U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

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Potential Vulnerabilities in CMS Oversight of Medicare Add-on Payments for COVID-19 Tests Show That Oversight of Incentive Payments Could Be Improved

Key Takeaways

Our analysis of data for January 2021 through June 2022 showed the following:

- ✓ Medicare paid more than $339 million for add-on payments for COVID-19 tests.
- ✓ More than 4 million enrollees received COVID-19 tests for which Medicare made add-on payments.
- ✓ Medicare paid approximately 9,000 laboratories for add-on payments for COVID-19 tests.
- ✓ More than two-thirds of laboratories (68 percent) that billed Medicare at least once for the add-on payment during our audit period billed for that payment with all of their COVID-19 tests.

We identified the following potential vulnerabilities related to CMS's oversight of add-on payments for COVID-19 tests: (1) CMS requirements related to supporting documentation for add-on payments were vague, and laboratory documentation was inconsistent; and (2) CMS and Medicare Administrative Contractors did not perform adequate reviews of claims for add-on payments.

Purpose of This Data Brief

The goal of testing for COVID-19 is to quickly and accurately identify infected individuals to enable treatment or isolation and prevent spread of the virus. In October 2020, the Centers for Medicare & Medicaid Services (CMS) announced that, effective January 2021, the Medicare payment for COVID-19 tests that used advanced, high-throughput technology would be lowered from $100 to $75, with a $25 add-on payment for tests that met certain criteria related to the turnaround times of the test results. CMS established the add-on payment to incentivize laboratories to promptly complete COVID-19 tests. Therefore, we consider the add-on payment to be an incentive payment.

Our preliminary analysis of Medicare claims data for COVID-19 tests showed potential vulnerabilities in laboratories' compliance with Medicare requirements when billing for COVID-19 tests, including billing for the add-on payment.

The objective of this audit was to analyze data related to add-on payments for COVID-19 tests and determine whether there were any vulnerabilities in CMS's oversight of these payments.

The information in this data brief may help CMS, the Medicare Administrative Contractors (MACs), and other stakeholders in considering how to oversee add-on payments and in developing rules and regulations related to incentive payments in general, especially in the event of a future public health emergency (PHE).

Background

Medicare Program

The Medicare program provides health insurance to people aged 65 and over, people with disabilities, and people with end-stage renal disease. Medicare Part B provides insurance for preventative and medical services, including clinical laboratory tests (such as COVID-19 diagnostic tests).

CMS administers the Medicare program and contracts with MACs to, among other things, process and pay Medicare Part B claims, conduct reviews and audits, safeguard against fraud and abuse, and educate providers on Medicare billing requirements. A provider generally submits claims to the MAC that serves the jurisdiction in which the provider is physically located.

COVID-19 Testing

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) declared a national PHE as a result of confirmed U.S. cases of COVID-19, a highly contagious disease caused by the SARS-CoV-2 coronavirus. On May 11, 2023, the PHE officially ended. Although the emergency phase of the response to COVID-19 has ended, responding to the spread of COVID-19 is still a public health priority for HHS.

The goal of testing for COVID-19 is to quickly and accurately identify infected individuals to enable treatment or isolation and prevent spread of the coronavirus. In a COVID-19 diagnostic test, a specimen is taken from a person's nose or mouth to test for the presence of a COVID-19 infection. There are two main types of COVID-19 tests: nucleic acid amplification tests (NAATs) and antigen tests.[1] NAATs are most often performed in a laboratory. Antigen tests are rapid tests that produce results in about 15 to 30 minutes and include self-tests (i.e., at-home tests).

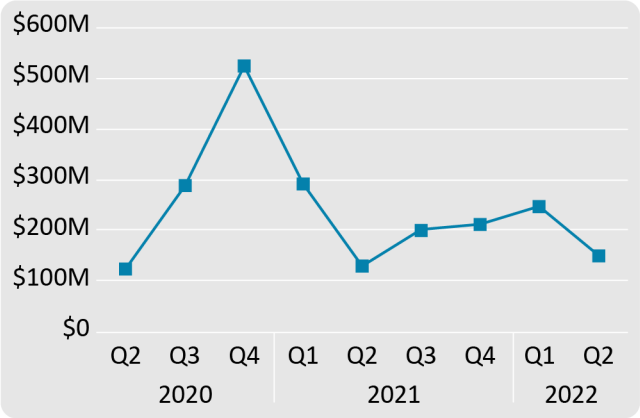
Throughout the PHE, multiple factors affected the amount of COVID-19 testing that laboratories performed, such as surges in COVID-19 cases caused by different variants of the virus and the increased availability of at-home COVID-19 tests.

