The payment rates are updated only when CMS collects another round of private-payer data.

Before PAMA was enacted, Medicare's payment rates substantially exceeded private-payer rates for many laboratory tests, and consequently, transitioning to private payer–based rates was expected to result in large payment rate reductions. Therefore, PAMA established a long phase-in of payment reductions to mitigate the impact on laboratories and allow them time to adjust their operations. CLFS payment rates can decrease by no more than 10 percent per year for the first three years under the new payment system and no more than 15 percent per year in the next three years. Because of a one-year delay implementing the new payment system and legislation that eliminated all reductions in 2021, payment rate reductions resulting from private payer–based rates are not expected to be fully phased in until 2025. In contrast, payment rate increases resulting from private payer–based rates were fully implemented in 2018 (Figure 9-1).

Independent laboratories were overrepresented in the first round of data reporting

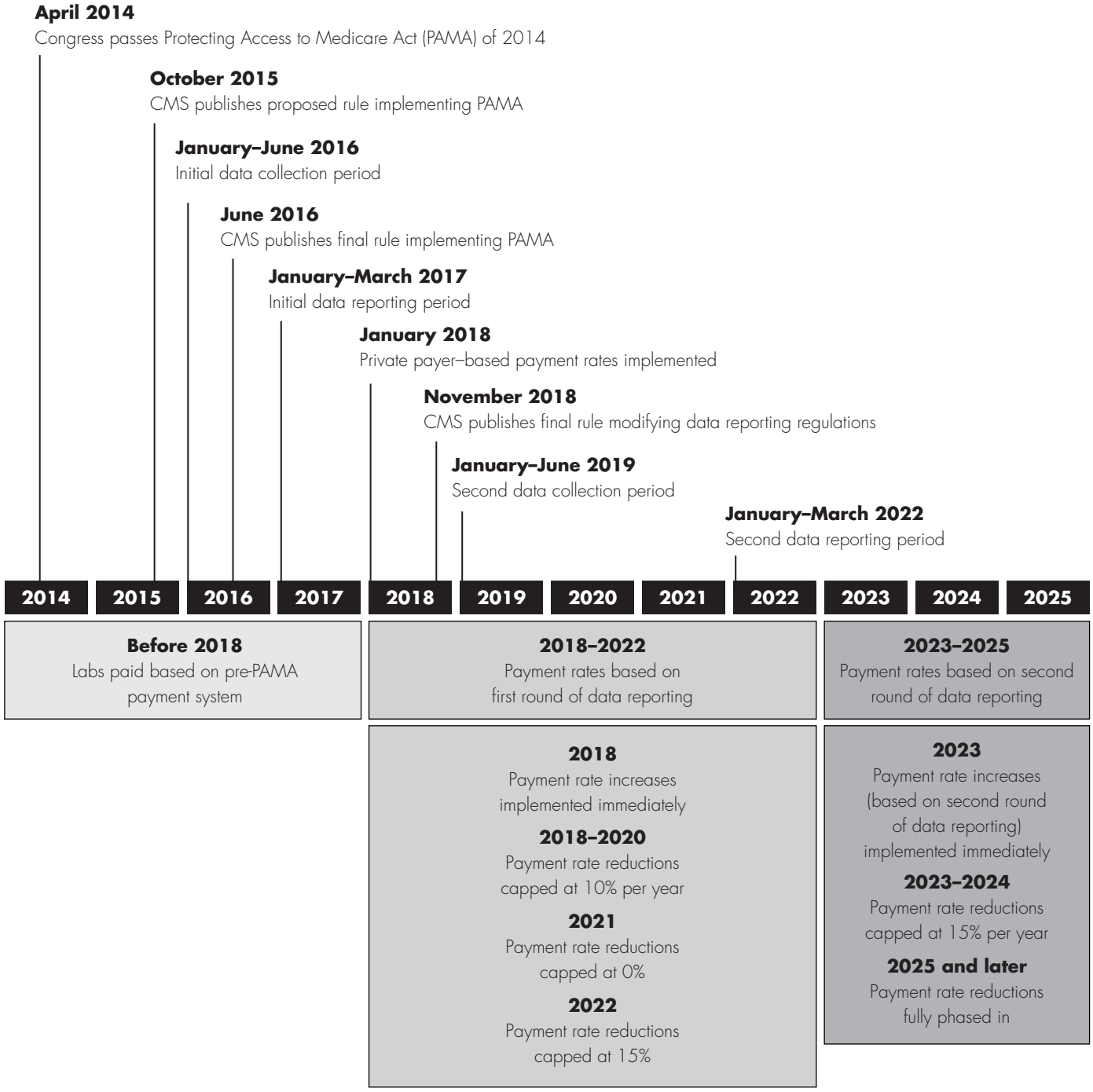
In the first round of data reporting, CMS collected private-payer data from laboratories that accounted for 51 percent of total Medicare CLFS spending in 2016.[11] However, reporting was not consistent across types of laboratories. Medicare paid independent laboratories $3.8 billion for CLFS laboratory tests in 2016, and CMS received private-payer data from independent laboratories that accounted for $3.2 billion in CLFS spending in the same year, meaning that CMS received data from laboratories that accounted for 85 percent of independent laboratory spending (Table 9-3, p. 308). In contrast, CMS received private-payer data from laboratories that accounted for 19 percent and 3 percent of Medicare CLFS spending among physician-office and hospital outpatient laboratories, respectively.

Hospital outpatient and physician-office laboratories were underrepresented in the first round of data reporting for several reasons. First, many physician-office laboratories furnish a relatively low volume of CLFS tests; these laboratories would not have met the low-expenditure threshold. Indeed, CMS established the low-expenditure threshold for the explicit purpose of relieving small laboratories from the administrative burden of data reporting, which industry representatives have noted was substantial.

Second, while some hospital outpatient laboratories also may not have met the low-expenditure threshold, more hospital outpatient laboratories likely did not report private-payer data because they did not meet the majority of Medicare revenues threshold (i.e., the requirement that a laboratory receive more than 50 percent of its total Medicare payments from the CLFS or the physician fee schedule). For example, a hospital outpatient laboratory billing under its parent hospital's NPI likely would have revenues associated with inpatient and outpatient hospital

FIGURE 9–1

Time line of CMS's implementation of private payer–based CLFS payment rates



Note: CLFS (clinical laboratory fee schedule). While the initial data reporting period was January through March of 2017, CMS announced that it accepted data, without penalty, until May 30. CMS delayed the implementation of private payer–based rates from 2017 to 2018. The Further Consolidated Appropriations Act, 2020, delayed the second round of data reporting from 2020 to 2021. The Coronavirus Aid, Relief, and Economic Security Act of 2020 capped payment rate reductions at 0 percent in 2021, shifted the 15 percent per year cap on payment rate reductions from 2021 to 2023 to 2022 to 2024, and delayed the second round of data reporting from 2021 to 2022. While the data reporting period has been delayed until 2022, the data collection period for the second round of reporting has not changed, meaning laboratories will report private-payer rates based on claims from January 2019 through June 2019 during the 2022 data reporting period.

Source: MedPAC analysis of CMS regulations.

TABLE 9–3

CMS collected data from laboratories that accounted for about half of Medicare FFS CLFS spending in 2016, but reporting was inconsistent across different types of laboratories

Type of laboratory	Medicare FFS CLFS spending by laboratory type, 2016 (in millions)	Medicare FFS CLFS spending among laboratories that reported private-payer data to CMS, 2016 (in millions)	Share of Medicare FFS CLFS spending accounted for by laboratories that reported private-payer data to CMS
Independent	$3,762	$3,179	85%
Physician office	1,248	238	19
Hospital outpatient	1,741	45	3
Other	36	<1	1
Total	6,786	3,462	51

Note: FFS (fee-for-service), CLFS (clinical laboratory fee schedule). Components may not sum to totals because of rounding.

Source: MedPAC analysis of CLFS claims and private-payer data from CMS.

services that far outweigh revenues from the CLFS and physician fee schedule. Industry representatives have said that hospital outpatient laboratories commonly bill Medicare under their parent hospital's NPI.

Other issues may have caused additional underreporting. Laboratories that furnished a high share of tests to Medicare Advantage beneficiaries may have been excluded for technical reasons (see text box on CMS changes to increase the number of laboratories required to report data). Other laboratories may have not adequately complied with the law. Laboratories determine whether they are required to report their private-payer rates; CMS does not make this determination.[12] CMS has said that it does not have sufficient data to determine which laboratories are required to report (Office of Inspector General 2018). Nevertheless, some laboratories that were required to report likely did not do so.[13] For example, OIG identified 20 high-volume independent laboratories that likely were required to report but did not do so (Office of Inspector General 2018). PAMA gave CMS the authority to levy civil monetary penalties on laboratories for failure to report their private-payer data. However, to date, CMS has not exercised that authority.

For the second round of data reporting, CMS has made changes designed to address a few of these issues and increase the number of laboratories that are required to report private-payer data (see text box on CMS changes to increase the number of laboratories required to report data).

Representatives of the laboratory industry claim that private payer–based rates established through the first round of data reporting are fundamentally flawed because a disproportionate share of the data was reported by the independent laboratories owned by LabCorp and Quest, which are located in large urban areas and have lower cost structures than other laboratories. These representatives claim that, compared with independent laboratories, hospital outpatient and physician-office laboratories receive higher private-payer rates; thus, their underrepresentation in the first round of data reporting artificially lowered Medicare's payment rates.

Implementing private payer–based rates substantially lowered CLFS rates, but rates for some tests increased

We estimate that Medicare CLFS payment rates will decrease by an average of 24 percent once private-payer rates are fully phased in in 2025.[14] However, payment rate changes are not uniform across types of laboratory tests. The transition to private payer–based rates has resulted in much larger payment reductions for low-cost, routine tests compared with newer, more expensive tests.

CMS made changes designed to increase the number and type of laboratories required to report data in the future

CMS made two technical changes to the definition of laboratories that are required to report their private-payer rates for the second round of data reporting, which is scheduled to occur in 2022. These changes were made to increase the total number of laboratories required to report.

