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Labs With Questionably High Billing for Additional Tests Alongside COVID-19 Tests Warrant Further Scrutiny

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Report in Brief

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Why OIG Did This Review

Medicare Part B spending on COVID-19 lab tests increased steadily between spring 2020 when Medicare first started paying for these tests—and the end of that year. Preliminary analysis of Medicare Part B claims data indicated that some diagnostic testing laboratories billed for other diagnostic tests—such as individual respiratory tests (IRTs), respiratory pathogen panels (RPPs), genetic tests, and allergy tests—along with COVID-19 tests. We refer to these four types of tests billed with COVID-19 tests as add-on tests. Although it is not unusual for labs to bill for COVID-19 tests and other diagnostic tests on the same claim, certain billing patterns—such as a high volume of or high payments for add-on tests—raise concerns of potential waste or fraud.

How OIG Did This Review

We performed outlier analysis to identify labs that billed for add-on tests at questionably high levels compared to other labs that billed for COVID-19 tests. We identified two kinds of outlier labs: (1) those for which add-on tests constituted a high proportion of each lab's total *number* of tests, and (2) those for which add-on tests constituted a high proportion of each lab's total *payments* for tests.

We examined all Medicare Part B claims paid for COVID-19 tests during 2020, and for the following types of add-on tests: IRTs, RPPs, genetic tests, and allergy tests.

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Key Takeaway

Certain labs billed Medicare Part B for questionably high levels of add on tests alongside COVID 19 tests in 2020. This significantly increased the payments they received for claims that included COVID 19 tests. Such high levels of billing for add on tests raise concern about potential waste or fraud, suggesting a need for further scrutiny of billing by these labs.

What OIG Found

We found that 378 labs billed Medicare Part B for add-on tests at questionably high levels—in volume, payment amount, or both—compared to the 19,199 other labs. This includes 276 labs that billed for high volumes of add-on tests on claims for

COVID-19 tests, and 263 labs that billed for high payment amounts from add-on tests on claims for COVID-19 tests. Further, 161 of these labs billed for both high volumes of add-ons and high payment amounts from add-ons on claims for COVID-19 tests. We also found a small number of labs that had at least 10 claims where 2 labs had billed for the same enrollee for the same tests on the same day, which may be an indication of a fraud scheme involving the sharing of enrollee information.

On their claims for COVID-19 tests, some of the 378 labs billed for add-on tests in combinations that had little if any variation across patients. This may indicate that these tests were not specific to individual patients' needs. The add-on tests significantly increased the per-claim amounts that Medicare Part B paid to these labs. For example, one outlier lab regularly billed for a combination of five add-on respiratory tests on almost all of its claims for COVID-19 tests. As a result, the average per-claim Medicare payment to this outlier lab was \$666, covering both COVID-19 and add-on tests, compared to an average payment of \$89 to all other labs that billed for COVID-19 tests and any add-on tests. Although billing for add-on tests was generally allowable, and Medicare Part B pays for these tests when they are medically appropriate, these patterns of questionably high billing raise concerns that some tests may have been wasteful or potentially fraudulent.

What OIG Concludes

Our analysis suggests that further scrutiny of billing by the 378 outlier labs is needed and, therefore, OIG has referred these labs to the Centers for Medicare & Medicaid Services (CMS) for further review. Outlier labs exceeded the thresholds for one or both measures of questionable billing, raising concerns about potential waste or fraud.

