Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS Could Improve Its Procedures for Setting Medicare Clinical Diagnostic Laboratory Test Rates Under the Clinical Laboratory Fee Schedule for Future Public Health Emergencies

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Report in Brief
Date: April 2024
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

CMS Could Improve Its Procedures for Setting Medicare Clinical Diagnostic Laboratory Test Rates Under the Clinical Laboratory Fee Schedule for Future Public Health Emergencies

Why OIG Did This Audit

On March 13, 2020, the White House declared the COVID-19 outbreak a national emergency. This emergency posed unprecedented challenges to the delivery of health care including the establishment of sufficient lab testing capacity to help combat COVID-19. In response to the public health emergency (PHE) and these challenges, CMS had to quickly establish billing codes for new clinical diagnostic laboratory tests (CDLTs) and payment rates that would be adequate to cover labs' costs for conducting the tests.

Our objective was to determine whether CMS's procedures for CDLT rate setting could be improved for future PHEs.

How OIG Did This Audit

We reviewed applicable laws and regulations effective as of January 2018 related to CMS setting rates for new CDLTs. We reviewed those principles in the *Standards for Internal Controls in the Federal Government* (Green Book) that we determined were relevant to our audit objective. We also conducted interviews with CMS and Medicare administrative contractor's (MAC's) pricing coordinators to obtain an understanding of the rate setting process that occurred from February 2020 through January 2021. We conducted interviews with officials from two laboratory associations to obtain an understanding of the communication they had with CMS and MACs during the PHE rate setting process.

What OIG Found

CMS's procedures for CDLT rate setting could be improved for future PHEs. Specifically, CMS could improve its: (1) communication with laboratory associations and the MACs' pricing coordinators, and (2) procedures to provide the MACs with additional flexibility when they set interim CDLT rates to respond to a PHE. Neither the Clinical Laboratory Fee Schedule (CLFS) statute nor its implementing regulations specifically address how pricing coordinators could quickly set rates for new CDLTs before the lengthy public consultation rate setting process. Normally, CMS fills that delay by using its longstanding MAC interim rate setting policy. Accordingly, in March 2020, MACs set rates for new COVID-19 viral tests through CMS's interim MAC rate setting policy. However, CMS had to take additional action beyond its standard rate setting procedures to set and adjust rates for CDLTs.

As a result, CMS's standard rate setting procedures did not allow the MACs to set rates that were adequate to cover the cost of conducting COVID-19 viral tests for all laboratories during a time when CMS was working to increase testing capacity. CMS may have missed opportunities to obtain important information that could have improved its response to the COVID-19 pandemic from laboratory associations and the MACs' pricing coordinators when it made decisions about the new CDLT rates.

What OIG Recommends and CMS Comments

We recommend that CMS: (1) establish procedures to improve communication among stakeholders involved in setting new CDLT rates during a PHE; and (2) improve its procedures, which may require seeking legislative authority, for setting and adjusting rates for new CDLTs during a PHE.

In written comments on our draft report, CMS did not explicitly state its concurrence or nonconcurrence with our recommendations but stated that it will take our findings and recommendations into consideration for future PHEs. CMS stated that it engaged with stakeholders to identify and address barriers and needs to ensure the availability and timeliness of testing throughout the COVID-19 PHE. Additionally, by following typical and established procedures, MACs had the ability to set payment amounts for new test codes in their respective jurisdictions until Medicare established the CLFS payment rates. We maintain that our recommendations remain valid.

The full report can be found on the OIG website.

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INTRODUCTION

WHY WE DID THIS AUDIT

The White House declared the COVID-19 outbreak a national emergency on March 13, 2020. This emergency posed unprecedented challenges to the delivery of health care including the establishment of sufficient laboratory testing capacity to help combat the COVID-19 pandemic. In an April 2020 report, the Office of Inspector General (OIG) described how, in late March 2020, hospitals' reliance on external laboratories contributed to delays in COVID-19 viral testing. The report noted that these laboratories became overwhelmed with tests to process from around the State or country.[1] The backlogs were partly due to the limited number of laboratories conducting testing. As noted in a *USA Today* article, the Centers for Medicare & Medicaid Services' (CMS's) Administrator stated that a lot of laboratories were not performing the tests.[2] According to the OIG report, laboratories also noted difficulty and increased costs in obtaining the necessary equipment and supplies to conduct the necessary testing. Furthermore, the Centers for Disease Control and Prevention (CDC) issued guidance for laboratories that established priorities for the order in which individuals with suspected COVID-19 infections should be tested to help ensure those most in need of tests could access them as quickly as possible.[3] These challenges made it more difficult for CMS to ensure that people enrolled in Medicare (enrollees) were able to receive COVID-19 test results in a timely manner.