First, CMS made it easier for laboratories to meet the majority of Medicare revenues threshold by removing Medicare Advantage (MA) plan revenue from the denominator of the calculation. To meet the majority of Medicare revenues threshold, a laboratory must receive more than 50 percent of its total Medicare revenues from fee-for-service payments under the clinical laboratory fee schedule (CLFS) or the physician fee schedule. In the first round of data reporting, CMS instructed laboratories to include all Medicare revenue, including MA revenue, in the denominator of that calculation. Thus, laboratories that predominantly served MA beneficiaries were likely not required to report. In 2019, about 41 percent of Part B beneficiaries were enrolled in MA, and in some areas, more than 60 percent of Part B beneficiaries were enrolled in MA (Boards of Trustees 2020, Medicare Payment Advisory Commission 2020).

Second, CMS made it easier for hospital outreach laboratories to meet the majority of Medicare revenues threshold by determining their eligibility separate from their parent hospital. A hospital outreach laboratory is a hospital-based laboratory that furnishes laboratory tests to patients other than admitted inpatients or registered hospital outpatients (Centers for Medicare & Medicaid Services 2019b). CMS created a new pathway to require hospital outreach laboratories to report their private-payer data, based on Form CMS-1450 14x type of bill. If a hospital outreach laboratory bills under its own national provider identifier (NPI), then whether it meets the majority of Medicare revenues threshold is based on its own NPI (no change from the first round of data reporting). However, if a hospital outreach laboratory bills under its parent hospital's NPI, then whether it meets the majority of Medicare revenues threshold is determined using only the Medicare revenues from tests reported on the Form CMS-1450 14x type of bill. CMS-1450 is the standard form institutional providers, including hospitals, use to submit claims to Medicare and other payers. The 14x type of bill is used only for hospital outreach laboratory tests; other services are billed under other bill types.[15] Because the 14x type of bill is used only for hospital outreach laboratory tests, nearly all hospital outreach laboratories should meet the majority of Medicare revenues threshold for the next round of data reporting.[16]

The actual effect of these two revisions will not be fully understood until the second data reporting period, which is currently scheduled for January through March of 2022 (see Figure 9-1, p. 307). ■

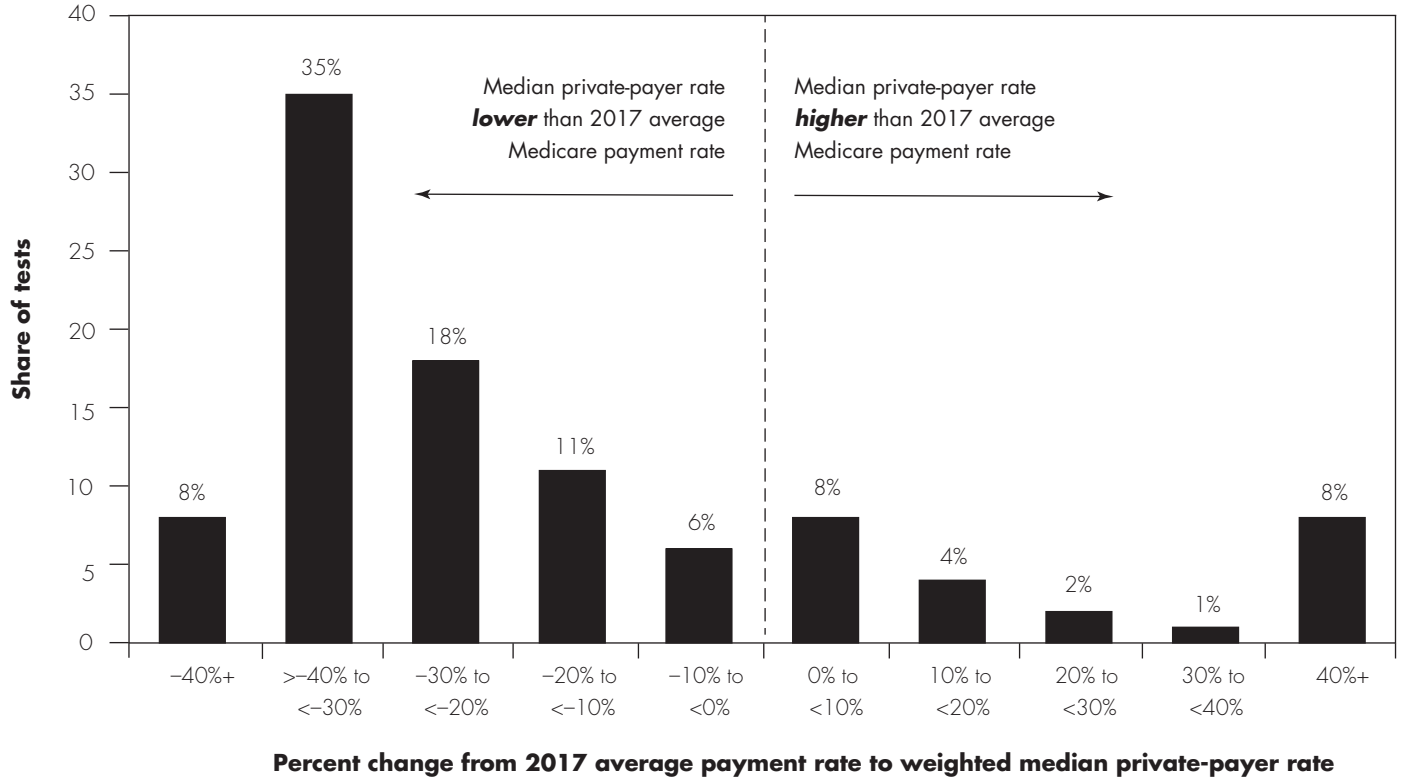
Average Medicare rates are projected to fall by 24 percent by 2025

To establish our projection of a 24 percent drop in average CLFS payment rates, we calculated the average payment rate for each CLFS test in 2017 and compared those calculations with the weighted median private-payer rate that CMS began using to set payment rates in 2018.[17] (The full 24 percent reduction will not be realized until 2025 because of the long phase-in of payment rate reductions.) We then weighted payment rate changes by Medicare CLFS spending for each CLFS test.

Private payer–based rates reported by laboratories were lower than Medicare's 2017 average payment rates for most (but not all) laboratory tests. The Commission found that reported private payer–based rates were lower than Medicare's 2017 average payment rates for 77 percent of laboratory tests, but higher for 23 percent of tests. Figure 9-2 (p. 310) shows a distribution of payment rate changes for the 1,184 laboratory tests we analyzed.

FIGURE 9–2

Private payer–based rates were lower than Medicare's 2017 average payment rate for most CLFS laboratory tests



Note: CLFS (clinical laboratory fee schedule). Payment rate changes reflect the fully phased-in weighted median private-payer rates.

Source: MedPAC analysis of Medicare CLFS claims and CMS-published weighted median payment rates.

Transitioning to private-payer rates has resulted in smaller price declines or price increases for newer, high-cost laboratory tests

The transition to private payer–based rates has resulted in much larger payment reductions for low-cost, routine tests compared with newer, more expensive tests. Once private payer–based rates are fully phased in, we estimate that payment rates for routine, low-cost tests, such as chemistry tests, will decline on average between 20 percent and 30 percent (Table 9-4). In contrast, on average, newer, more expensive tests will tend to have smaller payment rate declines (e.g., molecular pathology tests) or payment rate increases (e.g., genomic sequencing procedures and multianalyte assays with algorithmic analyses). For example, in the multianalyte assays with algorithmic analyses category, two tests with relatively high Medicare spending drove the results. The 2018 median private-payer rate for one test (HCPCS code 81528) was nearly identical to Medicare's average payment rate in 2017 at just over $500 per test, and for a second test (HCPCS code 81519), the median private-payer rate was about 15 percent above Medicare's average payment amount ($3,873 vs. $3,374) (data not shown).

While the field of genetic testing is still nascent and changing rapidly, these early results suggest that private payers may not be able to negotiate lower prices for newer, more expensive laboratory tests in the same

TABLE 9–4

On average, transitioning to private payer–based rates has led to large reductions for routine tests but not for newer, high-cost tests

Type of test	Number of tests (unique HCPCS codes)	Average percent change from 2017 payment rate to weighted median private-payer rate
Multianalyte assays with algorithmic analyses	18	12.2%
Genomic sequencing procedures	13	1.0
Molecular pathology	117	–11.7
Other	90	–18.0
Organ- or disease-oriented panels	10	–19.4
Screening procedures	8	–21.2
Urinalysis	10	–23.7
Microbiology	206	–27.1
Immunology	186	–27.1
Drug assays	47	–27.3
Chemistry	385	–27.8
Hematology and coagulation	94	–30.5
Total	1,184	–24.2

Note: HCPCS (Healthcare Common Procedure Coding System). Payment rate changes reflect the fully phased-in weighted median private-payer rates. Average percent change was weighted by 2017 Medicare fee-for-service spending for each HCPCS code. HCPCS codes were excluded from this analysis if they did not have Medicare fee-for-service utilization in 2017 or a weighted median private-payer rate. After these exclusions, this analysis included more than 99 percent of CLFS spending in 2017.

Source: MedPAC analysis of carrier file, outpatient file, and CMS-published weighted median payment private-payer data.

manner as they do for more routine tests. In the private market, payers have responded to the growth in laboratory spending, especially among new high-cost tests, using an array of utilization management tools, most of which are not available in FFS Medicare (see text box, pp. 312–313).

Use of CLFS tests has been stable under new payment rates, but spending increased

Representatives of the laboratory industry cautioned that the new market-based payment rates would "create severe disruptions in access to laboratory services" (American Clinical Laboratory Association 2017). However, overall utilization of CLFS laboratory tests has remained relatively unchanged following CMS's implementation of private payer–based rates, suggesting stable access to CLFS laboratory tests among Medicare FFS beneficiaries. In contrast to relatively flat utilization rates, Medicare CLFS spending has increased after CMS implemented private payer–based rates. This spending increase was predominantly driven by new, high-cost tests.