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BACKGROUND

OBJECTIVE

To identify labs with questionably high billing for respiratory, genetic, and/or allergy tests on Medicare Part B claims that included COVID-19 tests

Preliminary Office of Inspector General (OIG) analysis of 2020 Medicare Part B claims data raised concerns that some labs may have billed for unnecessary diagnostic tests on their claims for COVID-19 tests to increase their Medicare reimbursements. Since billing for add-on tests alongside COVID-19 tests can significantly inflate Medicare's payments to labs, it is important to identify labs that billed for questionably high levels of add-on tests. Although there can be legitimate patient-specific reasons to perform such tests, unnecessary or excessive billing of add-on tests

For the purposes of this report, we define add on tests as the following diagnostic tests that labs billed for on their Medicare Part B claims for COVID 19 tests:

- individual respiratory tests (IRTs),
- respiratory pathogen panels (RPPs),
- genetic tests, and
- allergy tests.

could indicate waste or potential fraud. For example, the Department of Justice (DOJ) brought criminal charges against a lab owner for bundling COVID-19 tests with more expensive, medically unnecessary add-on tests, including respiratory pathogen panels (RPPs) and genetic tests. Another concern involves schemes wherein labs encourage practitioners to order unnecessary tests. For example, a lab paid \$256 million to resolve multiple allegations, one of which was that it used so-called "custom profiles" that caused physicians to order excessive numbers of certain tests. Rather than tailoring the lab test orders to individual patients, physicians ordered a large number of pre-selected tests not based on an individualized assessment of each patient's needs.²

Medicare Part B Coverage of COVID-19 Testing and Other Diagnostic Tests

In 2020, the Centers for Medicare & Medicaid Services (CMS) made regulatory changes to Medicare to respond to the serious threat posed by the spread of COVID-19. These changes expanded Medicare Part B coverage for COVID-19 testing.³ Further, because symptoms associated with COVID-19 can present in the same way as respiratory illnesses, such as influenza, CMS worked quickly to expand access to certain respiratory tests when needed.⁴ These actions aligned with guidance from the Centers for Disease Control and Prevention (CDC) that

encouraged practitioners to consider testing for other respiratory illnesses alongside COVID-19 testing to confirm or rule out a diagnosis other than COVID-19.⁵ As more information about COVID-19 became available, CMS adjusted its coverage policies on COVID-19 and other respiratory-related tests.

Related Work

Early in the pandemic, OIG began issuing public alerts about various fraud schemes related to COVID-19, including scams whereby personal information is collected and used to fraudulently bill Federal health care programs and commit medical identity theft.⁶ OIG has also worked on cases that highlight fraud schemes involving billing for COVID-19 tests.⁷ In these schemes, along with their claims for COVID-19 tests, practitioners submitted claims for unrelated, medically unnecessary, and far more expensive lab tests, such as cancer genetic tests, allergy tests, and RPPs. Prior to the COVID-19 pandemic, OIG collaborated with law enforcement partners in 2019 to investigate a pattern of fraudulent genetic tests that were medically unnecessary but ordered in exchange for illegal kickback payments to physicians.⁸

Methodology

This evaluation used two measures to identify labs that billed Medicare Part B for questionably high levels of add-on tests. We developed these measures based on past OIG analysis and fraud investigations of health care practitioners, including labs. The measures identified (1) labs for which add-on tests constituted a high proportion of each lab's total number of tests, and (2) labs for which add-on tests constituted a high proportion of each lab's total payments for tests. This evaluation is national in scope. The data that we used included paid Medicare Part B claims for COVID-19 tests billed alongside add-on tests from February through December 2020.

Analysis

From the claims data, we identified 19,577 labs that received Medicare Part B payments for claims for COVID-19 tests in 2020. We then determined and calculated the percentage of labs that billed for add-on tests (i.e., IRTs, RPPs, genetic tests, and allergy tests) on the same claim as a COVID-19 test at least once during the year and labs that never billed for add-on tests. For the purposes of this study, we use the term "test" to mean one line of service on a claim. See Appendix A for the list of COVID-19 tests and add-on tests that were included in our analysis.⁹

We conducted an outlier analysis of labs that billed for add-on tests on claims for COVID-19 tests. Of the 8,582 labs that billed for add-on tests, we excluded from our analysis 2,994 labs that billed Medicare for fewer than 100 COVID-19 and add-on tests. We did not include these labs because they billed a relatively low volume of tests. Thus, our outlier analysis focused on 5,588 labs.