In response to the Public Health Emergency (PHE) and these challenges, CMS had to quickly establish billing codes for new Medicare clinical diagnostic laboratory tests (CDLTs) under the Clinical Laboratory Fee Schedule (CLFS) and payment rates that would be adequate to cover laboratories' costs for conducting the tests. As with any newly created billing codes under the CLFS, Medicare administrative contactors (MACs) set the payment rates for the newly created codes for the COVID-19 viral tests.[4] However, given the unprecedented challenges the COVID-19 pandemic continued to cause, CMS issued a ruling to increase the payment rate for

[1] *Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020* (OEI 06-20-00300) Apr. 3, 2020.

[2] Mansfield, Erin, *USA Today*, "Coronavirus testing in the U.S. was limited for months because of low Medicare payments." Available online at https://www.usatoday.com/story/news/2020/04/30/coronavirus-testing-stunted-low-medicare-reimbursement/3048943001/. Accessed on May 18, 2020.

[3] The Centers for Disease Control and Prevention (CDC), "Priorities for Testing Patients With Suspected COVID-19 Infection." Available online at https://web.archive.org/web/20200326143907/https:/www.cdc.gov/coronavirus/2019-ncov/downloads/priority-testing-patients.pdf. Accessed on Feb. 8, 2023.

[4] In March 2020, MACs set the Medicare payment rate for new COVID-19 viral tests at $51.

high-throughput-testing technology that could lead to increased testing capacity.[5, 6] In a statement to *USA Today*, the CMS Administrator acknowledged that the payment rate initially set by the MACs may have played a role in testing shortages.[7] The CMS Administrator also noted that a lot of laboratories were not performing the tests and acknowledged that the initial payment rate may have been set too low. Additionally, the CMS Administrator said that an increase in the payment rate should lead to an increase in testing capacity.

COVID-19 has created extraordinary challenges for the delivery of health care and human services to the American people. As the oversight agency for the Department of Health and Human Services (HHS), OIG oversees HHS's COVID-19 response and recovery efforts. This audit is part of OIG's COVID-19 response strategic plan.[8]

OBJECTIVE

Our objective was to determine whether CMS's procedures for CDLT rate setting could be improved for future PHEs.[9]

BACKGROUND

The Medicare Program and the Role of the Centers for Medicare & Medicaid Services

The Medicare program provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. CMS administers Medicare. CMS's goal is to provide a high-quality health care system that ensures better care, access to coverage, and improved health for Medicare enrollees. Furthermore, CMS describes one of its roles as facilitating access and payment for CDLTs for Medicare enrollees. Medicare Part B provides supplementary medical insurance for medical and other health services, including

[5] CMS, "Ruling CMS-2020-01-R" (issued on Apr. 14, 2020). Available online at https://www.cms.gov/files/document/cms-2020-01-r.pdf. (Accessed on July 7, 2021.) This rule increased the Medicare payment rate for high-throughput COVID-19 viral tests to $100. The ruling explained that high-throughput technology uses a platform of highly sophisticated equipment that employs automated processing of more than 200 specimens a day. This allows for increased testing capacity and faster results to combat the spread of COVID-19 more effectively. However, this equipment requires more intensive technician training and time intensive processes.

[6] CMS rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, utilization and quality control peer review, private health insurance, and related matters.

[7] See footnote 2.

[8] *OIG Strategic Plan: Oversight of COVID-19 Response and Recovery*. Available online at https://oig.hhs.gov/coronavirus/strat.asp.

[9] We audited the CDLT rate setting process under the Medicare CLFS.

CDLTs performed in a laboratory or a physician's office that generally have no cost to Medicare enrollees.

CMS contracts with 7 MACs for 12 jurisdictions 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.[10]

Clinical Diagnostic Laboratory Tests

CDLTs examine substances from the human body for diagnosis, prevention, disease treatment, or to assess a medical condition. Medicare Part B pays for most CDLT codes under the CLFS.[11] This includes tests performed in laboratories in hospitals, physician offices, independent laboratories, dialysis facilities, and nursing facilities among other institutions.[12] Beginning in 2018, the Protecting Access to Medicare Act of 2014 requires that CMS sets rates for the CLFS at the weighted median of private payer rates.[13] CMS collects private payer information for each CDLT every 3 years, and this information includes the rates paid by each private payer for each test and the volume of each test performed. However, CMS informed us that due to congressional delays, there has only been one round of data collection.

