

Department of Health and Human Services
Office of Inspector General



Office of Audit Services

February 2025 | A-06-23-06000

Medicare Paid Claims That Were Not In Accordance With the Over- the-Counter COVID-19 Test Kits Demonstration Quantity Limitation

REPORT HIGHLIGHTS



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Medicare Paid Claims That Were Not in Accordance With the Over-the-Counter COVID-19 Test Kits Demonstration Quantity Limitation

Why OIG Did This Audit

- CMS launched the Over-the-Counter COVID-19 Test Demonstration (the Demonstration) to cover and pay for up to eight over-the-counter (OTC) COVID-19 tests per calendar month for Medicare enrollees (monthly quantity limit). The Demonstration period ran from April 4, 2022, through May 11, 2023. Medicare no longer covers or pays for OTC COVID-19 tests.
- Media outlets reported that some Medicare enrollees complained of having received Medicare-covered OTC COVID-19 tests that they did not order, need, or want—a signal that individuals may have been using enrollees' Medicare information to improperly bill the Federal Government. We performed an initial analysis of Medicare claims data and determined that some enrollees received more OTC COVID-19 tests than the quantity limit allowed under the Demonstration.
- This audit assessed whether Medicare paid claims for OTC COVID-19 tests in accordance with the Demonstration quantity limit.

What OIG Found

Medicare may have paid up to \$454 million in potentially improper payments to providers for 38.7 million OTC COVID-19 tests furnished to nearly 3.2 million enrollees that exceeded the monthly quantity limit. These potentially improper payments primarily occurred because CMS did not implement nationwide system edits to prevent multiple Medicare Administrative Contractors from paying providers for claims for OTC COVID-19 tests that exceeded the quantity limit. As such, this systemic vulnerability allowed providers to improperly bill Medicare for excessive OTC COVID-19 tests.

In addition, we identified 95,955 Medicare enrollees (less than 1 percent of all enrollees) who collectively received 4.4 million OTC COVID-19 tests more than the 112-quantity limit for the duration of the Demonstration period.

What OIG Recommends

We recommend that, for items or services for which the Medicare program establishes a quantity limit, CMS use the results of this audit to research and determine the best method(s) (e.g., nationwide system edits) to detect and prevent improper payments to providers.

CMS did not indicate concurrence or nonconcurrence with our recommendation but detailed the actions that it took after the Demonstration period ended to prevent further improper payments for OTC tests.

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INTRODUCTION

WHY WE DID THIS AUDIT

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency (PHE) concerning COVID-19. The PHE posed extraordinary challenges for the delivery of health care and human services to the American people. One of those challenges was ensuring access to COVID-19 testing for every American during the PHE, including at-home tests when they became available, to reduce the spread of COVID-19.

The Centers for Medicare & Medicaid Services (CMS) launched the Over-the-Counter COVID-19 Test Demonstration (the Demonstration) to cover and pay for over-the-counter (OTC) COVID-19 tests (OTC tests) for people with Medicare Part B coverage and individuals enrolled in Medicare Advantage (MA) plans¹ (both referred to throughout this report as “enrollees”). Under the Demonstration, each eligible enrollee could get up to eight tests per calendar month, which we refer to in this report as the “monthly quantity limit.” The goal of the Demonstration was to help prevent the spread of COVID-19 and to determine whether Medicare payments for OTC tests would improve access to testing and result in Medicare savings from a less expensive mode of testing and from more effective utilization of services.² The Demonstration ran from April 4, 2022, through May 11, 2023 (the Demonstration period). Medicare no longer covers or pays for OTC tests.

In February 2023, the Office of Inspector General (OIG) issued an alert about fraud schemes related to COVID-19. In it, OIG noted that individuals were using testing sites, telemarketing calls, text messages, social media platforms, and door-to-door visits to offer COVID-19 services in exchange for personal details, including Medicare information.³

As the Demonstration period neared its end, media outlets reported that some enrollees complained of having received OTC tests that they did not order, need, or want—a signal that individuals may be using enrollees’ Medicare information to improperly bill the Federal Government.⁴

Based on this potential fraud, we performed an initial analysis of Medicare claims data and determined that some enrollees received more OTC tests than what the Demonstration

¹ Because MA plan rates may not have considered the projected cost for OTC tests, Medicare payment for OTC tests during the Demonstration period for individuals enrolled in MA plans were made through the Medicare Part B program.