Next, we used a standard data analysis technique to identify labs that were outliers on each of the measures (i.e., labs that were above the 75th percentile plus three times

the interquartile range).¹⁰ Exhibit 1 describes the measures we used, the calculations for each measure, and the thresholds.

In addition to the two measures, we identified claims where an outlier lab billed for the same enrollee to receive the same tests on the same day as another lab, which may be indicative of a fraud scheme in which two labs agree to share an enrollee's Medicare number and bill for tests that only one or neither lab performed to increase the payments one or more lab receives from Medicare.

Exhibit 1: Outlier thresholds analysis

Billing Pattern		Calculation for Each Lab	Thre	shold
High Proportion of Add-On Tests	=	Total number of add-on tests Total number of COVID-19 tests and add-on tests	≥	38%
High Proportion of Payments for Add-On Tests	=	Total payment for add-on tests Total payment for COVID-19 tests and add-on tests	_ ≥	33%

Source: OIG calculations of each lab's Medicare Part B claims for COVID-19 tests from February through December 2020.

Limitations

This study is limited to an evaluation of Medicare Part B lab claims and does not include COVID-19 tests provided by other programs, such as community testing efforts, unless they were paid for by Medicare Part B. COVID-19 tests and add-on tests paid for under Part A and C programs are not included in this analysis.

The outlier analysis does not provide conclusive evidence of wasteful or potentially fraudulent billing; rather, it identifies labs with high levels of billing for add-on tests relative to all other labs. Further investigation is needed to determine whether the labs identified through the analysis in fact billed for any inappropriate or fraudulent Medicare Part B claims for COVID-19 or add-on tests.

Standards

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

FINDINGS

Of the 19,577 labs that billed Medicare Part B for COVID-19 tests in 2020, more than half (10,995) did not bill for any add-on tests. The remaining labs (8,582) each billed Medicare Part B for at least one add-on test (i.e., an IRT, an RPP, a genetic test, or an allergy test) on the same claim as for COVID-19 tests.

56%

of labs did <u>not</u> bill for any add on tests on claims for COVID 19 tests in 2020.

44%

of labs billed for add on tests on claims for COVID 19 tests in 2020.

More than 370 outlier labs billed Medicare Part B for questionably high levels of add-on tests

We identified 378 outlier labs that exhibited at least 1 of 2 questionable billing patterns. ¹¹ More than one-third of these labs (161) exhibited both questionable billing patterns. Over the span of 11 months in 2020, Medicare Part B paid these 378 labs more than \$67 million for add-on tests. On a per-claim basis, whereas Medicare paid an average of \$89 to all other labs for claims for COVID-19 tests, Medicare paid outlier labs an average of \$227. ¹² One outlier lab was paid, on average, about \$1,000 for each claim.

More than 270 labs billed for a high proportion of add-on tests alongside COVID-19 tests

Outlier analysis identified that 276 labs billed for a high proportion of add-on tests relative to COVID-19 tests. For these 276 labs, the volume of add-on tests made up at least 38 percent of the labs' billing for COVID-19 and add-on tests. Twenty-four of these labs billed for add-on tests on almost all (90 percent or more) of their claims for COVID-19 tests. See Lab Profile #1 below for an example of a lab that billed for a high proportion of add-on tests on its claims for COVID-19 tests.