From 2017 to 2019, the average number of laboratory tests Medicare FFS beneficiaries received increased by less than 1 percent, from 12.8 tests to 12.9 tests per beneficiary.[18] For most categories of laboratory tests, utilization changed modestly from 2017 to 2019. However, during this period, utilization increased rapidly for four categories of tests—molecular pathology, multianalyte assays with algorithmic analyses, proprietary laboratory analyses, and genomic sequencing procedures—that comprise many new, high-cost tests (Table 9-6, p. 314).[19]

Private payers increasingly use utilization management tools to address laboratory spending

Private payers (including Medicare Advantage plans) employ a variety of utilization management tools to reduce spending on laboratory tests. These tools are largely unavailable in fee-for-service Medicare. Table 9-5 describes common utilization management tools private payers use to manage their laboratory benefits.

Many tools used by private payers to manage their laboratory benefits have long been used for other types of health care services or products, such as physician-administered drugs and advanced imaging services. For example, prior authorization is one of the most common tools payers use to manage their laboratory benefits. Given the administrative burden associated with prior authorization, payers more commonly use this tool for new, high-cost laboratory tests rather than low-cost, routine tests.

Private payers have also recently invested in efforts to shift laboratory tests away from higher cost providers toward lower cost providers, typically by shifting utilization from hospital outpatient and physician-office laboratories to independent laboratories. UnitedHealthcare's designated diagnostic provider program, under which laboratories must agree to certain efficiency and quality requirements to continue being paid by the plan, is one high-profile example of this trend (Bannow 2021). Payers justify these efforts by noting that some laboratories receive payment rates that are far higher, often five times higher, than other laboratories. Such high prices can drive up enrollee premiums and, because cost sharing for laboratory tests is more common among the commercially insured population than in Medicare, directly increase costs for patients as well.

Finally, one area of increasing activity is the use of laboratory benefit managers (LBMs). Similar to pharmacy benefit managers, LBMs contract with payers to manage laboratory test utilization. LBMs often create and manage payers' coverage policies for laboratory tests and can influence pricing and site of service. While LBMs have not been studied as well as pharmacy benefit managers, recent research has found that three of the four largest commercial payers use LBMs, suggesting their use is prevalent (Phillips and Deverka 2019). ■

(continued next page)

While overall utilization of CLFS tests remained stable, Medicare CLFS spending increased after CMS implemented private payer–based rates. From 2017 to 2019, Medicare CLFS spending increased from $7.1 billion to $7.5 billion, an increase of 6 percent (Table 9-6, p. 314).[20] This increase was predominantly driven by spending increases for new, high-cost tests in the molecular pathology, multianalyte assays with algorithmic analyses, proprietary laboratory analyses, and genomic sequencing procedures categories. For other categories of tests (e.g., organ- or disease-oriented panels), expected declines in Medicare spending associated with the transition to private payer–based rates had yet to occur as of 2019 or were smaller than anticipated. A small number of technical issues drove the higher-than-expected spending for these tests (see text box, pp. 316–317).

Independent laboratories gained market share after CMS implemented private payer–based rates

The number of CLFS laboratory tests billed by independent laboratories increased after CMS implemented private payer–based rates, while the number performed by hospital outpatient and physician-office laboratories decreased slightly. From 2017 to 2019, the number of laboratory tests per beneficiary billed by independent laboratories rose by 2.4 percent, while the number of tests per beneficiary billed by hospital

Private payers increasingly use utilization management tools to address laboratory spending (cont.)

TABLE 9–5 **Common private-payer utilization management tools for laboratory tests**

Utilization management tool	Description
Preferred laboratory network	Payers work with specific laboratories and providers to create a network of preferred contractors to provide services at reduced rates for patients.
Prior authorization	Payers must authorize the use of a service before the patient receives it. Typically, this tool is used for certain high-cost genetic and molecular pathology laboratory tests.
Laboratory test registry	Laboratories must submit unique test codes for each service they provide and bill the appropriate code on all claims. Each test code submitted on a claim must match a corresponding laboratory test registration provided in advance.
Genetic counseling	Patients must meet with a genetic counselor to become fully informed about complex genetic tests and make an informed decision about testing.
Laboratory test formulary	Payers create a system of tiers of approval for laboratory tests, where higher tiers need additional approval and can have higher patient cost sharing associated with them.
Cost sharing*	Payers create a system of variable cost sharing based on the type of laboratory test or the type of laboratory furnishing the test.
Bundled payments*	Payers use claim-editing systems that bundle the payment for individual laboratory tests into one payment to recognize the efficiencies associated with furnishing multiple, similar tests at the same time.

Note: *Differential cost sharing and bundled payments are often considered pricing rather than utilization management tools. We include them in this list because private payers employ them to manage their laboratory benefit, and the Medicare fee-for-service program generally does not.

Source: MedPAC analysis of private-payer policies.

outpatient and physician-office laboratories both fell by 1.0 percent (Table 9-7, p. 315). The shift that occurred after private payer–based rates were implemented was slight and may be at least partially related to a longer-term trend of LabCorp and Quest increasing their market shares (data not shown).

Medicare CLFS spending for tests billed by independent laboratories also increased after CMS implemented private payer–based rates, while spending associated with hospital outpatient and physician-office laboratories decreased. From 2017 to 2019, spending for independent laboratories rose by 16.1 percent, while spending for hospital outpatient and physician-office laboratories fell by 9.0 percent and 5.8 percent, respectively (Table 9-7, p. 315). Spending among independent laboratories grew because these laboratories billed for nearly all the new, high-cost tests for which spending increased over the period. For example, in 2019, independent laboratories accounted for 93 percent of all CLFS spending for molecular pathology tests, whereas hospital outpatient and physician-office laboratories accounted for only 6 percent and 1 percent, respectively (data not shown). Meanwhile, Medicare spending fell for hospital outpatient and physician-office laboratories because of the small utilization declines and because their billings were concentrated in routine, low-cost tests (e.g., chemistry tests) that experienced payment rate reductions under the new private payer–based rates.

Despite the modest shift in site of service toward independent laboratories (and away from hospital outpatient and physician-office laboratories), relatively flat CLFS laboratory test utilization from 2017 to 2019 suggests that the introduction of private payer–based

TABLE 9–6

From 2017 to 2019, overall use of CLFS tests remained relatively steady, but Medicare spending increased due to greater use of new, high-cost tests

	2017		2019		Percent change (2017–2019)	
Type of test	Medicare spending (in millions)	Tests per beneficiary	Medicare spending (in millions)	Tests per beneficiary	Medicare spending	Tests per beneficiary
Chemistry	$2,692	5.16	$2,327	5.21	–13.5%	1.0%
Organ- or disease-oriented panels	1,052	2.64	1,057	2.64	0.5	0.0
Drug assays	988	0.33	944	0.34	–4.4	0.3
Molecular pathology	240	0.03	844	0.05	251.5	79.4
Microbiology	618	0.96	739	1.09	19.6	13.4
Hematology and coagulation	615	2.18	481	2.05	–21.8	–6.1
Multianalyte assays with algorithmic analyses	290	0.01	461	0.02	59.1	64.4
Immunology	375	0.67	343	0.70	–8.6	5.1
Proprietary laboratory analyses	N/A	N/A	116	0.00	N/A	N/A
Screening procedures	91	0.11	73	0.11	–19.4	–0.8
Urinalysis	87	0.69	70	0.68	–18.7	–2.5
Genomic sequencing procedures	23	0.00	46	0.00	104.5	126.0
Other	31	0.03	27	0.03	–12.5	–6.0
Total	7,102	12.81	7,531	12.90	6.0	0.7

Note: CLFS (clinical laboratory fee schedule), N/A (not applicable). We used the number of Part B fee-for-service beneficiaries to calculate the number of tests per beneficiary. From 2017 to 2019, the number of Part B beneficiaries decreased by 1.4 percent. Data from 2019 may be slightly less complete than 2017 data because the data were pulled before the standard 18-month runoff of claims was complete. The proprietary laboratory analyses category did not have substantial utilization in 2017. The drug assay category includes therapeutic drug assays, definitive drug testing, and presumptive drug class screening. Categories with at least $40 million in Medicare spending in 2019 are listed separately. The "other" category includes several categories of tests, such as cytopathology tests. Components may not sum to totals because of rounding.

Source: Acumen LLC analysis of Medicare CLFS claims for MedPAC and 2020 annual report of the Boards of Trustees of the Medicare trust funds.

payment rates had little impact on FFS beneficiaries' access to laboratory tests. However, the rate reductions were not fully implemented in 2018 and 2019. To the extent that the payment changes ultimately result in utilization changes, the effect might not become evident for several years. In addition, beginning in 2020, the coronavirus pandemic has substantially affected the laboratory industry by temporarily depressing demand for routine laboratory tests and creating demand for a new class of tests for COVID-19. These changes likely will complicate longitudinal analyses of laboratory test utilization patterns.

Clinical laboratories played a critical role in responding to the coronavirus pandemic. Some industry stakeholders have suggested that the pandemic has negatively affected the finances of laboratories and that the payment rate reductions under PAMA should therefore be suspended. However, the Commission's review of the financial reports of several large, publicly traded laboratories suggests that COVID-19 testing has been extremely profitable for laboratories that perform a high volume of such tests, and the increased income associated with COVID-19 testing has more than offset lost income from pandemic-related declines in routine testing and PAMA-mandated payment rate reductions. Laboratories that did not perform many

TABLE 9–7

After private payer–based rates were implemented, CLFS spending and utilization increased for independent laboratories but decreased for hospital outpatient and physician-office laboratories

	2017		2019		Percent change (2017–2019)	
Laboratory type	Medicare spending (in millions)	Tests per beneficiary	Medicare spending (in millions)	Tests per beneficiary	Medicare spending	Tests per beneficiary
Independent	$4,057	6.2	$4,710	6.3	16.1%	2.4%
Hospital outpatient	1,711	3.7	1,557	3.7	–9.0	–1.0
Physician office	1,284	2.8	1,210	2.8	–5.8	–1.0
Other	50	0.1	54	0.1	7.8	7.3
Total	7,102	12.8	7,531	12.9	6.0	0.7

Note: CLFS (clinical laboratory fee schedule). We used the number of Part B fee-for-service beneficiaries to calculate the number of tests per beneficiary. Data from 2019 might be slightly less complete than 2017 data because the data were pulled before the standard 18-month runoff of claims was complete. "Other" laboratories include those located in settings such as nursing facilities or end-stage renal disease facilities.