[1] NAATs, such as polymerase chain reaction-based tests (commonly known as PCR tests), detect viral genetic material, and antigen tests detect proteins called antigens from the virus.

Medicare Coverage of Payments for COVID-19 Tests

To receive Medicare payment for a COVID-19 test, a laboratory submits a claim, which contains details regarding each provided service (42 CFR § 424.5(a)(5)). Providers, such as laboratories, must use the appropriate procedure codes on claim forms for outpatient services, including COVID-19 tests. CMS created multiple Healthcare Common Procedure Coding System (HCPCS) codes for laboratories to use to bill for COVID-19 diagnostic tests. On April 14, 2020, CMS introduced two new HCPCS codes (U0003 and U0004) for COVID-19 clinical diagnostic laboratory tests that use high-throughput technologies (Administrative Ruling CMS-2020-1-R).[2] High-throughput technology involves highly sophisticated equipment that requires more intensive technician training and more time-intensive processes to ensure test quality. Because of these increased resources, CMS set the payment amount for each of the two HCPCS codes at $100.[3]

Figure 1: Payments Increased Rapidly for Tests Billed With HCPCS Codes U0003 and U0004 During the Third and Fourth Quarters of 2020



From April 2020 through June 2022, Medicare spent $2.2 billion for COVID-19 tests billed with HCPCS codes U0003 and U0004. Payment for tests billed with these HCPCS codes increased significantly from April through December 2020. After December 2020, payments initially dropped off sharply and fluctuated through June 2022. See Figure 1.

Medicare Coverage of Add-on Payments for COVID-19 Tests

In an October 15, 2020, press release, CMS announced that it would provide a payment incentive for laboratories to deliver timely COVID-19 test results.[4] CMS determined that timelier test results benefit individual patients, their immediate communities, and the public at large.

Impact on Enrollees of Faster Turnaround Times for COVID-19 Tests

In its October 15, 2020, press release, CMS stated that it was working to ensure that enrollees who test positive for COVID-19 are alerted quickly so they can self-isolate and receive medical treatment. Faster turnaround times for COVID-19 tests enable enrollees and physicians to act quickly and decisively with respect to decisions about treatment and the need for physical isolation and contact tracing.

[2] HCPCS code U0003 is billed when using a specific technique to test for COVID-19, and HCPCS code U0004 is billed when any technique is used to test for COVID-19.

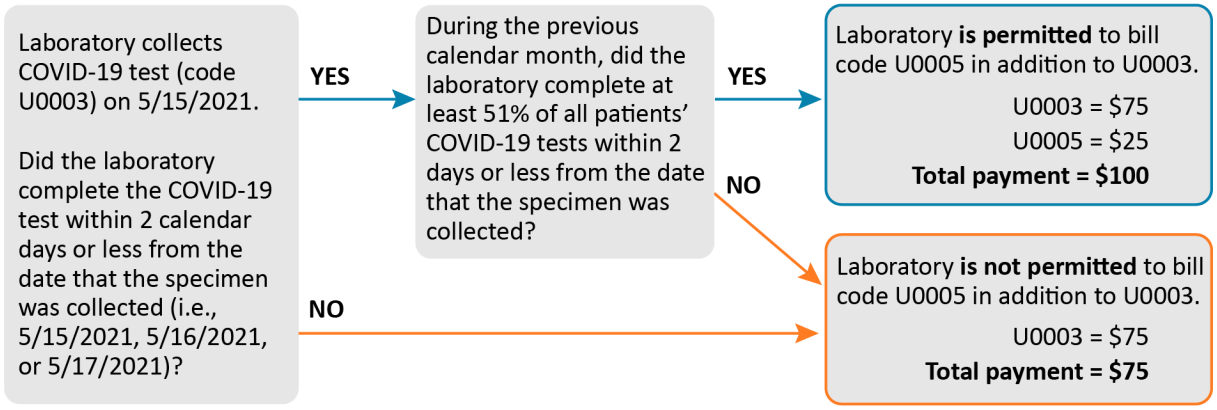
[3] Payment for COVID-19 diagnostic tests performed without high-throughput technology was set at $51.

[4] Available at https://www.cms.gov/newsroom/press-releases/cms-changes-medicare-payment-support-faster-covid-19-diagnostic-testing. Accessed on Feb. 27, 2024.