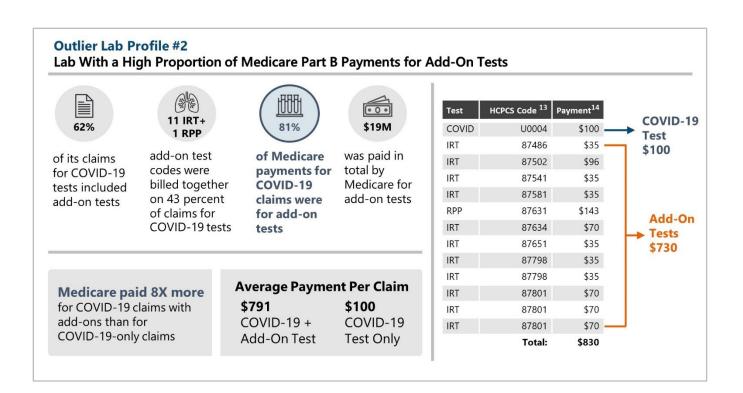
billed for add on tests on at least 90 percent of their claims for COVID 19 tests

Outlier Lab Profile #1 Lab Billed Medicare Part B for Add-On Tests With Almost All of Its COVID-19 Tests This lab often billed for multiple add-on tests with COVID-19 tests \$5.6M 5 IRT between April and September 2020, peaking in June 2020. add-on test of its claims of Medicare was paid in codes were for COVID-19 payments for total by 20,000 billed together tests included COVID-19 Medicare for on 65 percent **Add-On Tests** add-on tests claims were for add-on tests of claims for 15,000 add-on tests COVID-19 tests 10,000 5,000 Medicare paid 7X more **Average Payment Per Claim COVID-19 Tests** for COVID-19 claims with \$666 \$96 add-ons than for 0 COVID-19 + COVID-19 COVID-19-only claims Apr May Jun Jul Aug Sep Add-On Test Test Only

More than 260 labs received a high proportion of their Medicare Part B COVID-19 claim payments from add-on tests

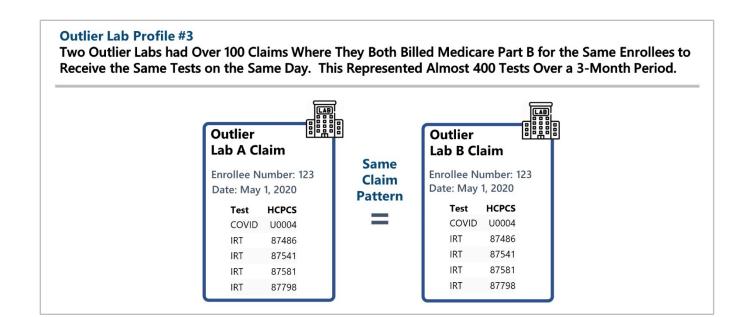
When compared to all other labs, 263 labs received a high proportion of their Medicare payments from add-on tests. For these 263 labs, payment for add-on tests made up at least 33 percent of the total payment on claims for COVID-19 tests. Moreover, 30 of these labs received more than 80 percent of their payments for these claims from add-on tests rather than the COVID-19 tests. See Lab Profile #2, on the next page, for an example of a lab with a high proportion of payment received from Medicare Part B for add-on tests.





Eight outlier labs exhibited another concerning billing pattern that may indicate a potential fraud scheme involving the sharing of enrollee information

We also identified eight outlier labs that billed Medicare Part B for the same tests for the same enrollee on the same day as another lab. Such billing is sometimes indicative of a fraud scheme in which two labs agree to share an enrollee's Medicare number and bill for tests that only one or neither lab performed to increase the payments they recieve from Medicare. While there could at times be legitimate reasons for two labs to bill for the same test for the same enrollee on the same day, repeated instances of this type of billing could indicate a potential fraud scheme. See Lab Profile #3 on the next page for an example of a lab that exhibited a pattern of billing for the same enrollee for the same test on the same day as another lab.



Individual respiratory tests (IRTs) and respiratory pathogen panels (RPPs) accounted for most of the payments that outlier labs received for add-on tests

\$67M

Medicare Part B
paid to outlier labs
for respiratory
add-on tests billed
with COVID-19 tests
in 2020

The most common types of add-on tests that drove up volume and Medicare Part B payments for COVID-19 tests in 2020 were IRTs and RPPs. In general, these types of tests diagnose respiratory complications and illnesses, such as influenza and pneumonia, which may present similar symptoms to those of COVID-19. Thus, practitioners may have legitimately ordered these add-on tests alongside COVID-19 tests for their patients who had respiratory symptoms, for example, to rule out or confirm diagnoses of other respiratory illnesses. Although far less frequent than IRTs and RPPs, other add-on tests billed by outlier labs on the same claims as for COVID-19 tests were for allergy tests and genetic tests. See the exhibit below for information about each type of add-on test billed by outlier labs on claims for COVID-19 tests.