² CMS, “[Over-the-Counter COVID-19 Test Demonstration](#),” dated Apr. 28, 2023. Accessed on Sept. 25, 2024.

³ OIG, [Fraud Alert: COVID-19 Scams](#), issued Feb. 28, 2023.

⁴ National Public Radio, “[Seniors got COVID tests they didn't order in Medicare scam](#),” May 18, 2023; Tampa Bay, Florida, NBC Channel 8WFLA News Channel 8, “[Mystery companies sending Florida seniors unwanted COVID-19 tests, billing Medicare](#),” May 2, 2023. Accessed on May 24, 2023.

quantity limit allowed.⁵ We performed this audit to determine whether there were vulnerabilities that might result in potential improper payments for OTC tests covered under the Demonstration.

OBJECTIVE

Our objective was to determine whether Medicare paid claims for OTC tests in accordance with the Demonstration quantity limit.

BACKGROUND

The Medicare Program

The Medicare program, established by Title XVIII of the Social Security Act (the Act), provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the Medicare program.

CMS contracts with Medicare Administrative Contractors (MACs) for 12 defined geographic areas (known as MAC jurisdictions) to, among other things, process and pay Medicare Part B claims, conduct reviews and audits, safeguard against improper payments, and educate providers on Medicare billing requirements. Claims processing includes receiving claims from providers, performing claim edits, and adjudicating claims.⁶

Medicare Demonstration Projects and the Over-the-Counter COVID-19 Test Demonstration

CMS conducts and sponsors numerous innovative demonstration projects and model tests to measure the effect of potential program changes. These demonstrations and model tests study the likely impact of new methods of service delivery, coverage of new types of service, and new payment approaches on enrollees, providers, health plans, States, and the Medicare Trust Funds.⁷

⁵ OIG developed a COVID-19 response strategic plan to guide its oversight activities. As part of this plan, available at [HHS-OIG's Oversight of COVID-19 Response and Recovery | HHS-OIG](#), OIG has been conducting a series of audits related to COVID-19.

⁶ An edit is programming within the standard claims processing system that selects certain claims; evaluates or compares information on the selected claims or other accessible sources; and, depending on the evaluation, acts on the claims, such as paying them in full, paying them in part, or suspending them for manual review.

⁷ Section 402(a)(1)(B) of the Social Security Amendments of 1967, as amended (codified as 42 U.S.C. § 1395b-1(a)(1)(B)), authorizes the Secretary of HHS to engage in demonstration projects testing the effectiveness of Medicare covering otherwise non-covered services such as OTC tests.

Under the Demonstration, Medicare covered and paid for up to eight OTC tests per enrollee, per calendar month, without any cost to enrollees. Therefore, during the 14-month Demonstration period, each enrollee could have received up to 112 OTC tests.⁸