Federal Laws and Regulations for Setting New Clinical Diagnostic Laboratory Test Rates

Federal regulations require rates for new CDLTs to be set after the public consultation process established in 42 CFR § 414.506, which CMS uses to determine whether the "crosswalking" or "gapfilling" methodologies as outlined in 42 CFR § 414.508 will be used as the basis for setting new rates.[14, 15]

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[10] CMS, "Jurisdiction Map" (as of June 2021). Available online at www.cms.gov/files/document/ab-jurisdiction-map-jun-2021.pdf. Accessed on July 20, 2022. For each jurisdiction, CMS enters into a contract with one entity to serve as the Medicare contractor. Although there are 12 jurisdictions, there are only 7 MACs because 5 MACs were awarded contracts for 2 jurisdictions each.

[11] Medicare does not cover clinical laboratory screenings (tests done on patients with no personal disease history and with no disease signs or symptoms) with certain exceptions. For example, these exceptions include cardiovascular disease, diabetes, cervical cancer, colorectal cancer, and prostate cancer.

[12] 42 CFR § 410.32(d) outlines who may furnish tests in order for the tests to be covered by Medicare Part B.

[13] Federal regulation (42 CFR § 414.502) defines private payer rates as the final amount that is paid by a private payer for a CDLT.

[14] The Social Security Act § 1834A(c), 42 U.S.C. § 1395m-1(c), details the statutory payment requirements for new CDLTs.

[15] *Medicare Learning Network,* "Clinical Laboratory Fee Schedule Annual Payment Determination Process" (published June 2020). Available online at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/mln-determining-clfs-payments_0.pdf. Accessed on Oct. 19, 2022.

Crosswalking is used when a new CDLT is determined to be comparable to an existing test, multiple existing tests, or a portion of an existing test. Payment for the new test is made based on the amount established for the comparable existing CDLT. CMS uses the gapfilling methodology when no comparable test exists. Gapfilling bases payment on other information, such as charges for the test, routine discounts to charges, payment amounts determined by other payers, resources required to perform the test, and other criteria CMS determines appropriate. Gapfilling payment rates are set by the MACs for the first year.[16] During the second year, the rate paid is the median of MAC-specific rates (42 CFR § 414.508).

Before CMS determines the basis for payment (i.e., crosswalking or gapfilling) and the amount of payment for a new CDLT, CMS must conduct a public consultation process. During this process, CMS presents a list of codes to the public for which an established payment amount is being considered for the next calendar year. CMS then publishes notice of an annual meeting in the Federal Register. At this meeting, CMS officials receive public comments on which recommendations are based for determining the appropriate basis (crosswalking or gapfilling) for establishing new payment amounts for CDLTs. In addition, CMS consults with an expert outside advisory panel that provides CMS with input on the establishment of payment rates and recommendations.[17] Using the public comments, recommendations, and advisory panel input, CMS develops and makes publicly available a proposed basis for the payment amount and data on which the recommendations are based for each code and requests written public comments on the proposed determination. Next, CMS develops and makes publicly available final payment determinations for each code with responses to comments and suggestions from the public. Furthermore, CMS also provides the rationale for both proposed and final determinations (42 CFR § 414.506).

This public consultation process that is established in regulation can take several months to determine whether the crosswalking or gapfilling basis will be used to set new rates (42 CFR § 414.506). New rates that are finalized through the public consultation process are set until applicable information is available to establish a payment amount using the weighted median of private payer rates (42 CFR § 414.508).[18] Therefore, these rates cannot be adjusted quickly based on new information.

[16] After CMS posts the interim MAC-specific gapfilled rates, CMS accepts written comments on those interim rates from the public for 60 days. Then, after CMS posts the final MAC-specific gapfilled rates, CMS accepts reconsideration requests on those final rates for 30 days (42 CFR § 414.509).