Source: Acumen LLC analysis of Medicare CLFS claims for MedPAC and 2020 annual report of the Boards of Trustees of the Medicare trust funds.

COVID-19 tests were likely negatively affected financially by the pandemic, as declines in these laboratories' routine testing were not offset by higher revenue from COVID-19 testing. (See text box on financial performance, p. 319).

Sampling laboratories could produce accurate rates with less burden on laboratories

Ahead of the second round of data reporting, the Congress directed the Commission to examine alternatives to CMS's initial methodology used to set 2018 payment rates. We worked with a third-party contractor, RTI International (RTI), to examine survey methodologies that could be used to collect a representative and statistically valid sample of independent, hospital outreach, and physician-office laboratories.[21] (We present a brief summary of RTI's work in this chapter; the full report is available on the Commission's website (RTI International 2021).)

RTI concluded that collecting private-payer data by surveying a sample of laboratories could produce accurate estimates of private-payer rates for independent, hospital outreach, and physician-office laboratories. RTI also found that using a survey could reduce the number of laboratories that would be required to report private-payer data by up to 70 percent. While RTI's analyses demonstrate the feasibility of surveying laboratories to collect private-payer data, the work should be considered a proof of concept; further analysis would be needed if a survey were implemented to set Medicare payment rates.

RTI evaluated two sampling methods

RTI evaluated two sampling methods: stratified sampling and Maximal Brewer Selection (MBS). Stratified sampling is a commonly used sampling method that divides the sampling frames into mutually exclusive and exhaustive subpopulations, known as sampling strata. In this case, the sampling strata are the HCPCS codes and the sampling units are the laboratories. Typically, in stratified sampling, sampling units are unique to each sampling strata. For example, if sampling people by age and sex categories, each person (the sampling unit) is in only one age-sex category (sampling strata). However, when sampling laboratories, most laboratories (the sampling unit) bill for multiple HCPCS codes (sampling strata). RTI concluded that the fact that laboratories commonly bill for many HCPCS codes created challenges for its stratified sampling process.

Increased use of new, high-cost tests and technical implementation issues boosted Medicare spending after private payer–based rates were implemented in 2018

In contrast to expectations, Medicare clinical laboratory fee schedule (CLFS) spending increased after CMS implemented private payer–based rates. From 2017 to 2019, Medicare CLFS spending rose from $7.1 billion to $7.5 billion, an increase of 6 percent. We identified four key factors that drove this increase from 2017 to 2019:

1. ***Rapid rise in the use of new, high-cost tests*—**The rapid rise in the use of new, high-cost laboratory tests was the main driver of the growth in CLFS expenditures after private payer–based rates were implemented. However, the new rates did not directly cause higher expenditures on such tests. Rather, the introduction and broader adoption of new, high-cost tests is a secular trend in the laboratory industry that predates the transition to private payer–based rates (e.g., these tests also contributed to growth in Medicare spending from 2016 to 2017, before private payer–based rates were implemented). Greater use of the high-cost tests could also be due in part to fraud and abuse: In 2019, the Department of Justice alleged that numerous defendants fraudulently billed Medicare more than $2.1 billion for cancer genetic tests (Department of Justice 2019).
2. ***Phase-in of payment rate reductions using national limitation amounts*—**In 2018 and 2019, payment rate reductions were capped at 10 percent per year. CMS calculated the 10 percent decrease on the basis of national limitation amounts. However, before the reductions, Medicare paid less than the national limitation amount for some tests, so a 10 percent reduction from the national limitation amount could actually result in a payment rate increase. For example, for a comprehensive metabolic panel (Healthcare Common Procedure Coding System (HCPCS) code 80053), Medicare's 2017 national limitation amount was $14.49 and the private payer–based rate was $9.08, 37 percent less. After accounting for the phase-in, Medicare's payment rate in 2018 was $13.04. However, because Medicare paid for many metabolic panels at rates lower than the national limitation amount, Medicare's actual average payment rate in 2017 was $11.16. So from 2017 to 2018, Medicare's payment per test increased from $11.16 to $13.04.[22] While this issue increased Medicare spending during the 2017 to 2019 period, the effect is transient and lessens each year as payment rate reductions are phased in.

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The second sampling method RTI evaluated, MBS, does not require explicit stratification by HCPCS code. Previously, MBS has been used to collect data for commodities produced by farms, in which farms can produce different sets of commodities. Since this previous application of MBS is analogous to collecting data for HCPCS codes billed by laboratories, in which laboratories can bill different sets of HCPCS codes, MBS is likely a more appropriate method to survey laboratories than a stratified sampling method.[23]

Because RTI believed MBS was better suited to collect private-payer laboratory rates, we present results for only that survey methodology. (The full results for both MBS and stratified sampling methods are included in RTI's report (RTI International 2021).)

A survey of laboratories could produce accurate results and reduce the burden of reporting on laboratories

RTI assessed whether a survey could produce accurate results by measuring the extent to which their simulated survey resulted in unbiased estimates of payment rates. To

Increased use of new, high-cost tests and technical implementation issues boosted Medicare spending after private payer–based rates were implemented in 2018 (cont.)

3. ***Immediate implementation of payment rate increases*—**In contrast to payment rate reductions, payment rate increases were effective immediately. Medicare's payment rates increased for about one in five tests under the private payer–based system. For example, from 2017 to 2018, Medicare's payment rate for one molecular pathology test (HCPCS code 81295) went from about $153 to $382 per test, which boosted Medicare expenditures by about $26 million in 2018 and 2019.

4. ***Separate payment instead of bundled rates for more tests***—Before 2018, Medicare paid a bundled rate for 23 chemistry tests when 2 or more of them were performed as a group, referred to as "panel tests." Some combinations of these chemistry tests are common enough that they have their own HCPCS codes. For example, renal function panels consist of 10 chemistry tests and are billed under a distinct HCPCS code (80069) (Centers for Medicare & Medicaid Services 2020a). Other combinations of chemistry tests do not have separate HCPCS codes from their component tests. Before 2018, CMS used a claims processing algorithm to pay for these tests on a bundled basis instead of paying for each individual HCPCS code. This payment mechanism recognized the efficiencies associated with performing multiple tests at the same time and paid laboratories only modestly more for each additional test.

   For the second group of tests (i.e., those without a separate HCPCS code), CMS has asserted that the Protecting Access to Medicare Act of 2014 requires each test to be paid separately, based on private-payer rates. As a result, Medicare stopped paying bundled rates for such tests in 2018, and Medicare's average payment for these tests increased.[24] For example, from 2017 to 2018, Medicare's average payment per test for an assay of phosphorus (HCPCS code 84100) climbed by about 71 percent, from $3.31 to $5.65. In aggregate, from 2017 to 2018, Medicare spending for these 23 chemistry tests increased by 79 percent, from $109 million to $196 million, and then declined to about $164 million in 2019 as payment rate reductions continued to be phased in.

   While the increase in Medicare spending for tests that were once paid on a bundled basis has been moderate, the unbundled rates likely do not accurately reflect the costs of furnishing these tests. To address this issue, the Congress could consider giving CMS authority to bundle payments for these and other tests that the Secretary deems appropriate. Further, to the extent that private payers increasingly bundle payments for multiple tests, giving CMS this additional authority could help ensure that the Medicare's payment rates accurately reflect private-payer rates in the future. ■

measure bias, RTI calculated the difference between the mean payment rate estimate from a sample of laboratories and the mean payment rate from all laboratories and then divided that difference by the mean payment rate from all laboratories. For example, to measure the bias for a given HCPCS code among independent laboratories, RTI calculated the difference between the mean payment rate estimate from a sample of independent laboratories (which RTI simulated using Medicare claims and private-payer data) and the mean payment rate from all independent laboratories and then divided that difference by the mean payment rate from all independent laboratories.[25]

Given time and resource limitations, RTI calculated the potential bias for 10 HCPCS codes for samples of independent, hospital outreach, and physician-office laboratories.[26] For these 10 tests, RTI found that MBS produced unbiased results; that is, the empirical bias was

TABLE 9–8

Simulated survey of physician-office laboratories resulted in unbiased estimates of payment rates for 10 illustrative laboratory tests

	Minimum number of laboratories sampled for each HCPCS code		
HCPCS code	**10**	**20**	**30**
80053 (2,508 laboratories with data)			
Number of laboratories in sample	957	1,303	1,523
Empirical bias	0.000	0.000	0.002
80061 (2,498 laboratories with data)			
Number of laboratories in sample	947	1,291	1,508
Empirical bias	–0.004	–0.001	–0.001
82378 (338 laboratories with data)			
Number of laboratories in sample	206	254	278
Empirical bias	0.001	–0.001	–0.002
83036 (2,671 laboratories with data)			
Number of laboratories in sample	934	1,289	1,520
Empirical bias	–0.002	–0.002	0.003
84445 (54 laboratories with data)			
Number of laboratories in sample	44	47	51
Empirical bias	0.000	0.000	0.000
86003 (155 laboratories with data)			
Number of laboratories in sample	107	124	138
Empirical bias	–0.018	–0.003	0.001
86148 (19 laboratories with data)			
Number of laboratories in sample	18	19	19
Empirical bias	0.000	0.000	0.000
87150 (12 laboratories with data)			
Number of laboratories in sample	11	12	12
Empirical bias	0.000	0.000	0.000
87902 (33 laboratories with data)			
Number of laboratories in sample	30	32	33
Empirical bias	0.000	0.000	0.000
88262 (10 laboratories with data)			
Number of laboratories in sample	10	10	10
Empirical bias	0.000	0.000	0.000

Note: HCPCS (Healthcare Common Procedure Coding System). Empirical bias was calculated as the difference between the mean payment rate estimate from the sample and the mean payment rate from the sampling frame divided by the mean payment rate from the sampling frame. This table contains results for physician-office laboratories using Maximal Brewer Selection; see the full contractor report for the results for independent and hospital outreach laboratories and for results using stratified sampling (RTI International 2021). RTI restricted physician-office laboratories to those with spending greater than or equal to $25,000 in 2018.