CMS issued Administrative Ruling CMS-2020-1-R2, which amended Administrative Ruling CMS-2020-1-R, effective January 1, 2021. This ruling lowered the base payment amount from $100 to $75 for a COVID-19 diagnostic test run on high-throughput technology (i.e., billed with either HCPCS codes U0003 or U0004) and established a $25 add-on payment (i.e., billed with add-on HCPCS code U0005) to be made to a laboratory for such a test if the laboratory: (1) completed the test within 2 calendar days or less from the date that the specimen was collected and (2) completed the majority of its COVID-19 diagnostic tests that used high-throughput technology in the previous calendar month within 2 calendar days or less from the date that the specimen was collected (for all of its patients, not just its Medicare patients).[5] According to this amended Administrative Ruling, CMS considers the test to be "completed" when the results of the test are finalized and "ready for release." This amended Administrative Ruling does not provide further detail on when a test is considered ready for release or how that relates to the results being delivered to the patient or the patient's treating provider.

Figure 2 shows an example of how a laboratory would determine whether to bill add-on HCPCS code U0005.

Figure 2: Example of How a Laboratory Determines Whether To Bill the Add-on Code for a COVID-19 Test



According to CMS's Administrative Ruling CMS-2020-1-R2, in the event of an audit or a medical review, a laboratory needs to produce documentation of timeliness of the COVID-19 diagnostic tests performed based on its performance in the month preceding the month identified by the date of service for the corresponding COVID-19 diagnostic test (represented by HCPCS codes U0003 or U0004). A laboratory also needs to produce documentation to support the add-on payment established in this amended Administrative Ruling (i.e., to show that the COVID-19 test associated with the add-on payment as well as the majority of its COVID-19 tests in the previous calendar month were completed within 2 calendar days or less), even if such documentation would not otherwise be required under Medicare regulations for the COVID-19 test itself. To determine its performance in the preceding month, a laboratory would identify the turnaround times for all of its COVID-19 diagnostic tests performed using high-throughput

[5] For the purposes of Administrative Ruling CMS 2020-1-R2, "majority" means 51 percent or greater.

technologies and would determine the percentage of tests that were completed within 2 calendar days of the specimen being collected.

Because the PHE ended on May 11, 2023, HCPCS codes U0003, U0004, and U0005 are no longer payable for dates of service on or after May 12, 2023.

CMS and Medicare Administrative Contractor Oversight of Laboratories' Billing of the Procedure Code for Add-on Payments for COVID-19 Tests

CMS and the MACs did some monitoring of the utilization of add-on HCPCS code U0005 and performed some medical reviews, but the reviews generally did not focus on turnaround times for COVID-19 tests billed with HCPCS code U0005. Although there were not specific requirements regarding what documentation laboratories needed to produce to support the add-on payment, CMS officials stated that they would expect to review all documentation in support of a laboratory's billed services, which could include obtaining patient medical records from the laboratory or the provider that ordered the COVID-19 test. CMS issued the document *COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for Service (FFS) Billing*, which provides guidance on payment, billing, turnaround time, and other requirements related to HCPCS code U0005.[6]

Data Used To Develop This Data Brief

Our primary source of data for this data brief was Medicare Part B claims for add-on payments for COVID-19 tests billed with add-on HCPCS code U0005. We identified approximately $339.4 million in Medicare payments made to 9,380 laboratories for approximately 13.6 million add-on payments for COVID-19 tests that had dates of service from January 1, 2021, through June 30, 2022 (audit period). We also used summary data on Medicare Part B claims for COVID-19 tests billed with HCPCS codes U0003 or U0004 (with or without HCPCS code U0005) and identified approximately $1.2 billion in Medicare payments made to 12,811 laboratories for approximately 16.7 million COVID-19 tests that had dates of service during our audit period.

Number of Laboratories That Billed Medicare for Add-on Payments and for COVID-19 Tests

9,380 laboratories billed add-on payments for COVID-19 tests with HCPCS code U0005 at least once

12,811 laboratories billed for COVID-19 tests with HCPCS codes U0003 or U0004

We used these claims data to perform our analysis of add-on payments for COVID-19 tests paid under Medicare Part B. We also used the add-on HCPCS code U0005 data to judgmentally select 10 laboratories. To select the laboratories, for each laboratory in the HCPCS code U0005 data, we first identified the MACs that processed the claims, the total payments for HCPCS code U0005, and the percentage of tests for which the laboratory added HCPCS code U0005 to its

[6] Available at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf. Accessed on Feb. 27, 2024.

billing of COVID-19 tests using HCPCS codes U0003 or U0004. Then, we judgmentally selected the 10 laboratories to ensure that each MAC was represented and that the laboratories selected were not similar to each other (i.e., had varying amounts of total payments for HCPCS code U0005 and varying percentages of COVID-19 tests for which the laboratories had billed HCPCS code U0005). Finally, to identify vulnerabilities related to the supporting documentation for add-on payments for COVID-19 tests, for each of the 10 laboratories, we requested and reviewed supporting documentation for a single claim billed with HCPCS code U0005 on a single date of service to determine whether the laboratory: (1) completed the COVID-19 test within 2 calendar days or less from the date that the specimen was collected and (2) completed the majority of its COVID-19 diagnostic tests that used high-throughput technology in the previous calendar month within 2 calendar days or less from the date that the specimen was collected. We did not review supporting documentation for all of the add-on HCPCS code U0005 claims data.