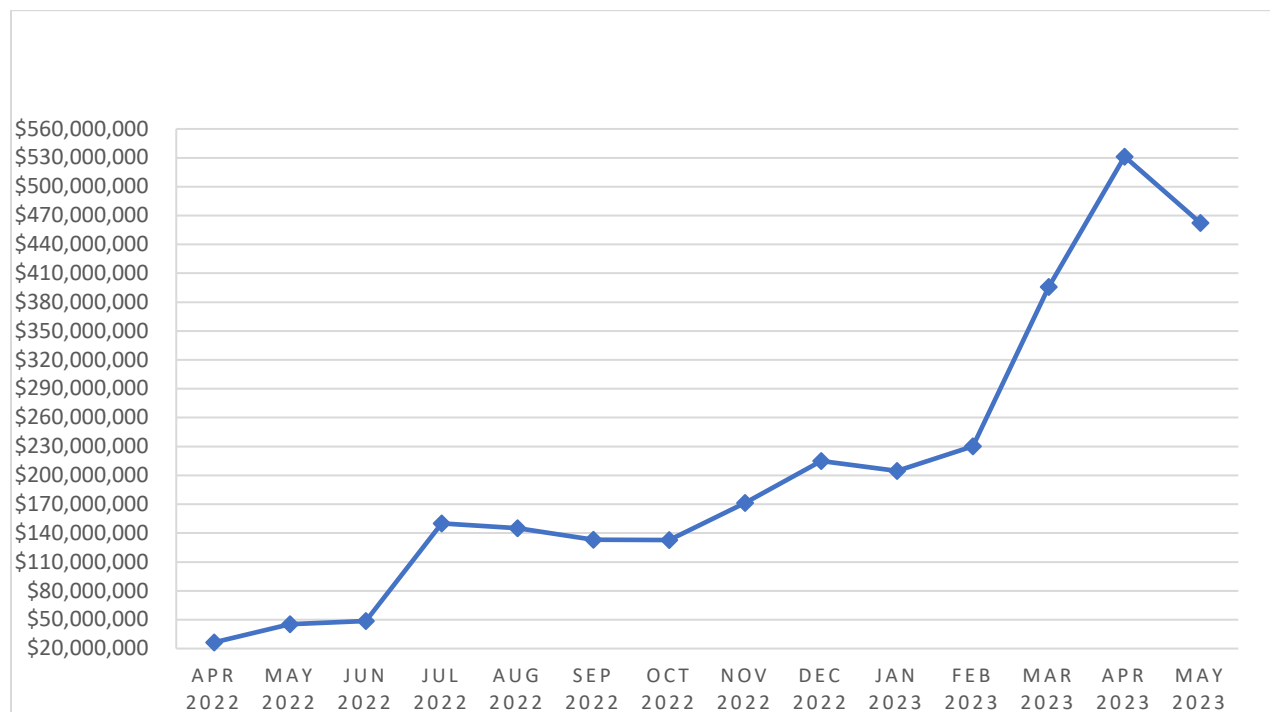
CMS encouraged providers to ask enrollees seeking OTC tests whether they had already received other OTC tests during the current calendar month. CMS also told providers that, if an enrollee was not sure or did not know about the quantity limit, providers could voluntarily give the enrollee an Advanced Beneficiary Notice of Non-Coverage (ABN) before they gave the enrollee any OTC tests.⁹ While an ABN was not required, it informed enrollees about the number of OTC tests they could receive and that they would have had to pay out-of-pocket costs for any OTC tests over the quantity limit unless they had additional health care coverage (e.g., Medicaid) that covered OTC tests over the Medicare quantity limit.

For the Demonstration period, Medicare paid \$2.9 billion for OTC tests. Figure 1 on the next page shows the total monthly paid claim amounts for OTC tests during the Demonstration period. We noted that, from April 2022 through January 2023, monthly payments for OTC tests steadily increased. In February 2023, payments for OTC tests totaled \$230.3 million and more than doubled 2 months later, in April 2023, to \$531.3 million.

⁸ If the enrollee received 8 OTC tests per month over the 14-month demonstration period, we calculated that the enrollee would have received up to 112 OTC tests.

⁹ An ABN helps Medicare fee-for-service patients make informed decisions about items and services Medicare usually covers but may not in specific situations. For example, the items or services may not be medically necessary for a patient.

Figure 1: Monthly Paid Amounts for Over-the-Counter Tests During the Demonstration Period¹⁰



Eligible Providers Who Furnish Over-the-Counter COVID-19 Tests

To be eligible to participate in the Demonstration and furnish OTC tests, providers must have been enrolled in Medicare and be able to provide Part B outpatient services (e.g., preventative vaccines and clinic visits). Providers included, but were not limited to, physicians and other non-physician practitioners in private practice, hospital outpatient departments, skilled nursing facilities, home health agencies, federally qualified health centers, rural health clinics, opioid treatment programs, independent laboratories, mass immunizers,¹¹ and certain pharmacies depending on how they were enrolled in Medicare.¹²

¹⁰ Payment data were obtained from CMS's Integrated Data Repository in May 2024. The data are updated on a continuous basis and are therefore subject to change.

¹¹ Mass immunizers provide COVID-19, flu, and pneumococcal vaccines to groups of individuals (e.g., people who live in a retirement community). A mass immunizer may be a traditional provider, like a physician, or a non-traditional provider, like a drug store, public health clinic, or senior center.

¹² For example, a Clinical Laboratory Improvement Amendments-certified laboratory, mass immunizer, or providers under the enrollment of a professional (e.g., nurse practitioner) could participate in the Demonstration.