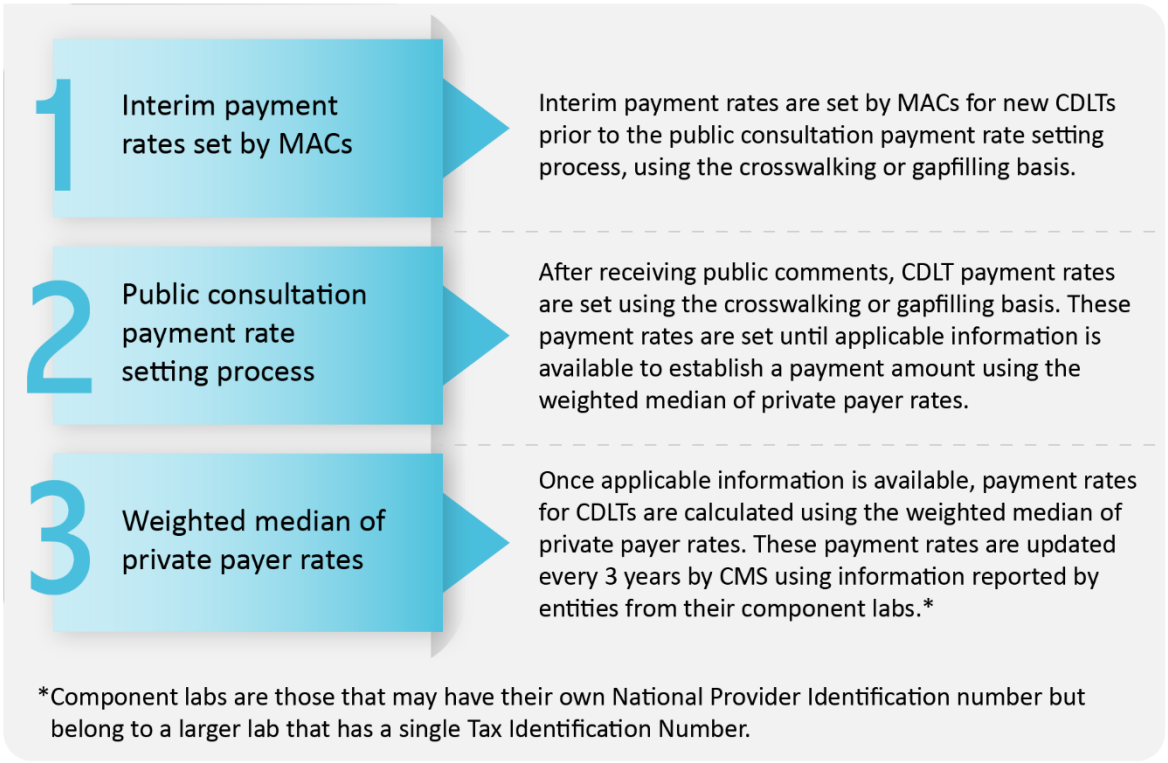
[17] The advisory panel may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics in issues related to CDLTs.

[18] Per 42 CFR § 414.502, "applicable information" with regards to each CDLT means: (1) each private payer rate for which final payment has been made during the data collection period, (2) the associated volume of tests performed corresponding to each private payer rate, and (3) the specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

CMS's MAC Interim Rate Setting Policy for New Clinical Diagnostic Laboratory Tests

In addition to the public consultation rate setting process, CMS officials stated that CMS has a longstanding policy in which MACs set interim rates when new codes are published and effective for new CDLTs in their respective jurisdictions prior to the public consultation process. Thus, CMS's standard rate setting procedures for new CDLTs include both the public consultation payment rate setting process and MAC interim rate setting policy. CMS explained that it uses its longstanding MAC interim rate setting policy because it is important that Medicare enrollees have access to new services as they become available. During this MAC interim rate setting process, MACs set interim rates using either the crosswalking or gapfilling methodologies outlined in 42 CFR § 414.508. (See the figure below for more on the rate setting process.)

Figure: Rate Setting Process for New CDLTs



During our interviews, we were informed that each of the MACs use designated pricing coordinators, which are individuals or entities that calculate interim payment rates for new CDLTs for one or more MACs. The seven MACs use three pricing coordinators to set new CDLT rates. Two of the three pricing coordinators we interviewed set the interim payment rates for new COVID-19 viral testing codes for more than one MAC. We conducted interviews with representatives of these pricing coordinators instead of interviewing each MAC individually. For the purpose of this report, we will refer to these representatives as the MACs' pricing coordinators.

Rate Setting During the COVID-19 Pandemic

In March 2020, MACs set rates for new COVID-19 viral tests through CMS's longstanding MAC interim rate setting policy. CMS directed the MACs to set new rates under this policy to ensure that Medicare enrollees had access to these tests as they became available. MACs informed us that during the MAC interim rate setting process, they used the crosswalking methodology to set the payment rates for new COVID-19 viral tests because they were similar to a preexisting Zika test (87662).[19] The MACs explained that COVID-19 viral tests shared similar testing methodologies with Zika tests that were already priced and had previously been used under an emergency use authorization. Therefore, the MACs used a similar crosswalk and applied factors to the rates as needed to account for the increased costs of supplies such as personal protective equipment. As a result, MACs set the rates for the new COVID-19 viral testing codes (87635 and U0002) at $51.[20] However, the MACs noted that although there were similarities, the Zika test was not priced during a pandemic and did not have a high-throughput variant. In April 2020, CMS issued a ruling (CMS-2020-01-R) that created two additional new codes (U0003 and U0004) and set the payment rates for these codes at $100 to more accurately reflect the cost of acquiring sophisticated high-throughput-testing equipment that required more intensive technical training and more time intensive quality assurance processes.[21] CMS stated that this was done to incentivize laboratories to invest in high-throughput-testing platforms that would enable them to increase testing capacity.