Source: RTI International analysis of 2018 Medicare claims and CMS private-payer data.

close to zero. The empirical bias is close to zero when the mean payment rates of the surveyed laboratories were nearly identical to the mean payment rates of all laboratories of the same type. For example, for a comprehensive metabolic panel test (HCPCS code 80053), RTI found that the mean payment rate of the surveyed physician-office laboratories was nearly identical to the mean for all physician-office laboratories—that is, the empirical bias ranged from 0.000 to 0.002 (Table 9-8). In addition to the empirical bias, Table 9-8 also shows the total number of laboratories that billed Medicare for each test in 2018 and the number of sampled laboratories when the minimum number of laboratories surveyed for all CLFS HCPCS codes was set at 10, 20, or 30.[27]

Financial performance of laboratories during the coronavirus pandemic

During the coronavirus pandemic, revenues and operating profits have increased substantially for the two largest laboratory companies in the U.S. From 2019 to 2020, LabCorp's revenue increased by 32 percent ($7.0 to $9.3 billion), and the company's operating profit increased by 143 percent ($1.1 to $2.6 billion) (Laboratory Corporation of America 2021a).[28] Over the same period, Quest's revenue increased by 22 percent ($7.7 to $9.4 billion), and the company's operating profit increased by 60 percent ($1.2 to $2.0 billion) (Quest Diagnostics 2021a). In 2020, LabCorp's and Quest's operating profit margins were 28 percent and 21 percent, respectively.

When the coronavirus pandemic began in the spring of 2020, routine clinical laboratory testing declined substantially, by 50 percent or more for some laboratories (Laboratory Corporation of America 2020b). However, routine clinical laboratory testing rebounded throughout the year, with estimates suggesting volume was less than 10 percent below prepandemic levels as of the fourth quarter of 2020 (Laboratory Corporation of America 2021b). COVID-19 testing increased throughout 2020 and peaked in the fourth quarter. As a result, laboratory revenues and profits were lower earlier in 2020 and much higher later in the year. For example, compared with the fourth quarter of 2019, LabCorp's and Quest's operating profits in the fourth quarter of 2020 increased by 345 percent and 119 percent, respectively (Laboratory Corporation of America 2021b, Quest Diagnostics 2021b).

These financial results suggest that, for these two laboratories, COVID-19 testing has been very profitable and has more than offset the losses attributable to lower routine testing volume and Medicare's payment rates reductions stemming from the Protecting Access to Medicare Act of 2014. As a result, LabCorp and Quest announced they will return all the funding they received through the Coronavirus Aid, Relief, and Economic Security Act, $132 million and $138 million, respectively (Laboratory Corporation of America 2020a, Quest Diagnostics 2020).

While LabCorp's and Quest's financial performance has improved substantially during the coronavirus pandemic, other laboratories may be less profitable in general or may not have similarly benefited financially from the increase in volume associated with COVID-19 testing. For example, one national laboratory had a negative operating margin in 2019, but because the company performed a large volume of COVID-19 tests, their laboratory revenues increased 76 percent from 2019 to 2020 and the company was profitable in 2020 (OPKO Health Inc. 2021). In addition, laboratories that perform few COVID-19 tests, and thus face lower routine testing volume without the benefit of increased COVID-19 testing, have likely been negatively financially affected by the coronavirus pandemic. ■

Beyond the underrepresentation of physician-office and hospital outpatient laboratories, one of the main concerns regarding the first round of private-payer data reporting was the burden it created for laboratories. Stakeholders from the laboratory industry have said that complying with the data reporting requirements cost one company over $1 million and more than 20,000 hours of employee time. In addition, CMS exempted low-expenditure laboratories, partially out of concern that complying with the requirement might be burdensome.

Given the concerns regarding burden, RTI assessed the burden of a survey. Once a laboratory was surveyed, the burden of data reporting would largely be the same as during the first round of data reporting, so RTI measured burden in terms of the number of laboratories expected to be surveyed under varying assumptions.

Relative to the total number of laboratories, RTI found that using a survey to set Medicare rates could reduce the number of laboratories that would be required to submit

TABLE 9–9

Collecting private-payer data through a survey could reduce the reporting burden on laboratories

Type of laboratory	Number of laboratories in sampling frame	Number of HCPCS codes with at least one test	Minimum number of laboratories for each HCPCS code	Expected number of laboratories sampled	Share of laboratories expected to be sampled
Independent	2,772	1,197	10	867	31%
			20	1,118	40
			30	1,287	46
Hospital outreach	3,321	1,105	10	1,139	34
			20	1,572	47
			30	1,828	55
Physician office	4,627	1,023	10	1,381	30
			20	1,935	42
			30	2,305	50

Note: HCPCS (Healthcare Common Procedure Coding System). This table contains results for Maximal Brewer Selection; see the full contractor report for the results for stratified sampling (RTI International 2021). RTI restricted physician-office laboratories to those with spending greater than or equal to $25,000 in 2018. The expected sample size for Maximal Brewer Selection is for all HCPCS codes.

Source: RTI International analysis of 2018 Medicare claims data.

private-payer data by up to 70 percent. For example, assuming that data were collected from at least 10 laboratories for each CLFS HCPCS code, only 30 percent of physician-office laboratories would need to be surveyed (1,381 of 4,627) (Table 9-9). While these results suggest many laboratories would not be required to submit their private-payer data if CMS used a survey to collect data, further accommodations could be made to exempt certain classes of laboratories. For example, the numbers in Table 9-9 exclude physician-office laboratories with less than $25,000 in Medicare CLFS spending in 2018.

RTI's report demonstrates that collecting private-payer rates from a representative sample of independent, hospital outreach, and physician-office laboratories is feasible and could substantially reduce the burden on laboratories. However, further analysis would be needed to comprehensively explore this alternative rate-setting process.

In addition to using a survey to collect private-payer rates, some stakeholders have suggested other alternatives to setting Medicare's CLFS payment rates (see text box on alternative methods, pp. 322–323).

Basing CLFS rates on a representative sample of laboratories would increase spending

To examine the extent to which incorporating data from a representative sample of independent, hospital outpatient, and physician-office laboratories would affect Medicare's CLFS spending, we first analyzed how hospital outpatient and physician-office laboratories' private-payer rates compared with those received by independent laboratories. If hospital outpatient and physician-office laboratories receive higher private-payer rates than independent laboratories, increasing hospital outpatient and physician-office laboratories' representation in the data CMS uses to calculate CLFS payment rates could result in higher Medicare spending for laboratory tests.

To study private-payer rates across types of laboratories, we primarily relied on private-payer data reported to CMS and supplemented those data with commercial insurer data from FAIR Health and a large, national preferred

TABLE 9–10

Physician-office and hospital outpatient laboratories reported higher private-payer rates than independent laboratories in 2016

	Payment rates as a percentage of independent laboratory rates (among top 100 CLFS laboratory tests in 2016)	
	Physician-office laboratories	**Hospital outpatient laboratories**
5th percentile	110%	106%
25th percentile	150	142
Weighted average	153	145
75th percentile	164	154
95th percentile	193	167

Note: CLFS (clinical laboratory fee schedule). Other types of laboratories also received higher private-payer rates compared with independent laboratories but were excluded from this table because they accounted for less than 1 percent of Medicare CLFS spending in 2016. The average is weighted by 2016 Medicare spending for each laboratory test. A small number of the top 100 HCPCS codes were excluded from this analysis because they were exclusively furnished by independent laboratories.

Source: MedPAC analysis of carrier file, outpatient file, and CMS-collected private-payer data.

provider organization. We focused our analyses on the 100 laboratory tests with the highest Medicare CLFS spending in 2016. These 100 tests accounted for 85 percent of all CLFS spending in 2016.[29]

Our analysis of private-payer data reported to CMS found that hospital outpatient and physician-office laboratories were paid, on average, rates that were 45 percent and 53 percent higher, respectively, than those paid to independent laboratories (Table 9-10).[30] While results varied for each of the 100 laboratory tests we examined, hospital outpatient and physician-office laboratories were paid higher rates than independent laboratories for nearly all of the tests we examined. For example, at the 5th and 95th percentile of the tests we examined, physician-office laboratories were paid rates 10 percent higher and 93 percent higher, respectively, compared with independent laboratories (Table 9-10).

While we focused primarily on comparisons between types of laboratories, payment rates also varied within laboratory types.[31] Variation of private-payer rates within types of laboratories has important implications when considering the potential effects of increasing reporting from hospital outpatient and physician-office laboratories. For example, during the first round of data reporting, independent laboratories reported about 90 percent of the volume for lipid panel tests (HCPCS code 80061), and hospital outpatient and physician-office laboratories accounted for nearly all the remaining 10 percent. Independent laboratories had a weighted median payment rate of $10.86 per test, much lower than the weighted median payment rates for hospital outpatient ($17.14) and physician-office ($18.24) laboratories (Figure 9-3, p. 324). Based on the combination of these data, CMS set the weighted median payment rate at $11.23, slightly above the median independent laboratory rate. On the one hand, these results suggest that enhanced data reporting from hospital outpatient and physician-office laboratories could increase weighted median payment rates, even if independent laboratories account for most of the volume because of variations in payment rates within laboratory types. On the other hand, these results underscore that, even with enhanced data reporting from hospital outpatient and physician-office laboratories, weighted median payment rates are likely to be substantially below the median payment rates for hospital outpatient and physician-office laboratories because the rates would be set using most of the volume from independent laboratories and the left-hand part of the price distribution for hospital outpatient and physician-office laboratories.

CMS collected data from laboratories that accounted for the vast majority of Medicare CLFS spending associated with independent laboratories (see Table 9-3, p. 308). In contrast, physician-office laboratories and hospital

Alternative methods for setting Medicare payment rates for laboratory tests

Stakeholders have suggested additional alternative methods to set Medicare's payment rates for laboratory tests, including competitive bidding and relying on private-payer databases.