Under the Demonstration, providers furnished Food and Drug Administration-approved OTC tests to enrollees at pharmacies and stores. Providers also shipped tests directly to enrollees when requested online and by phone.¹³

Billing Medicare for Over-the-Counter COVID-19 Tests

During the Demonstration, CMS established Healthcare Common Procedure Coding System (HCPCS)¹⁴ code K1034, which providers were required to use when billing Medicare for a single OTC test. For example, if providers furnished the enrollee with two OTC tests, they would bill Medicare for two units of HCPCS code K1034.

CMS established a fixed national payment rate of \$12 per OTC test. If a provider usually charged (e.g., retail price) less than \$12 per test, Medicare paid the lesser of the two amounts. As such, the maximum Medicare would pay was \$12 per OTC test. Providers accepted the Medicare payment amount as payment in full and did not collect any additional amounts from enrollees for OTC tests provided within the monthly quantity limit. Medicare paid for claims in the order in which they were received; therefore, providers were encouraged to promptly submit claims. Medicare paid for OTC tests when providers submitted claims to Medicare—not when enrollees received OTC tests.¹⁵

Medicare Claims Processing System Edits

Each MAC jurisdiction uses a variety of program safeguards to promote provider compliance, including the use of claims processing system edits to prevent potential improper payments to providers. In March 2022, CMS implemented payment and coverage provisions through its Demonstration authority and provided instructions to MAC jurisdictions to process and pay claims for HCPCS code K1034. These instructions required MAC jurisdictions to implement regional system edits to automatically deny Medicare Part B claims for OTC tests that exceeded the monthly quantity limit (i.e., eight OTC tests). However, CMS did not have nationwide system edits to prevent multiple MAC jurisdictions from paying providers for more than eight OTC tests billed in a calendar-month for the same enrollee.

¹³ CMS, [Medicare Coverage of Over-the-Counter COVID-19 Tests: Frequently Asked Questions](#). Accessed on Sept. 25, 2024.

¹⁴ HCPCS codes are a collection of standardized codes that represent medical procedures, supplies, products, and repairs. These codes are used to facilitate Medicare's processing of health insurance claims.

¹⁵ For example, if an enrollee received 8 OTC tests on Jan. 2 from Provider A and 8 OTC tests on Jan. 30 from Provider B, but Provider B submitted a claim to Medicare for payment before Provider A, Provider B was paid for those OTC tests. Nevertheless, providers had up to 1 year after the date of service to submit claims.

HOW WE CONDUCTED THIS AUDIT

Our audit covered 32,590,601 Medicare Part B claims for 250,913,305 OTC tests furnished to 11,830,292 enrollees during the Demonstration period, for which Medicare paid \$2,891,606,712 to 36,773 providers.

To determine the number of Medicare-paid OTC tests per-enrollee, per-calendar month (referred to as an “enrollee-month”), we grouped the OTC test claims by enrollee ID and calendar month. As such, we identified 27,569,561 enrollee-months for which Medicare paid for 250,913,305 OTC tests during the Demonstration period and analyzed claims data for OTC tests to identify claims that may not have complied with the Demonstration quantity limit. We did not obtain or review documentation from providers.

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.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

Medicare paid claims for OTC tests for 24,311,293 enrollee-months in accordance with the Demonstration quantity limit. However, for 3,258,268 enrollee-months, Medicare may have paid up to \$453,804,367 in potentially improper payments to providers for 38,690,842 OTC tests that exceeded the monthly quantity limit. These potentially improper payments primarily occurred because CMS did not implement nationwide system edits to prevent multiple MAC jurisdictions from paying providers for claims for OTC tests that exceeded the monthly quantity limit. Additionally, MAC jurisdictions’ regional system edits did not always deny OTC tests that exceeded the monthly quantity limit.

In addition, we identified 95,955 of the 11,830,292 enrollees (less than 1 percent) who collectively received 4,377,777 OTC tests more than quantity limit for the duration of the Demonstration period.

MEDICARE PAID CLAIMS FOR OVER-THE-COUNTER TESTS THAT EXCEEDED THE MONTHLY QUANTITY LIMIT

During the Demonstration period, Medicare paid claims for up to the monthly quantity limit of eight OTC tests per-enrollee, per-calendar month, without any cost to the enrollees.

We identified 3,258,268 enrollee-months in which an enrollee received more than the monthly quantity limit. For those enrollee-months, Medicare made potentially improper payments of

up to \$453,804,367 for 38,690,842 OTC tests that exceeded the monthly quantity limit. This occurred because Medicare paid claims for OTC tests to multiple providers for the same enrollee during the same month.