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

The Appendix describes our audit scope and methodology.

RESULTS OF ANALYSIS

Based on our analysis of $339.4 million in Medicare add-on payments made to 9,380 laboratories for COVID-19 diagnostic tests provided to more than 4 million enrollees during our audit period, we determined that more than two-thirds of the laboratories that billed Medicare at least once for add-on HCPCS code U0005 billed for the add-on payment with all of their COVID-19 tests billed with HCPCS codes U0003 and U0004.

We also identified the following potential vulnerabilities related to CMS and the MACs' oversight of add-on payments for COVID-19 tests: (1) CMS requirements related to supporting documentation for add-on payments were vague, and documentation from the laboratories was inconsistent; and (2) CMS and the MACs did not perform adequate reviews of claims for add-on payments.

Amounts of Add-on Payments for COVID-19 Tests, the Number of Laboratories That Provided These Tests, and the Number of Enrollees Who Received These Tests

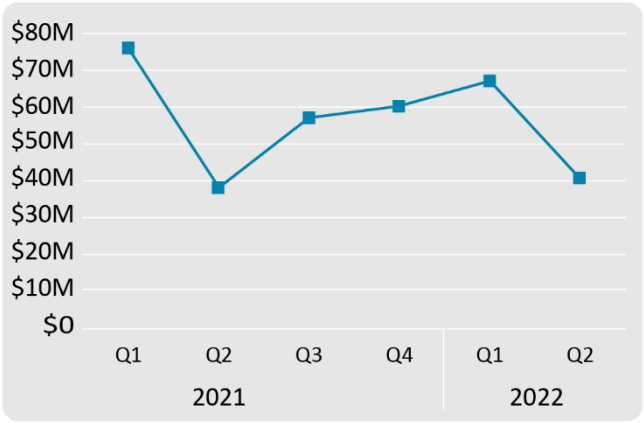
Medicare made hundreds of millions of dollars in add-on payments to thousands of laboratories for providing COVID-19 tests to millions of enrollees during our audit period. More than two-thirds of the laboratories that billed Medicare at least once for add-on HCPCS code

U0005 billed for the add-on payment with all of their COVID-19 tests billed with HCPCS codes U0003 and U0004.

Medicare paid $339.4 million for add-on HCPCS code U0005.

During our audit period, Medicare paid $339.4 million for HCPCS code U0005. In the first quarter of 2021, Medicare paid approximately $76 million for HCPCS code U0005. During the second quarter of 2021, payments dropped to $38 million. Payments then increased in the third and fourth quarters of 2021 and the first quarter of 2022 ($57 million, $60 million, and $67 million, respectively), before decreasing again in the second quarter to $41 million (Figure 3).

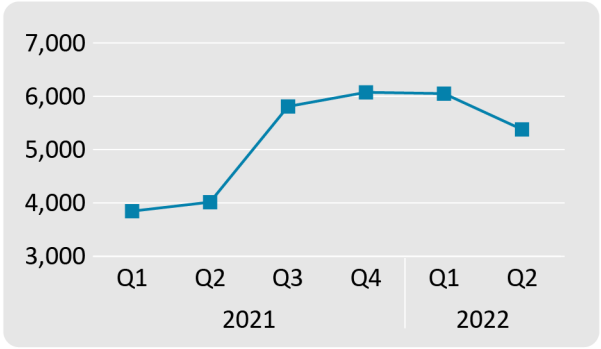
Figure 3: Payments for Add-on HCPCS Code U0005 by Quarter



Medicare paid thousands of laboratories for add-on HCPCS code U0005.