Exhibit 2: Add-on tests increased Medicare Part B payments to outlier labs by amounts ranging from \$66 to \$237 per test on average

Add-On Test Category	Average Payment per Test	Total Payment	Number of Tests	Number of Labs
IRTs	\$66	\$48,299,294	728,203	373
RPPs	\$237	\$18,611,493	78,672	178
Allergy Tests	\$155	\$178,124	1,150	18
Genetic Tests	\$198	\$36,123	182	16

Source: OIG analysis of Medicare Part B claims data from February through December 2020. See Appendix A for the list of add-on tests we examined.

Individual Respiratory Tests (IRTs)

IRTs were the most common add-on tests billed on claims for COVID-19 tests. The average payment for an IRT was \$66. Over 300 outlier labs (373) billed Medicare Part B for over 700,000 IRTs as add-on tests in 2020, costing Medicare about \$48 million in total payments. The most common IRT HCPCS code, billed by about 45 percent of all outlier labs, was HCPCS code 87798, a general test code used when a more specific code is not available and which can be used to indicate tests for measles, mumps, and norovirus among others. Other prevalent IRT HCPCS codes that labs billed were HCPCS code 87581 and HCPCS code 87486, both of which tests for a type of pneumonia. See Exhibit 3 below for the top three IRTs billed by outlier labs.

\$48M **Medicare Part B** paid to outlier labs for individual respiratory add on tests billed with COVID 19 tests in 2020

Exhibit 3: Three most common individual respiratory tests that outlier labs billed with COVID-19 tests

HCPCS Code	Test Description	Average Payment	Total Payment	Number of Tests	Number of Outlier Labs
87798	Detection test by nucleic acid for organism, amplified probe technique. This is a general test code that is used when a specific code is not available, and can be used to indicate tests for measles, mumps, norovirus among others.	\$116	\$19,172,455	165,861	171
87581	Detection test by nucleic acid for <i>Mycoplasma pneumoniae</i> (bacteria), amplified probe technique	\$43	\$5,187,088	120,151	161
87486	Detection test by nucleic acid for <i>Chlamydia pneumoniae</i> , amplified probe technique	\$40	\$4,530,897	113,549	149

Source: OIG analysis of Medicare Part B claims data from February through December 2020.

One of the concerning patterns we identified involved billing for the same combination of IRTs with COVID-19 claims. This billing pattern raises questions as to whether every patient needed the full combination of these tests, or rather, whether it was a standard practice for the labs or practitioners to routinely bill for these tests on claims for COVID-19 tests regardless of the patient's symptoms. See Lab Profile #4 on the next page for an example of a lab that billed for a series of IRTs for over 20 percent of their claims for COVID-19 tests. The resulting average payment for the COVID-19 claim with add-on test was six times more than the average payment for a COVID-19-only claim. This combination of billing for add-on tests significantly increased the amount that Medicare Part B paid the lab.

Outlier Lab Profile #4

A Lab Billed Medicare Part B for Multiple Individual Respiratory Tests on Claims for COVID-19 Tests.



of its claims for COVID-19 tests included add-on tests



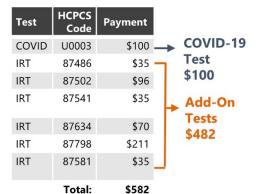
add-on test codes were billed together on 22 percent of claims for COVID-19 tests



of Medicare payments for COVID-19 claims were for add-on tests



was paid in total by Medicare for add-on tests



This lab billed for a specific group of 6 individual respiratory tests together

on 22 percent of their claims for

COVID-19 tests.