For 3,153,410 of the 3,258,268 enrollee-months (97 percent), at least two providers from different MAC jurisdictions were collectively paid for more than the monthly quantity limit for the same enrollee. For those 3,153,410 enrollee-months, on average, an enrollee received 20 OTC tests per month. More specifically, for 68 percent, or 2,146,953 of the 3,153,410 enrollee-months, we determined that two different providers from two different MAC jurisdictions (one provider from each) collectively provided at least 16 OTC tests to an enrollee in the same calendar month—double the monthly quantity limit. In addition, our analysis found that in 107,462 of the 3,153,410 enrollee-months, different providers from 5 or more different MAC jurisdictions (at least one provider from each) collectively provided more than the monthly quantity limit to an enrollee in the same calendar month.

For the remaining 104,858 of the 3,258,268 enrollee-months (3 percent), different providers within the same MAC jurisdiction were collectively paid for more than the monthly quantity limit for an enrollee. Further, our analysis determined that different providers in different States within the same MAC jurisdiction accounted for 84,349 of the 104,858 enrollee-months (80 percent).

Table 1 on the next page summarizes the number of MAC jurisdictions associated with each enrollee-month that exceeded the monthly quantity limit and the associated potentially improper payments.

Table 1: Number of MAC Jurisdictions That Paid Claims for Each Enrollee-Month That Exceeded the Monthly Quantity Limit and Potential Improper Payments

Number of MAC Jurisdictions That Paid Claims for Each Enrollee-Month	Number of Enrollee-Months That Exceeded Eight OTC Tests	Potential Improper Payments for Claims That Exceeded Eight OTC Tests
1	104,858	\$9,741,035
2	2,213,266	210,797,888
3	626,823	121,830,256
4	205,859	61,193,580
5	70,772	28,988,544
6	25,821	13,744,950
7	8,489	5,595,726
8	2,062	1,622,416
9	293	265,781
10	23	22,121
11	2	2,070
12	0	0
Total	3,258,268	\$453,804,367

This table indicates, for example, that for 205,859 of the 3,258,268 enrollee-months, four different MAC jurisdictions collectively paid up to \$61,193,580 in potential improper payments for OTC tests that exceeded the monthly quantity limit.

These potential improper payments primarily occurred because CMS did not implement nationwide system edits to prevent multiple MAC jurisdictions from paying providers for claims for OTC tests that exceeded the monthly quantity limit. In addition, although CMS instructed MAC jurisdictions to implement regional system edits related to the monthly quantity limit, those edits did not always detect and prevent potentially improper payments to automatically deny OTC tests that exceeded the monthly quantity limit for some of the MAC jurisdictions. Furthermore, a provider may have been unaware that another provider had already been paid for OTC tests provided to an enrollee if the provider did not give the enrollee an ABN prior to providing OTC tests to that enrollee.¹⁶