Competitive bidding is a process by which suppliers submit bids to provide certain products or services to Medicare beneficiaries, and Medicare sets its payment rates based on those bids. Most notably, a competitive bidding program has been used in Medicare to pay for durable medical equipment (DME). Competitive bidding has substantially reduced Medicare and beneficiary spending on DME since the program began in 2011. While some have suggested the design of the bidding system is flawed, others have noted that there is sparse empirical evidence to suggest the program has negatively affected beneficiaries' health outcomes (Centers for Medicare & Medicaid Services 2016a, Government Accountability Office 2018, Government Accountability Office 2016, O'Donnell et al. 2020). Some stakeholders believe that such a bidding program could also be implemented for laboratory tests.

The Congress mandated a competitive bidding demonstration project for clinical laboratory tests in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The law required CMS to conduct a demonstration project on the application of competitive bidding for clinical laboratory tests that would otherwise be paid under the Medicare Part B clinical laboratory fee schedule. CMS designed a demonstration to determine whether competitive bidding could be used to provide clinical laboratory tests at rates below current Medicare payment rates while maintaining quality and access to care. A U.S. district court granted an injunction blocking implementation of the first demonstration project scheduled to take place in the San Diego area after local laboratories alleged that the demonstration would result in substantial economic harm (Congressional Research Service 2008). The Medicare Improvements for Patients and Providers Act of 2008 eliminated the competitive bidding project. Therefore, while a competitive bidding demonstration for laboratory tests has been explored, the concept has not yet been actually tested in Medicare.

Proponents of competitive bidding suggest that many laboratory tests are highly automated and largely undifferentiated products that are suitable for competitive bidding. Further, they note that, in markets with many suppliers, competitive bidding has

(continued next page)

outpatient laboratories were underrepresented in the data. We therefore analyzed FAIR Health data and data from a large, national preferred provider organization to explore whether the physician-office and hospital outpatient laboratory rates reported to CMS were representative of the broader private-payer market for physician-office and hospital outpatient laboratory tests.

In each of the two alternative sources of private-payer data, physician-office laboratories' payment rates were lower (relative to independent laboratories) than those reported to CMS. For example, in one database, we found that, among the top 100 CLFS laboratory tests in 2016, physician-office laboratories were paid rates 38 percent higher than rates paid to independent laboratories, a difference that was slightly smaller than the 53 percent difference between rates paid to physician-office laboratories relative to independent laboratories in CMS's data.

The hospital outpatient laboratory payment rates reported to CMS in the first round of data collection may be representative of private-payer rates paid to hospital outreach laboratories but might be lower than the rates paid to all hospital outpatient laboratories in the private market. The small number of hospital outpatient laboratories that reported data to CMS in the first round of

Alternative methods for setting Medicare payment rates for laboratory tests (cont.)

a demonstrated history of driving down costs for the Medicare program and beneficiaries.

Opponents of competitive bidding for laboratory tests object to the characterization of laboratory tests as undifferentiated commodities. In contrast, they suggest that laboratory tests are not suited for competitive bidding precisely because they are highly specialized services. Further, they claim that competitive bidding would limit the number of laboratories serving the community and negatively impact access to care.

Still others suggest that setting Medicare rates based on private-payer rates, as CMS currently does, is one way to harness the benefits of competition without implementing a bidding system in Medicare. While not a formal bidding system, private payers essentially require laboratories to engage in a passive form of bidding when laboratories negotiate prices for tests and network coverage. In that vein, the first round of competitive bidding for DME lowered Medicare rates to be more similar to commercial rates obtained through price negotiations (Newman et al. 2017). So, while competitive bidding may produce larger savings than relying on private-payer rates, relying on private-payer rates may achieve a substantial amount of the cost savings without having to design a complex bidding system.

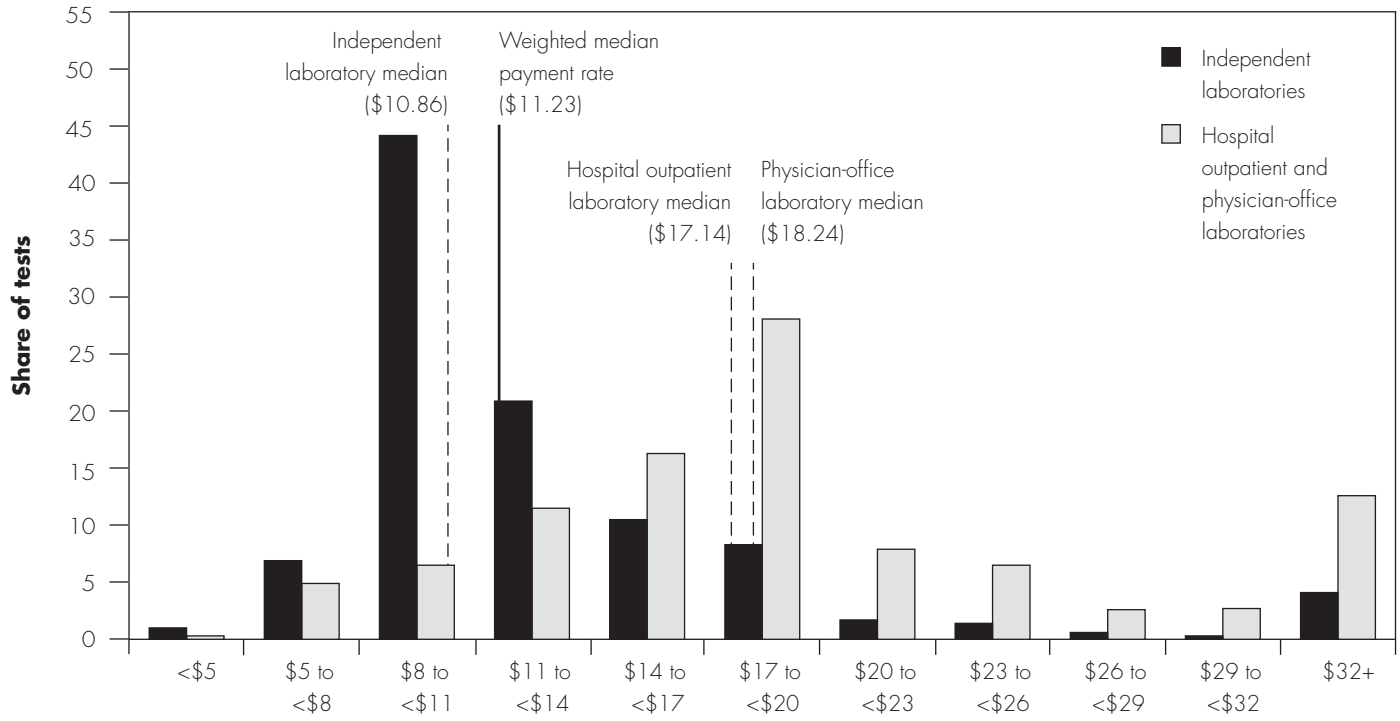
Other stakeholders have suggested that CMS could use third-party private-payer databases to collect private-payer rates for laboratory tests rather than having laboratories report rates. Databases of private-payer claims, such as FAIR Health and the Health Care Cost Institute, could inform CMS's rate-setting process. Private-payer databases are useful tools and allow many stakeholders, including academic researchers, the Commission, and others, to more fully understand how health care is delivered through private plans. However, relying on such databases as a means to set payment rates has some potential drawbacks. For example, CMS has no authority to compel payers to submit data to these private-payer databases, so payers may choose not to submit data if it is not beneficial to them. Additionally, CMS would have limited ability to ensure the quality of the data or that the content of the data is uniquely tailored to the needs of the program. For example, in the second round of data reporting, CMS specifically designed a reporting pathway to receive data from a specific type of hospital laboratory—hospital outreach laboratories. If Medicare were reliant on private-payer databases to set rates, it is unclear whether such customizations would be possible in all cases. ■

reporting are likely somewhat unique: Each of them billed under their own NPI and likely acted as hospital outreach laboratories. Our conversations with private payers suggest that they prefer (when possible) to negotiate rates for hospital outreach tests separately from hospitals' other lines of business in order negotiate lower payment rates for outreach tests than for tests performed on hospital patients. In our two other private-payer databases, we found that, among the top 100 CLFS tests in 2016, hospital outpatient laboratories were paid private-payer rates that were, on average, 116 percent (according to one database) and 331 percent (according to the other database) higher than the rates paid to independent laboratories. Therefore, the data reported to CMS might be a reasonable approximation of private-payer rates paid to hospital outreach laboratories, but the rates are likely lower than private-payer rates paid for all separately payable hospital outpatient laboratory tests.

Given these findings, we relied on the private-payer rates laboratories reported to CMS in order to simulate the effects of collecting private-payer rates from a representative sample of laboratories. Also, given the uncertainty surrounding private-payer rates for hospital outpatient laboratories, we simulated the combined effects of collecting private-payer rates from a representative sample of all laboratories and hospital outpatient laboratories reporting private-payer rates that

FIGURE 9–3

In 2016, independent laboratories had lower median private-payer rates than hospital outpatient and physician-office laboratories for lipid panels, but private-payer payment rates varied substantially within laboratory types



Note: The share of tests furnished within each payment rate range is calculated separately for (1) independent laboratories and (2) hospital outpatient and physician-office laboratories. The figure combines data for hospital outpatient and physician-office laboratories for simplicity; their weighted median private-payer rates are calculated separately. Figure represents data on lipid panel tests (HCPCS code 80061).

Source: MedPAC analysis of private-payer laboratory rates, carrier file, and outpatient file data from CMS.

were 50 percent higher than the rates hospital outpatient laboratories reported in the first round of data reporting.[32]

We ran four simulations on the 100 laboratory tests with the highest Medicare CLFS spending in 2016 to estimate the effect of setting Medicare's payment rates on a representative sample of laboratories. We used varying assumptions regarding private-payer payment rates and volume to demonstrate the potential effects of collecting data from different types of laboratories.[33] (See text box, pp. 326–327, for more details on our simulation methodology.)