Medicare paid 6X more

for COVID-19 claims with add-ons than for COVID-19-only claims Average Payment Per Claim

\$618 \$99 COVID-19 + COVID-19 Add-On Test Test Only

Respiratory Pathogen Panels (RPPs)

RPPs were the second most common type of add-on tests that outlier labs billed with COVID-19 tests in 2020. An RPP can use a single sample to test for a panel of different bacteria or viruses that cause respiratory symptoms. The average payment for an RPP add-on test was \$237, which is significantly more expensive per test on average than IRTs. Of the 378 outlier labs, 178 billed Medicare for at least 1 RPP add-on test on claims for COVID-19 tests, costing Medicare almost \$19 million in 2020. Two labs accounted for 36 percent of payments for RPP add-on tests.

\$19M

Medicare Part B
paid to outlier
labs for RPP
add on tests
billed with
COVID 19 tests
in 2020

While outlier labs billed for 5 different types of RPPs, by far the 2 most common were a panel test that targeted 3-5 respiratory viruses (HCPCS code 87631) and a panel test that targeted 12-25 respiratory viruses (HCPCS code 87633). The amount Medicare paid for each RPP add-on test depended on the number of tests conducted—the more tests conducted within a panel, the higher the Medicare payment. See Exhibit 4 below for the breakdown of RPPs most commonly billed by outlier labs.

Exhibit 4: Most common respiratory pathogen panels that outlier labs billed with COVID-19 tests

HCPCS Code	Test Description	Average Payment	Total Payment	Number of Tests	Number of Outlier Labs
87631	Detection test by nucleic acid for multiple types of respiratory virus, multiple types or subtypes, 3-5 targets	\$141	\$7,235,494	51,152	72
87633	Detection test by nucleic acid for multiple types of respiratory virus, multiple types or subtypes, 12-25 targets	\$413	\$11,018,560	26,687	138

Source: OIG analysis of Medicare Part B claims data from February through December 2020.

See Lab Profile #5 below for an example of a lab that billed Medicare for almost 2,000 RPP add-on tests with COVID-19 tests in 2020.

Outlier Lab Profile #5

Lab Billed Medicare Part B for Almost 2,000 RPP Tests in 2020 on Claims for COVID-19 Tests











of its claims for COVID-19 codes were add-on tests

add-on test tests included billed together COVID-19 on 12 percent of claims for **COVID-19 tests**

of Medicare payments for claims were for add-on tests

was paid in total by Medicare for add-on tests

Medicare paid 7X more

for COVID-19 claims with add-ons than for COVID-19-only claims

Average Payment Per Claim

\$727 \$100 COVID-19 + COVID-19 Add-On Test Test Only

This lab billed Medicare for almost 2,000 RPP add-on tests and was paid about \$400 per test. The \$823,000 in payments for these RPP tests represents 56 percent of the lab's total payments for add-on tests.

Test	HCPCS Code	Number of Tests	Total Payment
RPP	87633	1,426	\$594,120
RPP	0099U	550	\$228,946
	Total:	1.976	\$823,066

CONCLUSION

Our analysis suggests that further scrutiny of billing by the 378 outlier labs is needed and, therefore, OIG has referred these labs to CMS for further review. Outlier labs exceeded the thresholds for one or both measures of questionable billing, raising concerns about potential waste or fraud. Compared to their peers, these labs billed for a high proportion of add-on tests relative to COVID-19 tests or received a significant amount of payments for add-on tests or both.

We found that outlier labs billed for a high proportion of add-on tests with COVID-19 tests or received a high proportion of Medicare Part B payments from add-on tests billed with COVID-19 tests, or both. On their claims for COVID-19 tests, some of the 378 labs billed for add-on tests in combinations that had little if any variation across patients. The add-on tests significantly increased the per-claim amounts that Medicare Part B paid to these labs. As a result, some reimbursements for claims for COVID-19 tests with add-on tests were six times more than reimbursements for COVID-19 tests alone. These billing patterns raise concern about waste or potential fraud, suggesting a need for further scrutiny of billing by these labs.