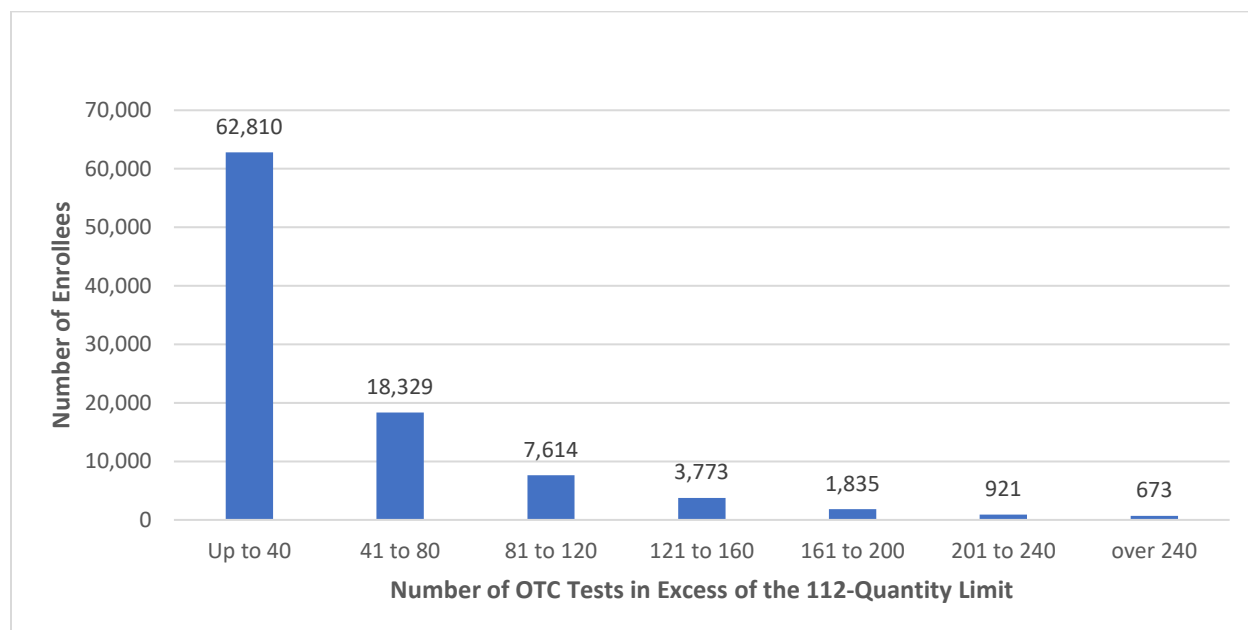
ENROLLEES RECEIVED MORE THAN THE 112 OVER-THE-COUNTER TESTS QUANTITY LIMIT

During the duration of Demonstration period, each enrollee could have received up to 112 OTC tests in accordance with the monthly quantity limit. However, we identified 95,955 out of 11,830,292 enrollees (less than 1 percent) who collectively received 4,377,777 OTC tests over

¹⁶ Delayed claim submissions and processing times may contribute to inaccurate ABN information.

the 112-quantity limit during the duration of the Demonstration period. Figure 3 summarizes the number of OTC tests over the 112-quantity limit by enrollee.

Figure 3: Number of Enrollees Who Received Over-the-Counter Tests Over the 112-Quantity Limit During the Demonstration Period



We noted that, as illustrated in Figure 3, 62,810 enrollees, or 65 percent, of the 95,955 enrollees received up to 40 OTC tests over the 112-quantity limit. In addition, 673 enrollees received at least 240 OTC tests over the 112-quantity limit. We determined that 5 providers received payments for OTC tests provided to 481 of the 673 enrollees (71 percent).

CONCLUSION

CMS launched the Demonstration to cover and pay for 8 OTC tests per-enrollee, per-calendar month. HHS OIG alerted the public about fraud schemes related to COVID-19. Based on this potential fraud, we performed this audit to identify vulnerabilities that might result in potential improper payments for OTC tests. We found that CMS did not implement nationwide system edits to prevent multiple MAC jurisdictions from paying providers for claims for OTC tests that exceeded the monthly quantity limit. As such, this systemic vulnerability allowed providers to improperly bill Medicare up to \$453,804,367 for excessive OTC tests.

RECOMMENDATION

We recommend that, for items or services for which the Medicare program establishes a quantity limit, CMS use the results of this audit to research and determine the best method(s) (e.g., nationwide system edits, information-sharing between providers, and other mechanisms) to detect and prevent improper payments to providers.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS did not indicate concurrence or nonconcurrence with our recommendation but detailed the actions that it took after the Demonstration period ended to prevent further improper payments for OTC tests.

Specifically, CMS stated that, in June 2023, it took “immediate action” to impose a temporary hold on all payments for OTC tests after using data analytics to identify potential program integrity risks and implemented approximately 150 provider payment suspensions. Further, CMS stated that, in August 2023, it implemented a nationwide system edit to deny claims for OTC tests that exceeded the monthly quantity limit across multiple MAC jurisdictions.¹⁷ CMS stated that, even though the majority of claims for OTC tests were submitted by this time, the edit was an important safeguard to put in place because providers have 1 year after the date of service to file a Medicare claim. Therefore, if a provider furnished an OTC test to an enrollee during the final days of the PHE, the provider had until May 2024 to submit a claim. As of November 2024, CMS stated that it has demanded over \$412 million from providers and continues to pursue investigations and administrative actions.

CMS requested that we remove or close as implemented our recommendation based on its actions described above. However, after reviewing CMS’s comments, we maintain that our recommendation is valid. We will close the recommendation as implemented after issuance of the final report. We acknowledge that CMS has demonstrated the functionality of nationwide system edits and that it will apply lessons learned from the PHE for future demonstration projects. CMS’s comments appear in their entirety as Appendix B.