During our audit period, Medicare paid 9,380 laboratories that billed for HCPCS code U0005 at least once. The number of laboratories that Medicare paid for HCPCS code U0005 increased each quarter in 2021 and decreased in the first two quarters of 2022. Specifically, in the first quarter of 2021, 3,846 laboratories were paid for HCPCS code U0005, and by the fourth quarter of 2021, this number had increased to 6,074 laboratories. However, in the first quarter of 2022, this number had decreased slightly to 6,050 laboratories and then decreased to 5,378 laboratories by the second quarter of 2022 (Figure 4).[7]

Figure 4: Number of Laboratories Medicare Paid for HCPCS Code U0005 by Quarter

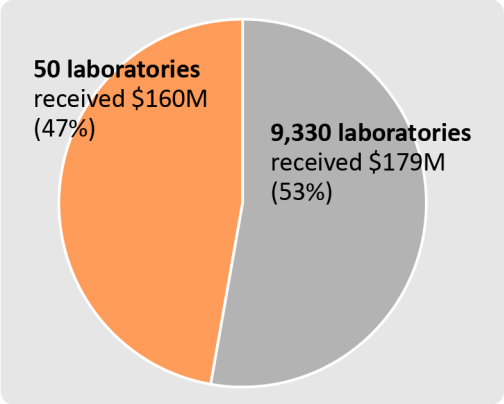


[7] The sum of the number of laboratories that Medicare paid for HCPCS code U0005 each quarter does not equal the 9,380 laboratories paid during the audit period because some laboratories may have been paid during multiple quarters and other laboratories may have been paid during only one quarter.

Medicare payments to the top 50 laboratories that billed add-on HCPCS code U0005 at least once made up almost half the total payments for this code.

During our audit period, of the 9,380 laboratories that billed HCPCS code U0005 at least once, 50 laboratories (less than 1 percent) made up almost 50 percent of the $339 million in total payments for this code, or more than $160 million (Figure 5). The amount paid to each of the top 50 laboratories ranged from $1.6 million to $8 million.

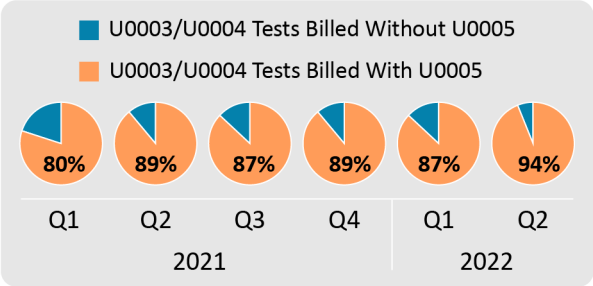
Figure 5: Percentage of Total Payments for HCPCS Code U0005 by Top 50 and Remaining Laboratories



Laboratories that billed Medicare at least once for add-on HCPCS code U0005 billed the add-on code with 87 percent of their COVID-19 tests.

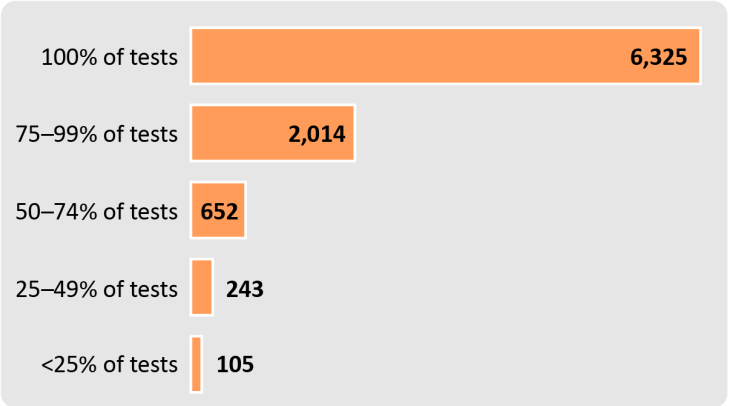
During our audit period, the 9,380 laboratories that billed Medicare at least once for HCPCS code U0005 billed for that code with 87 percent of their COVID-19 tests billed with HCPCS codes U0003 or U0004. When HCPCS code U0005 was implemented in the first quarter of 2021, laboratories billed this code for 80 percent of COVID-19 tests billed with HCPCS codes U0003 or U0004. Over the next four quarters, this percentage ranged from 87 percent to 89 percent. By the second quarter of 2022, this percentage had increased to 94 percent (Figure 6).

Figure 6: Percentage of COVID-19 Tests Billed With U0005 by Quarter



More than two-thirds of laboratories that billed Medicare at least once for add-on HCPCS code U0005 billed for the add-on payment with all of their COVID 19 tests.