APPENDIX

Appendix A: COVID-19 and Add-On Tests Included in This Analysis

COVID-19 Tests: To create a list of COVID-19 tests, we used Current Procedural Terminology¹⁶ test codes and HCPCS codes to identify 23 COVID-19 tests that were authorized for payment in 2020. This set of codes includes viral tests, antibody tests, and respiratory panel tests that include COVID-19 in the panel. We included only tests paid for by Medicare Part B in our analysis. See below for the list for HCPCS codes that we reviewed. Not all of these codes were billed with an add-on test in 2020.

COVID-19 HCPCS codes: 23 tests

87426, 87428, 87635, 87636, 87637, 87811, 0202U, 0223U, 0225U, 0240U, 0241U, U0001, U0002, U0003, U0004, 86318, 86328, 86769, 86408, 86409, 86413, 0224U, 0226U

Add-On Tests: We consulted with our OIG counterparts and CMS to identify the add-on tests to include in each of the add-on test categories that we used in our final analysis. We also reviewed relevant sections of the AMA codebook, as suggested by CMS, as well as other reports that analyzed these types of tests to create the list of tests included in each of the four add-on test categories. Note that there may be other tests that could be considered add-on tests (e.g., allergy tests, genetic tests, IRTs, and RPPs that were billed alongside COVID-19 tests) that were not included in our review. See below for the list of HCPCS codes that we reviewed for each of the four add-on test categories. Not all of the tests that we identified were actually billed with a COVID-19 test in 2020.

Individual Respiratory HCPCS codes: 47 tests

87265, 87275, 87276, 87278, 87279, 87280, 87281, 87299, 87300, 87305, 87385, 87400, 87420, 87430, 87449, 87483, 87485, 87486, 87487, 87501, 87502, 87503, 87540, 87541, 87542, 87555, 87556, 87557, 87580, 87581, 87582, 87634, 87650, 87651, 87652, 87653, 87797, 87798, 87799, 87800, 87801, 87802, 87804, 87807, 87880, 87899, 87999

RPP HCPCS codes: 8 tests

87631, 87632, 87633, 0098U, 0099U,0100U, 0115U, 0151U

Allergy HCPCS codes: 35 tests

95004, 95012, 95017, 95018, 95024, 95027, 95028, 95044, 95052, 95056, 95060, 95065, 95070, 95076, 95079, 95115, 95117, 95120, 95125, 95130, 95131, 95144, 95145, 95146, 95147, 95148, 95149, 95165, 95170, 95180, 95199, 86001, 86003, 86005, 86008

Genetic HCPCS codes: 456 tests

81105-81112, 81120, 81121, 81161-81168, 81170-81194, 81200-81279, 81283-81337, 81340-81348, 81350-81353, 81355, 81357, 81360-81364, 81370-81383, 81400-81408, 81410-81417, 81420, 81422, 81425-81427, 81430-81440, 81442-81443, 81445, 81448, 81450, 81455, 81460, 81465, 81470, 81471, 81479, 81490, 81493, 81500, 81503-81504, 81506-81512, 81518-81522, 81525, 81528, 81529, 81535, 81536, 81538-81542, 81545, 81546, 81551, 81552, 81595, 81596, 87153, 0001M, 0001U, 0002M, 0002U, 0003M, 0003U, 0004M, 0005U, 0006M, 0006U, 0007M, 0007U, 0008M, 0008U, 0009M, 0009U, 0010U, 0011M, 0011U, 0012M, 0012U, 0013M, 0013U, 0014M, 0014U, 0015M, 0016M, 0016U, 0017U, 0018U, 0019U, 0021U-0027U, 0029U-0056U, 0058U-0061U, 0067U, 0069U, 0080U, 0083U, 0084U, 0087U-0092U, 0101U-0103U, 0110U, 0111U, 0113U, 0120U, 0129U-0138U, 0153U, 0156U-0162U, 0168U-0171U, 0175U, 0177U, 0179U-0201U, 0203U-0205U, 0208U, 0209U, 0211U-0219U, G9143, S3800, S3840-S3842, S3844-S3846, S3849, S3850, S3852-S3854, S3861, S3865, S3866, S3870