¹⁷ CMS submitted documentation of the nationwide system edit to OIG in October 2023, after the start of our audit work.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 32,590,601 Medicare Part B claims for 250,913,305 OTC tests furnished to 11,830,292 Medicare enrollees from April 4, 2022, through May 11, 2023, for which Medicare paid \$2,891,606,712 to 36,773 providers.

To determine the number of Medicare-paid OTC tests per-enrollee, per-calendar month, we grouped the OTC test claims by enrollee ID and calendar month. As such, we identified 27,569,561 enrollee-months for which Medicare paid for 250,913,305 OTC tests during the Demonstration period. Table 2 summarizes the Medicare-paid OTC tests by enrollee-month.

Table 2: Medicare-Paid Over-The-Counter Tests by Enrollee-Month

Month-Year*	Paid Amount	Number of Enrollees	Number of Claims	Number of OTC Tests
April-22	\$26,457,763	370,948	381,790	2,416,308
May-22	45,484,195	598,006	612,453	4,069,395
June-22	48,560,417	631,869	648,164	4,361,867
July-22	149,920,284	1,702,512	1,755,301	13,142,109
August-22	144,940,936	1,667,890	1,721,008	12,834,480
September-22	133,222,560	1,513,819	1,554,343	11,762,819
October-22	132,638,061	1,487,918	1,535,063	11,678,947
November-22	171,304,355	1,834,358	1,938,182	14,925,979
December-22	214,910,761	2,306,174	2,436,826	18,771,208
January-23	204,696,211	2,148,704	2,307,144	17,774,110
February-23	230,312,828	2,242,690	2,599,409	19,985,206
March-23	395,658,848	3,382,996	4,360,147	34,122,595
April-23	531,268,397	4,084,911	5,767,364	45,529,288
May-23	462,231,096	3,596,766	4,973,407	39,538,994
Total	\$2,891,606,712	27,569,561	32,590,601	250,913,305

* Because the Demonstration started on April 4, 2022, and ended on May 11, 2023, the total monthly paid amount for those two months are 27 days and 11 days, respectively.

We analyzed the claims data for OTC tests to identify claims that may not have complied with the Demonstration quantity limit. We did not obtain or review documentation from providers.

We did not assess the overall internal control structures of CMS. Rather, we limited our review to CMS's internal controls for monitoring activities related to the findings in this report. Specifically, we interviewed CMS officials regarding the Demonstration guidance provided to the MAC jurisdictions and providers for the Demonstration. We also reviewed CMS Change

Requests and Technical Direction Letters for information on system edits and monitoring activities.

Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's Integrated Data Repository (IDR), but we did not assess the completeness of the file.

We performed audit work from September 2023 through November 2024.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials to gain an understanding of how OTC tests are billed and processed and the system edits in place to prevent potential improper payments to providers and promote compliance with the Demonstration guidance;
- obtained nationwide claims data for OTC tests from CMS's IDR;
- analyzed the claims data for OTC tests to identify claims associated with enrollees who received (1) more than 8 OTC tests in a calendar month and (2) more than 112 OTC tests during the entire Demonstration period;
- quantified the amount that Medicare paid providers for OTC tests that may not have complied with the Demonstration quantity limit; and
- discussed the results of our review with CMS officials.

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.

APPENDIX B: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: December 18, 2024

TO: Amy Frontz
Deputy Inspector General
Office of Inspector General

FROM: Chiquita Brooks-LaSure *Chiquita LaS*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Paid Claims for Over-the-Counter COVID-19 Test Kits That Were Not in Accordance With the Demonstration Quantity Limitation (A-06-23-06000)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

As part of CMS's efforts to expand access to free COVID-19 testing, CMS launched a demonstration project under the authority of Section 402(a)(1)(B) of the Social Security Amendments of 1967. The demonstration, which began on April 4, 2022, allowed Medicare beneficiaries to get up to eight COVID-19 over the counter (OTC) tests per month for free. Tests were available through eligible pharmacies and other participating entities. This demonstration applied to COVID-19 OTC tests approved or authorized by the U.S. Food and Drug Administration (FDA) and concluded May 11, 2023, with the end of the public health emergency (PHE).