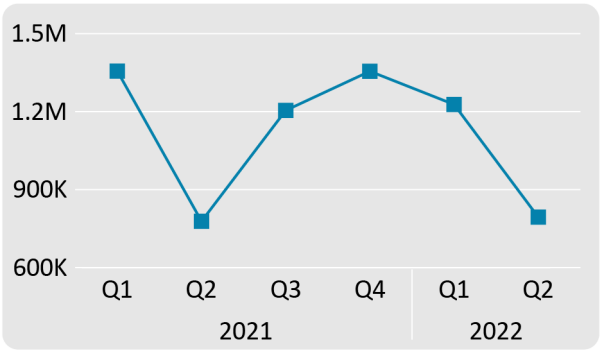
Figure 7: Number of Laboratories That Billed Add-on HCPCS Code U0005 at Least Once by Percentage of COVID-19 Tests Billed With the Add-on Code



Of the 9,380 laboratories that billed Medicare at least once for HCPCS code U0005 during our audit period, 41 laboratories billed Medicare for that code without HCPCS codes U0003 or U0004.[8] Of the remaining 9,339 laboratories that billed Medicare for HCPCS code U0005 with HCPCS codes U0003 or U0004, 6,325 (68 percent) billed U0005 with all of their COVID-19 tests billed with U0003 or U0004, and 2,014 laboratories billed U0005 with at least 75 percent of their tests billed with U0003 or U0004 (Figure 7).

Millions of enrollees received COVID-19 tests billed with add-on HCPCS code U0005.

Figure 8: Number of Enrollees Who Received Tests Billed With HCPCS Code U0005 by Quarter



During our audit period, approximately 4.7 million enrollees received COVID-19 tests that 9,380 laboratories billed with HCPCS code U0005.[9] The number of enrollees fluctuated by quarter (Figure 8). On average, during our audit period, each enrollee received approximately three COVID-19 tests billed with HCPCS code U0005. Approximately 86 percent of enrollees received tests that were at or below this average. However, 24 enrollees received 157 or more COVID-19 tests billed with HCPCS code U0005 during our audit period, which was an average of more than 2 tests a week for 18 months. For these 24 enrollees, 2 laboratories made up 83 percent of the payments for HCPCS code U0005.

[8] We consider the $3,000 of payments made to these 41 laboratories immaterial and kept the claims associated with these payments in the claims data.

[9] Of the 9,380 laboratories that billed HCPCS code U0005 during our audit period, 41 did not bill HCPCS codes U0003 or U0004. We consider the $3,000 of payments made to these 41 laboratories immaterial and kept the claims associated with these payments in the claims data.

Potential Vulnerabilities Related to CMS and Medicare Administrative Contractor Oversight of Add-on Payments for COVID-19 Tests

We identified the following potential vulnerabilities related to CMS and the MACs' oversight of add-on payments for COVID-19 tests: (1) CMS requirements related to supporting documentation for add-on payments were vague, and documentation from selected laboratories was inconsistent; and (2) CMS and the MACs did not perform adequate reviews of claims for add-on payments.

CMS requirements related to supporting documentation for add-on payments were vague, and documentation from selected laboratories was inconsistent.

CMS's Administrative Ruling CMS-2020-1-R2 states that in the event of an audit or a medical review, a laboratory will need to produce documentation of timeliness based on its performance in the month preceding the month identified by the date of service for the corresponding COVID-19 test represented by HCPCS codes U0003 or U0004 (i.e., to show that the majority of its COVID-19 tests in the previous calendar month were completed within 2 calendar days or less). However, there is no CMS guidance on what documentation needs to be maintained to support timeliness. Without clear guidance on what documentation is needed as support, a laboratory may not maintain sufficient documentation to show that the majority of its COVID-19 tests in the previous calendar month were completed within 2 calendar days or less.

For the 10 judgmentally selected laboratories, the documentation to support that each laboratory completed the COVID-19 test within 2 calendar days or less from the date that the specimen was collected was generally consistent among the 10 laboratories. However, the documentation to support that each laboratory completed the majority of its COVID-19 diagnostic tests that used high-throughput technology in the previous calendar month within 2 calendar days or less from the date that the specimen was collected was inconsistent among the 10 laboratories. This inconsistency shows the importance of CMS's providing guidance to laboratories on the documentation that should be maintained to support claims billed with add-on HCPCS code U0005.

To support that each test billed with HCPCS code U0005 was completed within 2 calendar days or less of from date that the specimen was collected, 9 of the 10 laboratories provided to us an electronic version of the COVID-19 test results showing the turnaround time.[10] For example, one of the nine laboratories provided us with an electronic file with documentation for the COVID-19 test results showing a collection date of January 29, 2022, and a completion date of January 31, 2022. This test was completed within 2 calendar days or less from the date the specimen was collected.

[10] All 10 laboratories completed the test billed with HCPCS code U0005 within 2 calendar days or less from the date that the specimen was collected.