In January 2021, CMS issued another ruling (CMS-2020-1-R2) to modify the payment rates established in the April 2020 ruling.[22] This new ruling set the payment rate for high-throughput

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[19] **The five-character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2018–2020 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 document should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.**

[20] Code 87635 is a CPT code created by the AMA for COVID-19 tests involving infectious agent detection by nucleic acid. Code U0002 is a HCPCS code created by CMS to allow laboratories to bill for tests created by entities unaffiliated with CDC (non-CDC COVID-19 tests). HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. HCPCS codes are divided into two groups: level I and level II. Level I is comprised of CPT codes, a numeric coding system maintained by the AMA, and is used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Level II is based on a standardized coding system and used primarily to identify products, supplies, and services not included in the CPT codes.

[21] CMS, "CMS-2020-01-R." Available online at https://www.cms.gov/files/document/cms-2020-01-r.pdf. Accessed on July 7, 2021. This ruling created the following two codes: (1) code U0003 allows laboratories to bill for COVID-19 tests involving infectious agent detection by nucleic acid (such as those under code 87635) making use of high-throughput technologies, and (2) code U0004 allows laboratories to bill for non-CDC COVID-19 tests (such as those under code U0002) making use of high-throughput technologies.

[22] CMS-2020-01-R2 can be accessed at: https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf. Accessed on July 7, 2021.

COVID-19 viral testing for codes U0003 and U0004 at $75 and created a $25 add-on payment under code U0005. If code U0005 was used for these two high-throughput tests, laboratories must have completed the tests within 2 days of specimen collection. Furthermore, the laboratory must have completed a majority of those tests in 2 days or fewer for all patients (including patients not enrolled in Medicare) during the prior calendar month. CMS explained this was done because it assumed the $100 rate from the April 2020 ruling would cover the additional costs laboratories would incur to meet the demands of the pandemic. In addition, it assumed the $100 rate would ensure tests were completed in a period short enough to maximize the clinical benefits. However, CMS noted that the April 2020 ruling did not account for a laboratory's ability to lower its resource costs by increasing the time between when it collected a specimen and completed the CDLT. CMS acknowledged in the January 2021 ruling that increasing the time between collection and testing could allow laboratories to run their high-throughput machines with less frequency and with fewer demands on staff. In response to the PHE and the challenges it posed, CMS officials stated that CMS needed to establish a uniformed rate quickly with the goal to incentivize the use of high-throughput technology; therefore, it issued the rulings independently (i.e., without input from the MACs). The table below contains a summary of payment rates for the COVID-19 viral test codes related to rulings CMS-2020-01-R and CMS-2020-1-R2.

Table: Summary for COVID-19 Viral Test Codes and Payment Rates

Initial			Modified Rates for High-Throughput		
CPT | HCPCS Codes	Payment Rate Mar. 2020		HCPCS Codes	Payment Rate Apr. 2020*	Payment Rate Jan. 2021†
87635 | U0002	$51		U0003 | U0004	$100	$75

* These codes and the $100 payment rates were established by CMS ruling CMS-2020-01-R in April 2020.

† This January 2021 payment rate was based on ruling CMS-2020-1-R2 that set the payment rate for high-throughput COVID-19 viral testing for codes U0003 and U0004 at $75 and created a $25 add-on payment under code U0005 for these two high-throughput tests for laboratories that completed the tests within 2 days of specimen collection if the laboratory also completed a majority of those tests for all patients during the prior calendar month in 2 days or fewer.

Office of Inspector General Data Brief on Medicare Payments for Laboratory Tests in 2020

In December 2021, OIG issued a data brief analyzing 2016 through 2020 spending on laboratory tests in Medicare Part B.[23] The data brief indicated that although the amount spent on non-COVID-19 testing decreased, from $7.7 billion in 2019 to $6.5 billion in 2020, overall spending for all laboratory tests increased to $8 billion in 2020. This increase in spending was primarily driven by $1.5 billion in new spending on COVID-19 tests. This spending on COVID-19

[23] *COVID-19 Tests Drove an Increase in Total Medicare Part B Spending on Lab Tests in 2020, While Use of Non-COVID-19 Tests Decreased Significantly* (OEI-09-21-00240) Dec. 30, 2021.

tests included a combined $1.26 billion for codes U0003 ($1.017 billion) and U0004 ($243.4 million). These are the high-throughput-testing codes established in CMS's April 2020 ruling (CMS-2020-01-R). Furthermore, the data brief showed that four COVID-19 viral test codes were listed in the top 25 test codes for spending on laboratory tests in 2020, which included codes 87635 ($70.8 million) and U0002 ($60.7 million).