We found that Medicare spending on the top 100 CLFS tests could increase by 10 percent if Medicare payment rates were based on (1) the payment rates laboratories reported to CMS in the first round of data reporting and (2) a volume of tests for independent, physician-office, and hospital outreach laboratories that was equal to the share of tests furnished by these types of laboratories under Medicare's CLFS. Using the same volume assumptions but assuming that hospitals' private-payer rates were 50 percent higher than those reported to CMS in the first round of data reporting, we found that Medicare spending could increase by 13 percent for the top 100 tests.

We ran two additional simulations with the same payment rate assumptions but assumed a volume of tests for independent, physician-office, and all hospital outpatient laboratories (not just outreach laboratories)

that was equal to the share of tests furnished by these types of laboratories under Medicare's CLFS. Under these assumptions, we found that Medicare spending could increase by 15 percent and 24 percent, respectively, relative to the spending that would result from CMS's current rates.

Basing CLFS rates on a representative sample of private-payer rates may be undesirable in certain circumstances

Medicare should set payment rates that ensure beneficiary access to high-quality laboratory tests while maintaining incentives for laboratories to be efficient to make the best use of taxpayers' and beneficiaries' resources. To do so, Medicare should ensure that payment rates are sufficient to cover the costs of relatively efficient laboratories but should not increase rates solely to accommodate laboratories that receive high private-payer rates. These principles suggest policymakers should consider not basing Medicare's laboratory payment rates on a representative sample of private-payer rates in two circumstances—for routine laboratory tests when higher private-payer rates likely reflect providers' negotiating leverage rather than the costs of furnishing the tests and for new, high-cost tests for which private payers may have a limited ability to negotiate rates effectively.

For many routine tests, the transition to private payer–based rates has substantially reduced Medicare's payment rates. Some stakeholders have argued that Medicare's rates are now too low and should reflect private-payer rates from a broader array of laboratories in the future. However, our analyses of the effects of collecting private-payer rates from a representative sample of laboratories suggest policymakers should be cautious about incorporating private-payer rates for certain types of laboratories. Based on our analyses of multiple private-payer databases and conversations with industry stakeholders, we believe that the higher rates hospital outpatient and physician-office laboratories are paid for laboratory tests often stem from their enhanced negotiating leverage with private payers based on their dominant market positions for nonlaboratory services, such as inpatient hospital services. Incorporating these higher rates likely does not further the cause of determining appropriate payment rates for laboratory tests and may expose the Medicare program to potentially large spending increases. This caution is especially warranted for private-payer rates associated with hospital outpatient laboratories that do not function as outreach laboratories, as our analyses suggest that their private-payer rates might far exceed the rates hospitals reported in the first round of data reporting.[34]

Setting Medicare payment rates to cover the costs of relatively efficient providers will likely ensure broad access to laboratory tests. Indeed, through the first two years of setting Medicare rates based on private-payer data, the use of laboratory tests remained relatively unchanged among Medicare FFS beneficiaries, suggesting stable access. As the transition to private payer–based rates continues, policymakers should monitor access to laboratory tests both in the aggregate and for particular areas of concern, such as among rural beneficiaries or for particular types of tests.[35] To the extent potential access issues arise, policymakers should consider implementing targeted payment adjustments instead of incorporating private-payer data from all laboratories that are paid high private-payer rates.[36] As our analyses show, incorporating private-payer data from such laboratories could substantially increase Medicare spending but would still result in setting payment rates far below the private-payer rates paid to those laboratories. Thus, incorporating more data from laboratories that receive high private-payer rates could result in Medicare overpaying more efficient laboratories while still paying hospital outpatient and physician-office laboratories less than the rates that they could negotiate with payers based on their market power. In contrast, targeted payment adjustments could help ensure access in particular circumstances without overpaying for all laboratory tests.

For new, high-cost tests, a complete reliance on private-payer data might produce suboptimal Medicare payment rates. Such tests are often innovative and create real benefits for beneficiaries, but private payers may have a limited ability to negotiate rates effectively for them. When PAMA was passed in 2014, nearly all laboratory tests billed under Medicare were relatively low-cost, routine tests. Given that mix of tests, relying on private-payer rates was expected to reduce (and has reduced) Medicare's payment rates for many laboratory tests. However, in the years since PAMA was enacted, new laboratory tests have been introduced that are typically more expensive, complex, and proprietary than more established tests. The result is that Medicare's framework for setting laboratory payment rates was designed at a time when the type of

Methodology for simulating the effects of basing CLFS payment rates on a representative sample of laboratories

To estimate the effect of setting Medicare's payment rates on a representative sample of laboratories, we used the private-payer data reported to CMS during the first round of data reporting to establish the distribution of private-payer laboratory rates. We used Medicare clinical laboratory fee schedule (CLFS) laboratory claims data to estimate the volume of tests independent, physician-office, and hospital outpatient laboratories would have furnished if they had performed the same share of private-payer tests as they did under Medicare's CLFS. Specifically, we took the following steps:

Estimating volume

- We summarized the volume of private-payer tests submitted for each Healthcare Common Procedure Coding System (HCPCS) code by the type of laboratory. We classified each laboratory in the private-payer data as an independent, physician-office, or hospital outpatient laboratory by merging CMS's private-payer data with Medicare CLFS claims data and characterizing a laboratory based on the place of service (for carrier file claims) or type of bill (for outpatient claims) associated with a plurality of the laboratory's Medicare CLFS spending.
- Because we found that laboratories that submitted private-payer laboratory data to CMS accounted for 84.5 percent of CLFS volume associated with independent laboratories in 2016, we multiplied the volume of private-payer data reported by independent laboratories by (1/0.845) for each HCPCS code to arrive at an imputed private-payer volume for independent laboratories.[37]
- For each HCPCS code, we then divided the imputed private-payer volume for independent laboratories by the share of Medicare CLFS volume independent labs furnished in 2016. (Thus, if independent laboratories reported, for example, 500 units of a given test in the private-payer data and independent laboratories furnished 50 percent of those tests under Medicare, we assumed that the total private-payer volume for that HCPCS code should be 1,000—or 500/0.5.)
- We then multiplied the imputed total private-payer volume for each HCPCS code by the share of volume each type of laboratory furnished under Medicare in 2016. This figure represents the total private-payer volume each type of laboratory would have reported if the share of private-payer volume they furnished were equal to the share of tests they furnished under Medicare.
- To determine the volume that we needed to add to the private-payer data already reported to CMS, we subtracted the volume of tests that was actually reported in the first round of data reporting from the volume each type of laboratory should have reported if they had furnished the same share of tests for private payers as they did for Medicare (calculated in the previous step).

Estimating the distribution of payment rates

After we established the amount of volume to be added to the CMS private-payer data, we determined what private-payer rates we should associate with the additional volume. The effect on the weighted median payment rate is sensitive to the distribution of payment rates (not just what the median is). So, to impute payment rates, we relied on the distribution of private-payer rates (by type of laboratory and HCPCS code) that was reported to CMS. Specifically, we took the following steps:

- For each combination of HCPCS code and laboratory type, we calculated 99 price points based on every percentile in the distribution of reported private-payer rates (i.e., each percentile from the 1st to the 99th became a price point).[38] This calculation resulted in just under 3,000 prices—99 price points multiplied by 100 HCPCS codes multiplied by 3 laboratory types.[39]

(continued next page)

Methodology for simulating the effects of basing CLFS payment rates on a representative sample of laboratories (cont.)

- We then divided the volume to be added evenly among the price points. For example, if we found that we needed to add 198 units for a given combination of a HCPCS code and laboratory type, we added 2 units (198/99) to each of our price points to mimic the distribution of the data submitted to CMS.
- We then stacked the data that CMS received with the added volume (and payment rates) and recalculated a volume-weighted median for each of the 100 HCPCS codes we studied.

Effect on Medicare spending

To determine the effect on spending of the recalculated weighted median payment rates, we multiplied actual 2018 Medicare CLFS utilization by the CMS-established weighted median payment rate (without accounting for the phase-in of payment rate reductions) to determine a baseline of spending. We then multiplied the same utilization figures by our recalculated weighted median payment rates to estimate spending using our alternative rates. We calculated the difference between these two spending amounts to estimate the net effect on Medicare spending.

We ran the above steps four separate times with slight variations in assumptions regarding (1) whether to include all CLFS tests furnished by hospital outpatient laboratories or only those furnished by hospital outreach laboratories (type of bill 14x) and (2) the payment rates reported by hospital outpatient laboratories (Table 9-11). ■

TABLE 9–11

Basing Medicare payment rates on a representative sample of laboratories would increase CLFS spending, but the magnitude of the increase varies based on certain assumptions

Simulation number	Volume assumptions	Payment rate assumptions	Estimated effect on Medicare spending in 2018 (relative to fully phased-in weighted median payment rates)
1	Private-payer volume matches share of Medicare CLFS tests furnished by independent, physician-office, and hospital outreach laboratories (type of bill 14x)	Payment rates match rates reported to CMS in the first round of data reporting	10% increase
2		Payment rates match rates reported to CMS for independent and physician-office laboratories; hospital outpatient laboratory rates 50% higher than rates reported to CMS	13% increase
3	Private-payer volume matches share of Medicare CLFS tests furnished by independent, physician-office, and all CLFS hospital outpatient laboratories	Payment rates match rates reported to CMS in the first round of data reporting	15% increase
4		Payment rates match rates reported to CMS for independent and physician-office laboratories; hospital outpatient laboratory rates 50% higher than rates reported to CMS	24% increase

Note: CLFS (clinical laboratory fee schedule). To estimate the effect of 50 percent higher hospital outpatient private-payer rates, we multiplied each of our 99 hospital price points by 1.5.

Source: MedPAC analysis of private-payer laboratory rates, carrier file, and outpatient file data from CMS.

tests that are now driving the growth in Medicare spending largely did not exist or were in their infancy. While the market for these newly developed tests is still nascent and changing rapidly, our analyses suggest that private payers may not be able to negotiate lower prices for newer, more expensive laboratory tests in the same manner they do for more routine tests. In the future, the Commission will explore ways to improve how Medicare sets prices for new high-cost technologies, including certain pharmaceuticals, devices, and laboratory tests. ■

Endnotes

1 CMS regulates all laboratory testing (except research) performed on humans in the U.S. through CLIA (Centers for Medicare & Medicaid Services 2020a). The objective of the CLIA program is to ensure quality laboratory testing.