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To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

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ABOUT THE OFFICE OF INSPECTOR GENERAL

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The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

ENDNOTES

- ¹ DOJ, *Lab Owner Pleads Guilty to \$6.9 Million Genetic Testing & COVID-19 Testing Fraud Scheme*, January 13, 2022. Accessed at https://www.justice.gov/opa/pr/lab-owner-pleads-guilty-69-million-genetic-testing-covid-19-testing-fraud-scheme on October 18, 2022.
- ² DOJ, Millennium Health Agrees to Pay \$256 Million to Resolve Allegations of Unnecessary Drug and Genetic Testing and Illegal Remuneration to Physicians, October 19, 2015. Accessed at https://www.justice.gov/opa/pr/millennium-health-agrees-pay-256-million-resolve-allegations-unnecessary-drug-and-genetic on October 18, 2022.
- ³ CMS, CMS Press Release, *CMS Develops Additional Code for Coronavirus Lab Tests*, March 5, 2020. Accessed at https://www.cms.gov/newsroom/press-releases/cms-develops-additional-code-coronavirus-lab-tests on October 18, 2022.
- ⁴ For example, in order to expand access to certain diagnostic respiratory tests, CMS removed the requirement for a practitioner order for those tests. See 85 Fed. Reg. 27558, 27620 (May 8, 2020) (amending 42 CFR § 410.32(a)). For a list of the tests see CMS, Commonly Ordered COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Allows One Test Without a Practitioner Order During the PHE, May 5, 2021. Accessed at https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf on November 28, 2022.
- ⁵ The CDC recommendations for COVID-19 testing have been developed on the basis of what is currently known about COVID-19 and are subject to change as additional information becomes available. CDC, *Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)*, March 8, 2020. Accessed at https://emergency.cdc.gov/han/2020/HAN00429.asp on October 18, 2022.
- ⁶ OIG, *Fraud Alert: COVID-19 Scams*, February 2, 2022. Accessed at <a href="https://oig.hhs.gov/fraud/consumer-alerts/fraud-alert-covid-19-scams/?utm-source=web&utm-web&utm-web&utm-covid-19-scams/?utm-source=web&utm-web&utm-campaign=covid-19-fraud-alert-on October 18, 2022.
- ⁷ DOJ, *DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19*, May 26, 2021. Accessed at https://www.justice.gov/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19 on October 18, 2022.
- ⁸ DOJ, Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over \$2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged, September 27, 2019. Accessed at https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against on October 18, 2022.
- ⁹ This report identifies tests by procedure code. The five character codes and descriptions included in this report are obtained from Current Procedural Terminology (CPT®), copyright 2021 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this design should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.
- ¹⁰ This is a standard exploratory method for identifying members of a population with unusually high values on a given statistic compared to the rest of the population when no benchmarks exist. See J.W. Tukey, *Exploratory Data Analysis*, Addison-Wesley, 1977.
- ¹¹ These 378 labs represent 2 percent of all labs that billed for COVID-19 tests in 2020.
- ¹² These averages included claims both with and without add-on tests.
- ¹³ See endnote 9 for AMA copyright notice.
- ¹⁴ Because of rounding, the sum of the individual tests listed in the payment column do not add up to the total of \$830 in the payment column.

¹⁵ Each of these 8 labs submitted at least 10 claims where both labs billed for the same enrollee for the same tests on the same day.
¹⁶ See endnote 9 for AMA copyright notice.