Collaboration Among the Federal Government and Laboratories for Laboratory Surge Testing Capacity During Public Health Emergencies

In July 2021, the Government Accountability Office (GAO) issued a report that recommended, among other things, that the CDC "should work with appropriate stakeholders—including public health and private laboratories—to develop a plan to enhance laboratory surge testing capacity. This plan should include timelines, define agency and stakeholder roles and responsibilities, and address any identified gaps from preparedness exercises."[24] The report acknowledged that HHS agreed with GAO's recommendation and, in collaboration with external partners, developed a plan in May 2022 to enhance laboratory surge testing capacity at laboratories other than CDC and public health laboratories.

In 2022, CDC revised its 2018 Memorandum of Understanding (MOU) for surge testing capacity to include the Food and Drug Administration, and additional non-Government stakeholders to collaborate on enhanced laboratory surge testing capacity outside of the CDC and public health laboratories before and during PHEs.[25] Additionally, this MOU states that it can be updated annually to include other relevant partners that express interest and have the ability to support laboratory testing capacity.

HOW WE CONDUCTED THIS AUDIT

We reviewed applicable laws and regulations effective as of January 2018 related to CMS setting rates for new CDLTs. In addition, we reviewed those principles in the *Standards for Internal Controls in the Federal Government* (Green Book) that we determined were relevant to our audit objective.[26] We also conducted interviews with CMS and the MACs' pricing coordinators to obtain an understanding of the rate setting process that occurred from February 2020 through January 2021 (PHE rate setting process). We conducted interviews with officials from two laboratory associations, which are trade associations that represent clinical

[24] GAO, "Continued Attention Needed To Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity." Available online at https://www.gao.gov/assets/gao-21-551.pdf. Accessed Mar. 4, 2022

[25] CDC, "Memorandum of Understanding" (dated April 2018). Available online at https://www.cdc.gov/csels/dls/documents/CDC-ACLA_APHL_CSTE_MOU_April_2018.pdf. Accessed on Dec. 8, 2021. CDC, "Memorandum of Understanding" (dated April and May 2022). Available online at https://www.cdc.gov/csels/dls/documents/2022-revised-mou-for-surge-capacity_final_signed.pdf. Accessed on July 13, 2023.

[26] GAO, "Standards for Internal Controls in Federal Government." Available online at https://www.gao.gov/assets/gao-14-704g.pdf. Accessed on Oct. 5, 2022.

laboratories, to obtain an understanding of the communication they had with CMS and MACs during the PHE rate setting process.[27] We also asked CMS, MACs, and the laboratory associations to provide us with input on how the rate setting process could be improved for future PHEs.

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 contains the details of our audit scope and methodology.

FINDINGS

CMS's procedures for CDLT rate setting could be improved for future PHEs. Specifically, CMS could:

- improve its communication, especially with the MACs' pricing coordinators and laboratory associations, to give CMS better access to quality information that can be used to achieve its objectives; and

- improve its procedures to provide the MACs with additional flexibility when they set interim payment rates in response to a PHE.

In the context of unprecedented challenges from the COVID-19 national emergency, CMS took steps to ensure that Medicare enrollees had access to needed laboratory services and testing during the COVID-19 pandemic. CMS ensured that payment rates for new CDLTs were quickly set and adjusted the payment rates as needed to increase nationwide testing capacity.

Neither the CLFS statute nor its implementing regulations specifically address how to quickly set rates for new CDLTs before the often-lengthy public consultation rate setting process described in the statute and regulations. Normally, CMS fills that delay by using its longstanding MAC interim rate setting policy. Accordingly, in March 2020, MACs set rates for new COVID-19 viral tests through CMS's longstanding MAC interim rate setting policy. However, these procedures did not allow MACs to set rates that were adequate to cover all laboratories' costs of conducting COVID-19 viral tests during a time when CMS was working to increase testing capacity. Furthermore, because CMS's standard rate setting procedures (i.e., the longstanding MAC interim rate setting policy and public consultation payment rate setting process) do not

[27] Although the rate setting process outlined in regulation requires CMS to consult with an expert outside advisory panel during the rate setting process, it does not explicitly mention the inclusion of laboratory associations or their laboratories. However, we interviewed laboratory associations, which represent both large and small laboratories, as their laboratories are ultimately the entities responsible for conducting testing and could provide feedback relevant to the process.

specifically address setting or adjusting rates for new CDLTs quickly in response to a PHE, CMS had to take additional action beyond its standard rate setting procedures and issue CMS rulings to set and adjust rates for CDLTs.