2 One notable exception is that critical access hospitals are paid on a cost basis for many laboratory tests.

3 National limitation amounts were initially set at 115 percent of the median of all local fee schedule amounts, but the Congress incrementally lowered this cap to generate savings (Office of Inspector General 2009). Since 1998, national limitation amounts were set at 74 percent of the median of all local fee schedule amounts (or 100 percent of the median for new tests performed on or after 2001).

4 The Office of Inspector General found that 89 percent of Medicare-covered laboratory tests were paid at national limitation amounts in 2007 (Office of Inspector General 2009).

5 Even after the Protecting Access to Medicare Act of 2014 was implemented, CMS has used similar crosswalking and gapfilling processes to set payment rates for new tests until private-payer data are collected.

6 In addition to the Affordable Care Act's reductions of 1.75 percent per year from 2011 to 2015, the Middle Class Tax Relief and Job Creation Act of 2012 reduced CLFS payment rates by 2 percent in 2013 (Public Law 112–96).

7 If the actual list charge of a new ADLT is greater than 130 percent of the weighted median private-payer rate, CMS recoups the difference between the actual list charge and 130 percent of the weighted median (Centers for Medicare & Medicaid Services 2018).

8 CMS chose to implement a low-expenditure threshold instead of a low-volume threshold because some laboratories account for substantial CLFS spending by performing a relatively low volume of high-cost laboratory tests.

9 This definition means that a laboratory must report each unique payment rate for each HCPCS code and its associated volume. For example, if a laboratory were paid for 1,500 tests associated with one HCPCS code during the data collection period and the laboratory were paid $10 per test for the first 1,000 tests and $9 per test thereafter, the laboratory would report two rows of data for the same HCPCS code—1,000 tests at $10 each and 500 tests at $9 each. For the purpose of data reporting, PAMA defined "private payers" as a health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service Act; group health plan as defined in Section 2791(a)(1) of the Public Health Service Act; Medicare Advantage plan; or Medicaid managed care organization.

10 If no private-payer data are reported, CMS uses crosswalking or gapfilling to set payment rates. These processes are also used for new HCPCS codes that are introduced between data collection periods.

11 Similarly, in the first round of data reporting, CMS collected private-payer data from laboratories that accounted for 45 percent of Medicare CLFS volume in 2016. To calculate these statistics, we merged private-payer data reported to CMS with Medicare CLFS claims data based on national provider identifiers.

12 Laboratories also had to attest to the accuracy of the information they submitted. CMS did not substantially edit or trim the data to account for outliers. CMS did make two trims—removing data (1) where the reported payment rates were zero and (2) from two taxpayer identification numbers (which reported for their component NPIs) that reported total spending instead of payment rates.

13 In contrast, other laboratories reported data when they likely were not required to do so. For example, about 37 percent of the laboratories that reported may have been below the low-expenditure threshold (Centers for Medicare & Medicaid Services 2017).

14 This estimate applies only to tests billed under the CLFS in 2017 and does not include tests that were introduced after 2017.

15 For example, a hospital that bills Medicare for a service covered under the outpatient prospective payment system would typically bill Medicare using a 13x type of bill.

16 In other words, both the numerator and denominator should consist almost entirely of the same laboratory revenues.

17 We relied on average payment rates in 2017 instead of national limitation amounts because using national limitation amounts may overstate the magnitude of payment rate reductions because some Medicare administrative contractors paid laboratories rates below national limitation amounts for some tests. Our estimate excludes laboratory tests that did not have Medicare CLFS utilization in 2017, a weighted median private-payer rate, and other laboratory tests and related services not priced based on private-payer data, including venipuncture, travel expenses, and tests billed under "unlisted" HCPCS codes.

18 We also examined alternative measures of utilization—number of claims, claim lines, and beneficiaries who received at least one CLFS test in a given year. All of these measures suggest that utilization of CLFS laboratory tests remained relatively unchanged from 2017 to 2019. For example, 82 percent of Part B FFS beneficiaries received at least one CLFS laboratory test in 2017 and 2019. From 2017 to 2019, the aggregate number of CLFS laboratory tests billed decreased by 0.7 percent, from 431 million to 428 million. However, over the same period, the number of Part B FFS beneficiaries decreased by 1.4 percent, from 33.6 million to 33.2 million (Boards of Trustees 2020).

19 While the use of these new, high-cost tests increased rapidly (on a percentage basis), their (absolute) level of utilization remained relatively low. Therefore, their increased use did not substantially increase overall CLFS laboratory test utilization.

20 Throughout this report, we present claims data processed through June 3, 2020. While substantially complete, 2019 data could be slightly less complete than prior years' data.

21 The extent to which CMS has the legal authority to conduct a survey of laboratories to set Medicare CLFS rates rather than the process they have established is beyond the scope of this report.

22 We calculated Medicare's payment per test in 2017 ($11.16) by dividing total Medicare spending by the total number of tests billed. The 2018 payment per test ($13.04) is the national payment rate.

23 In MBS, for each HCPCS code in each sampling frame (i.e., physician-office, independent, or hospital outreach laboratory), RTI calculated the HCPCS code–specific probability of selection for a laboratory. For each laboratory, the MBS probability of selection would be the largest HCPCS code–specific probability of selection from all the HCPCS codes for which the laboratory has reported testing volume. The expected sample size for all HCPCS codes can then be calculated as the sum of the MBS probabilities of selection.

24 Some stakeholders were concerned that, for panels with separate HCPCS codes, laboratories could increase their Medicare payments substantially by separately billing for the components of panel tests instead of using the panel HCPCS codes. However, our analyses suggest that laboratories did not substantially change their billing behavior from 2017 to 2019 to take advantage of this potential "loophole." CMS has also clarified that some unbundling activities are impermissible. Specifically, CMS has stated that if a laboratory performs all tests included in a panel with a separate HCPCS code, the laboratory shall report the HCPCS code for the panel and not the component tests (Centers for Medicare & Medicaid Services 2020b, Centers for Medicare & Medicaid Services 2019a).

25 RTI also calculated another measure of empirical bias using the difference between the median payment rate weighted by testing volume from the sample and that from the sampling frame divided by the weighted median payment rate from the sampling frame. The full results are available in the contractor report.

26 These 10 HCPCS codes included three of the five top codes in terms of testing volume in 2018 and codes with large differences between the weighted median price for independent and hospital outreach laboratories and between independent and physician-office laboratories.

27 The choice of requiring a minimum of 10, 20, or 30 laboratories was a judgmental decision. RTI did not test larger minimum sample sizes since the empirical bias they found was already minimal.

28 We present revenue and operating profits from LabCorp's laboratory diagnostics business and exclude information relating to the company's drug development business.

29 For tests outside the top 100, certain types of laboratories were more likely not to furnish a particular test or to furnish a low volume of the test. The inclusion of low-volume tests often led to improbable results (e.g., hospital outpatient laboratories being paid 300 times the rate of independent laboratories). After constructing various rules to exclude outliers, we found that the ratio of rates paid to physician-office laboratories and hospital outpatient laboratories relative to independent laboratories was similar among the top 100 CLFS tests compared with all CLFS tests. Therefore, for simplicity, we present the results for only the top 100 CLFS tests.

30 These results are weighted based on 2016 Medicare CLFS spending. We determined whether a laboratory was an independent, physician-office, or hospital outpatient laboratory by merging CMS's private-payer data with CLFS claims data and by characterizing a laboratory based on the place of service (for carrier file claims) or type of bill (for outpatient claims) associated with a plurality of the laboratory's Medicare CLFS spending.

31 For example, we divided all independent laboratories into two groups—large independent laboratories and all other independent laboratories—and found that all other independent laboratories were paid private-payer rates that were, on average, 18 percent higher than the rates paid to large independent laboratories for the top 100 CLFS tests in 2016.

32 We chose to simulate the effects of increasing hospital outpatient rates by 50 percent because doing so makes the rates reported to CMS closer to the range of hospital outpatient rates we observed in private-payer databases. For example, in the data reported to CMS, we found that hospital outpatient laboratories were paid 45 percent higher rates than independent laboratories, on average. Increasing the hospital outpatient rates that were reported to CMS by 50 percent results in the hospital outpatient rates being just over double the rates of independent laboratories (i.e., $1.45 \times 1.50 = 2.18$).

33 These estimates are limited to the top 100 CLFS tests in 2016 and do not reflect effects on total CLFS spending. In addition, these estimates are not intended to reflect the likely effects of the second round of data reporting.

34 Hospital outreach and physician-office laboratories also likely benefit from negotiating leverage associated with nonlaboratory services. However, some private payers appear to be able to negotiate for hospital outreach laboratory tests separately from all other hospital services, and physician groups tend to have less negotiating leverage with private payers relative to hospitals. These facts may help explain why private-payer rates for tests furnished by these types of laboratories substantially exceeded independent laboratory rates but were below the extremely high rates received by some hospital outpatient laboratories.

35 Any complete analysis of rural beneficiaries' access to laboratory tests should account for the fact that a higher share of rural beneficiaries' laboratory tests are paid on a cost basis through critical access hospitals and not under the CLFS. For example, in 2018, we found that rural beneficiaries had, on average, fewer tests billed under the CLFS compared with urban beneficiaries (10.1 vs. 13.6 tests per Medicare FFS beneficiary). However, after incorporating tests billed through critical access hospitals, rural and urban beneficiaries' use of clinical laboratory tests appeared more similar.

36 CMS may not currently have the statutory authority to make such adjustments, so additional legislative authority may be needed.

37 We also reran the simulation without this step (that is, assuming independent laboratories reported 100 percent of their private-payer data) and found similar results.

38 When calculating the percentiles, we weighted based on reported private-payer volume.

39 We added additional independent laboratory volume to our simulations. For this added volume, we assumed that the price distribution was the same as all independent laboratories. To the extent that large (lower priced) independent laboratories were more likely to report their private-payer rates than all independent laboratories, this assumption is likely conservative.

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