To support that the majority of COVID-19 diagnostic tests that used high-throughput technology were completed within 2 calendar days or less from the dates that the specimens were collected for all of its patients in the previous calendar month, the 10 laboratories provided the following:

- Three laboratories provided detailed support, which included listings (one of which was almost 4,000 pages long) of turnaround times for all of the COVID-19 tests performed in the previous calendar month.[11]

- Three laboratories provided summary data showing the number of COVID-19 tests completed in the previous calendar month and the percentage that met the 2-calendar-day turnaround time, but they did not provide detailed support.[12]

- Two laboratories indicated that they completed all of their COVID-19 tests within 2 days or less, but they did not provide detailed support or summary data. For example, one laboratory stated that the laboratory's standard operation is to complete testing within 2 days and frequently on the same day.

- One laboratory stated that it monitored turnaround times for COVID-19 tests with a "data dashboard" to ensure that the majority of tests were completed within 2 days of sample collection, but it did not provide detailed support or summary data.

- One laboratory stated that the majority of the tests that it had performed in the previous calendar month met the 2-calendar-day turnaround time, but it did not provide detailed support or summary data.

CMS and the MACs did not perform adequate reviews of claims for add-on payments.

Although CMS and the MACs did some monitoring of the utilization of add-on HCPCS code U0005 and performed some medical reviews, the reviews were not adequate. Specifically, the reviews generally did not focus on determining whether laboratories met the turnaround time requirements for the add-on payment. Without reviewing the claims for the add-on payments to determine turnaround times, CMS and the MACs would not have been able to determine whether the incentive payment was achieving the intended results, which was to encourage laboratories to have prompt turnaround times for COVID-19 tests.

[11] Based on the detailed support provided, we determined that all three laboratories completed the majority of COVID-19 diagnostic tests that used high-throughput technology within 2 calendar days or less from the dates that the specimens were collected for all of its patients in the previous calendar month.

[12] Based on the summary data provided, we were unable to determine whether all three laboratories completed the majority of COVID-19 diagnostic tests that used high-throughput technology within 2 calendar days or less from the dates that the specimens were collected for all of its patients in the previous calendar month.

According to CMS's Administrative Ruling CMS-2020-1-R2, in the event of an audit or a medical review, a laboratory needs to produce documentation to support the add-on payment established in this ruling, even if such documentation would not otherwise be required under Medicare regulations. Hypothetically, a laboratory could perform 100,000 tests per month. In this case, to verify that a laboratory appropriately billed HCPCS code U0005, a reviewer would need to review not only the supporting documentation for the date of service of the COVID-19 test to confirm that it was completed within 2 calendar days of the date that the specimen was collected but would also need to review supporting documentation for the 100,000 tests performed in the previous calendar month to confirm that the majority were completed within the required timeframe.

When we asked CMS what documentation it would expect a laboratory to maintain to support that the majority of its COVID-19 tests in the previous calendar month were completed within 2 calendar days or less, CMS told us that it would expect to review all documentation supporting a laboratory's billed services. Although CMS could make its own determination about how to review supporting documentation, based on what CMS told us, this review could include verifying the turnaround time for every single test performed in the previous calendar month to determine whether a laboratory completed the majority of its COVID-19 diagnostic tests that use high-throughput technology within 2 calendar days or less for all of its patients. Because there is no way to use Medicare claims data to determine turnaround times for COVID-19 tests, a manual review of the supporting documentation would be required, which could be difficult and costly to perform in the event of an audit or a medical review.

CONCLUSION

CMS established the $25 add-on payment to incentivize laboratories to promptly complete COVID-19 tests (i.e., within 2 calendar days or less). Our audit identified that Medicare made $339.4 million in add-on payments to 9,380 laboratories for COVID-19 diagnostic tests provided to more than 4 million enrollees during our audit period. Our audit also identified that CMS requirements related to supporting documentation for add-on payments were vague and CMS and the MACs did not perform adequate reviews of claims for add-on payments. To determine whether the incentive payment achieved the intended result of laboratories' prompt completion of COVID-19 tests, CMS would have had to perform manual reviews of supporting documentation, which could be difficult and costly to perform in the event of an audit or a medical review.

We understand that CMS had to quickly: (1) establish the payment rates for laboratories to bill for COVID-19 testing and create an add-on payment to incentivize laboratories to promptly complete COVID-19 tests and (2) establish documentation requirements to support the add-on payment. However, we believe that it is important for CMS and MACs to provide oversight of add-on payments to prevent fraud, waste, and abuse in the Medicare program. For incentive payments in general, it is important that CMS issue specific guidance on documentation that is

expected to be maintained to support incentive payments and provide oversight to ensure that these payments are supported, especially in the event of a future PHE.

We shared the draft data brief with CMS, and it informed us that it did not have comments.