As a result, CMS's standard rate setting procedures did not allow the MACs to set rates that were adequate to cover all laboratories' costs of conducting COVID-19 viral tests during a time when CMS was working to increase testing capacity. CMS may have missed opportunities to obtain important information from laboratory associations and the MACs' pricing coordinators when it made decisions about the new CDLT rates that could have improved its response to the COVID-19 pandemic. This may have resulted in CMS taking additional time to set adequate rates for high-throughput COVID-19 viral testing and an inefficient use of resources in responding to the PHE.

CMS COULD IMPROVE ITS COMMUNICATION WITH THE MACS' PRICING COORDINATORS AND LABORATORY ASSOCIATIONS TO GIVE CMS BETTER ACCESS TO INFORMATION

CMS could improve its communication with the MACs' pricing coordinators and laboratory associations to upgrade the quality of information it uses to achieve its objectives as required by the Green Book.[28] We believe this would allow CMS better access to quality information, such as cost information from laboratories. This quality information could then be used to facilitate access to and payment for CDLTs for Medicare enrollees.

During our interviews, the MACs' pricing coordinators and the laboratory associations stated that they did not have adequate communications with CMS during the MAC interim rate setting process and when CMS issued rulings to adjust the rates for COVID-19 viral tests. One MAC's pricing coordinator said that it would have liked to give input to CMS prior to the April 2020 ruling, which increased the payment rate to $100, to ensure the pricing more accurately reflected the costs relevant to conducting the tests. The MAC's pricing coordinator and a laboratory association both stated that some laboratories were able to conduct testing at the $51 payment rate established prior to CMS's ruling because they had efficiencies that allowed them to conduct high-throughput testing at a lower cost. However, the MAC's pricing coordinator noted that the adjusted $100 rate was adequate for all laboratories regardless of their efficiencies. The MAC's pricing coordinator explained that CMS rulings are binding on all MACs, and CMS does not have a process for the MACs to voice disagreement. Furthermore, laboratory associations explained that in some instances they had to initiate contact with CMS officials to obtain information. In summary, as stated by CMS officials, the rulings were issued independently—without outside information that could have been included in the decision-making process.

[28] The Green Book states that management uses quality information to support the internal control system. Effective information and communication are vital for an entity to achieve its objectives. Management needs access to relevant and reliable communication related to internal as well as external events. Management should use quality information to achieve the entity's objective (Principle 13) and externally communicate the necessary quality information to achieve the entity's objective (Principle 15).

CMS COULD IMPROVE ITS PROCEDURES TO PROVIDE THE MACS WITH ADDITIONAL FLEXIBILITY WHEN THEY SET INTERIM PAYMENT RATES TO RESPOND TO A PUBLIC HEALTH EMERGENCY

CMS could improve the design of its procedures to meet its objectives as required by the Green Book.[29] Because of the unprecedented challenges of the COVID-19 pandemic, CMS had to take additional action beyond its standard rate setting procedures by issuing a ruling to increase payment rates for CDLTs that utilized high-throughput technologies. CMS stated that its goal was to incentivize laboratories to increase testing capacity through the use of high-throughput technology. To meet this objective, CMS could improve its procedures to provide the MACs with additional flexibilities when they set interim CDLT rates to respond to a PHE.

During our interviews, the MACs' pricing coordinators explained that the MACs do not have the authority or flexibility to adjust payment rates to encourage laboratories to provide a particular service, such as a new CDLT during a PHE, if needed. Specifically, one of the MACs' pricing coordinators explained that it is not allowed the flexibility to adjust payment rates during the MAC interim rate setting process to encourage laboratories to invest in specific testing technologies, such as high-throughput-testing platforms to increase testing capacity. Additionally, another one of the MACs' pricing coordinators explained that if the MACs had additional flexibility to set prices under the PHE rather than using crosswalking or gapfilling the MACs' pricing coordinator could use alternative methods to encourage laboratories to respond to the need for increased testing during a PHE. Under the unprecedented challenges of the PHE, CMS resorted to issuing rulings to increase payment rates and stated its goal was to incentivize laboratories to increase testing capacity through the use of high-throughput technology. If CMS revised its longstanding MAC interim rate setting policy and public consultation rate setting process to allow the MACs to develop and adjust payment rates for tests, it could avoid having to issue rulings to increase payment rates. In addition, this could help cover the costs of providing testing services across all laboratories to better meet the demand of the pandemic and respond to a PHE.