The COVID-19 PHE was unprecedented and forced the Agency to be flexible, and act quickly and creatively in order to ensure beneficiaries had access to their health care needs, including access to these tests. CMS recognizes the importance of analyzing the impact of the changes associated with the COVID-19 PHE, and, as such, evaluated the waivers and flexibilities issued by the Agency to determine the potential for fraud, waste, and abuse in the Medicare program. This process included identifying program integrity risks and vulnerabilities associated with the waivers and flexibilities; prioritizing those with the largest potential for financial loss, beneficiary harm and/or likelihood of occurrence; and creating mitigations that addressed these program integrity risks and vulnerabilities, including those related to COVID-19 OTC tests.

One such mitigation strategy has been the continued use of data analytics to identify potential program integrity risks. CMS continued throughout the PHE and after the PHE had ended to analyze claims data to monitor, trend, and respond to existing fraud schemes and to detect and respond to potential new emerging fraud schemes.

Through this work, CMS identified instances of providers and suppliers who started billing for an unusually high volume of test kits. At the same time, CMS identified a significant number of complaints from beneficiaries who received test kits they did not order. CMS took immediate action to impose a temporary hold all payments for COVID-19 OTC test kits on June 22, 2023, and we also implemented approximately 150 provider and supplier payment suspensions.

As of November 26, 2024, CMS has demanded over \$412 million from 72 providers and suppliers. Thus far, CMS has recouped funds from 49 providers. Over \$26 million is being held in payment suspension from 48 providers and suppliers until investigations are completed. Additionally, 58 providers and suppliers are no longer enrolled in Medicare due to non-compliance and/or suspected fraud. There were 76 providers and suppliers referred to law enforcement. CMS continues to pursue investigations and administrative actions.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that for items or services for which the Medicare program establishes a quantity limit, CMS use the results of this audit to research and determine the best methods(s) (e.g., nationwide system edits, information-sharing between providers, and other mechanisms) to detect and prevent improper payments to providers.

CMS Response

The COVID-19 PHE was unprecedented and forced the Agency to be flexible, and act quickly and creatively in order to ensure beneficiaries had access to their health care needs, including access to these tests. CMS evaluated the waivers and flexibilities issued by the Agency to determine the potential for fraud, waste, and abuse in the Medicare program. This process included identifying program integrity risks and vulnerabilities associated with the waivers and flexibilities; prioritizing those with the largest potential for financial loss, beneficiary harm and/or likelihood of occurrence; and creating mitigations that addressed these program integrity risks and vulnerabilities, including those related to COVID-19 OTC tests.

As stated in the OIG's report, CMS instructed the Medicare Administrative Contractors to implement local system edits to automatically deny Medicare Part B claims for OTC tests that exceeded the monthly quantity limit. CMS would like to clarify that a nationwide system edit to deny claims for OTC tests that exceeded the quantity limit across multiple MAC jurisdictions was implemented in August 2023. Even though the majority of OTC test kit claims were submitted by this time, this edit was still an important safeguard to put in place because providers and suppliers have one year after the date of service to file a Medicare claim. Therefore, if eligible pharmacies and other participating entities provided beneficiaries with OTC test kits during the final days of the PHE, they had until May 2024 to submit claims. The Change Request for this edit is available online at: <https://www.cms.gov/files/document/r12214otn.pdf>. CMS notes that this Change Request was also submitted to OIG as part of this audit in October 2023.

Additionally, as stated above, as a result of our data analytics, CMS took immediate action to impose a temporary hold all payments for COVID-19 OTC test kits on June 22, 2023, and we also implemented approximately 150 provider and supplier payment suspensions.

As of November 26, 2024, CMS has demanded over \$412 million from 72 providers and suppliers. Thus far, CMS has recouped funds from 49 providers. Over \$26 million is being held in payment suspension from 48 providers and suppliers until investigations are completed. Additionally, 58 providers and suppliers are no longer enrolled in Medicare due to non-compliance and/or suspected fraud. There were 76 providers and suppliers referred to law enforcement. CMS continues to pursue investigations and administrative actions.

Given that CMS did implement safeguards, including a nationwide system edit based on the established quantity limit, CMS requested that this recommendation be removed. While CMS

recognizes the spirit of this recommendation, we continue to request that this recommendation be removed, or closed as implemented, based on the actions outlined above. CMS has demonstrated that the functionality for such editing exists and will apply the lessons learned from the COVID-19 PHE for future demonstrations.