APPENDIX: AUDIT SCOPE AND METHODOLOGY

Scope

Our primary source of data for this data brief was Medicare Part B claims for add-on payments for COVID-19 tests billed with add-on HCPCS code U0005. We identified $339,439,390 in Medicare payments to 9,380 laboratories for 13,615,712 add-on payments for COVID-19 tests that had dates of service from January 1, 2021, through June 30, 2022.[13]

We also used summary data on Medicare Part B claims for COVID-19 tests billed with HCPCS codes U0003 or U0004 for laboratories that billed HCPCS code U0005 with at least 1 of their COVID-19 tests and identified $1,175,303,278 in Medicare payments made to 9,339 laboratories for 15,698,655 COVID-19 tests that had dates of service during our audit period. In addition, we used summary data on Part B claims for COVID-19 tests billed with HCPCS code U0003 and U0004 (with or without add-on HCPCS code U0005) and identified $1,224,848,608 in Medicare payments made to 12,811 laboratories for 16,687,703 COVID-19 tests that had dates of service during our audit period.

We used these claims data to perform our analysis of add-on payments for COVID-19 tests paid under Medicare Part B. We also used the add-on HCPCS code U0005 data to judgmentally select 10 laboratories for which we requested and reviewed supporting documentation for a single claim billed with HCPCS code U0005 to determine whether the laboratory: (1) completed the COVID-19 test within 2 calendar days or less from the date that the specimen was collected and (2) completed the majority of its COVID-19 diagnostic tests that used high-throughput technology in the previous calendar month within 2 calendar days or less from the date that the specimen was collected. We did not review supporting documentation for all of the add-on HCPCS code U0005 claims data.

We did not perform an overall assessment of the internal control structure of CMS and the MACs. Rather, we limited our review to those controls that were significant to our objective. Specifically, we interviewed CMS and MAC officials about the oversight mechanisms in place related to add-on payments for COVID-19 tests and reviewed CMS requirements and guidance related to billing for add-on payments for COVID-19 tests. Because our audit was designed to provide only reasonable assurance that the internal controls we reviewed were effective, it would not necessarily have detected all internal control deficiencies.

Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History (NCH) file, but we did not assess the completeness of the file. We assessed the reliability of data obtained from the NCH file by: (1) considering prior data reliability assessments on data from the NCH file, such as tracing

[13] Of the 9,380 laboratories that billed HCPCS code U0005 during our audit period, 41 did not bill HCPCS codes U0003 or U0004. We consider the $3,000 of payments made to these 41 laboratories immaterial and kept the claims associated with these payments in the claims data.

claims to supporting documentation, and (2) performing electronic testing on the data, such as testing for missing data. We determined that the data were sufficiently reliable for the purposes of this audit.

We conducted our audit from September 2022 to April 2024.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance related to coverage of and billing for add-on HCPCS code U0005;

- met with CMS officials to obtain an understanding of CMS's oversight of add-on payments for COVID-19 tests;

- sent questionnaires to the 4 MACs whose payments made up the majority (86 percent) of payments for HCPCS code U0005, inquiring about oversight activities for HCPCS code U0005, and reviewed their responses;

- extracted from CMS's NCH file Medicare Part B claims data for 13,615,712 add-on payments for COVID-19 tests billed with HCPCS code U0005 that had dates of service during our audit period, totaling $339,439,390;

- extracted from CMS's NCH file Medicare Part B summary data for 16,687,703 COVID-19 tests billed with HCPCS codes U0003 or U0004 (with or without HCPCS code U0005) during our audit period, totaling $1,224,848,608;

- extracted from CMS's NCH file Medicare Part B summary data for 15,698,655 COVID-19 tests billed with HCPCS codes U0003 or U0004 for laboratories that billed HCPCS code U0005 with at least 1 of their COVID-19 tests during our audit period, totaling $1,175,303,278;

- analyzed claims data for HCPCS codes U0003, U0004, and U0005 to identify such data as amounts of add-on payments for COVID-19 tests, the number of laboratories that provided these tests, and the number of enrollees who received these tests during our audit period;

- analyzed the claims data for HCPCS code U0005 to judgmentally select 10 laboratories to ensure that each MAC was represented and that the laboratories had varying amounts of total payments for HCPCS code U0005 and varying percentages of COVID-19 tests for which the laboratories had billed HCPCS code U0005;

- for each of the 10 judgmentally selected laboratories, requested and reviewed supporting documentation related to the COVID-19 test turnaround time for a single claim billed with HCPCS code U0005 on a single date of service; and

- discussed the results of our audit with CMS officials.

We shared the draft data brief with CMS, and it informed us that it did not have comments.

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