CONCLUSION

CMS had a longstanding policy for MACs to set interim rates and a regulatory process for setting new CDLT payment rates through a public consultation process. However, these procedures did not allow MACs to set rates that were adequate to cover all laboratories' costs of conducting COVID-19 viral tests during a time when CMS was working to increase testing capacity. Furthermore, because CMS's standard rate setting procedures (i.e., the longstanding MAC interim rate setting policy and public consultation payment rate setting process) do not specifically address setting or adjusting rates for new CDLTs quickly in response to a PHE, CMS had to take additional action beyond its standard rate setting procedures and issue CMS rulings

[29] The Green Book states that control activities are the actions management establishes through policy and procedures to achieve objectives and respond to risk in the internal control system, which includes the entity's information system. Management should design control activities to achieve objectives and respond to risk (Principle 10) and implement control activities through policy (Principle 12).

to set and adjust rates for CDLTs. Prior to issuing these rulings, CMS may have missed opportunities to obtain important information from the MACs' pricing coordinators and laboratory associations when it made decisions about the new CDLT rates that could have improved its response to the COVID-19 pandemic. This may have resulted in CMS taking additional time to set adequate rates for high-throughput COVID-19 viral testing and an inefficient use of resources in response to the PHE.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- establish procedures to improve communication among all stakeholders involved in setting new CDLT rates during a PHE; and

- improve its procedures, which may require seeking legislative authority, for setting and adjusting rates for new CDLTs during a PHE by providing the MACs with the flexibility needed to set and adjust payment rates that would cover the laboratory costs of providing services when responding to a PHE.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS COMMENTS

In written comments on our draft report, CMS did not explicitly state its concurrence or nonconcurrence with our recommendations but stated that it will take our findings and recommendations into consideration for future PHEs.

In response to our recommendation to improve communication among all stakeholders, CMS stated that it engaged with stakeholders to identify and address barriers and needs to ensure the availability and timeliness of testing throughout the COVID-19 PHE. In addition, CMS stated that it considered public comments shared during the annual Laboratory Public Meetings, the expertise and recommendations from the Medicare Advisory Panel on CDLTs, and public comments submitted during the comment period for the annual payment determinations process under the CLFS.

In response to our recommendation to improve procedures for setting and adjusting rates for new CDLTs during a PHE, CMS stated that its current procedures allow for tests to be priced quickly. According to CMS, by following typical and established procedures, MACs had the ability to set payment amounts for new test codes in their respective jurisdictions until Medicare established the CLFS payment rates. Furthermore, CMS indicated that rulings are used periodically by the agency to provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions related to Medicare. During the COVID-19 PHE, CMS used the rulings to set payment for new COVID-19 tests because of the need to address the use of high throughput technology. CMS stated that its rulings were used to increase

resources for laboratories making use of high throughput platforms when performing COVID-19 tests and encouraged more laboratories to invest in technology that could keep up with the high demand of COVID-19 testing. CMS noted that MACs demonstrated flexibility by establishing initial payment rates for COVID-19 tests that were two and a half times higher than other similar tests to account for resources during the PHE.

Additionally, CMS provided a response regarding information presented in the Other Matters section of this report. CMS noted that funding for capital equipment purchases, use of local laboratories in rural areas, and implementation of a uniform laboratory test reporting system are outside of its scope and authority.

CMS also provided written technical comments, which we addressed as appropriate. CMS comments, excluding the technical comments, are included as Appendix B.

OFFICE OF INSPECTOR GENERAL RESPONSE

We maintain that CMS should establish procedures to improve communication among stakeholders involved in setting new CDLT rates during a PHE. During our audit, the MACs' pricing coordinators and the laboratory associations stated that they did not have adequate communications with CMS during the MAC interim rate setting process and when CMS issued rulings to adjust the rates for COVID-19 viral tests. For example, one MAC's pricing coordinator stated that it did not become aware of the first CMS ruling until the Technical Direction Letter was issued. Furthermore, CMS previously acknowledged that the rulings were issued independently.

We also maintain that CMS should improve its procedures for setting and adjusting rates for new CDLTs during a PHE. We acknowledge that the COVID-19 PHE posed unprecedented challenges and required CMS to be flexible and act quickly and decisively in order to ensure that beneficiaries had access to these important tests. However, CMS's standard rate setting procedures do not specifically address setting or adjusting rates for new CDLTs quickly in response to a PHE. Furthermore, the existing statutory and regulatory rate setting requirements for new CDLTs do not address the use of the MAC interim rate setting policy to quickly set rates for new CDLTs before the often-lengthy public consultation rate setting process. The requirements also do not specifically address how to adjust rates for new CDLTs quickly in response to a PHE. During the COVID-19 PHE, CMS had to take additional action beyond its standard rate setting procedures and issued rulings to set and adjust rates for CDLTs. However, CMS's use of its rulings to increase payment rates for the use of high-throughput testing technology does not appear to be consistent with CMS's stated purpose for CMS rulings. Specifically, CMS stated in its response that rulings are used periodically by the agency to provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions related to Medicare.

We acknowledge that some information presented in Other Matters may be beyond CMS's scope and authority. However, we present this information in Other Matters to provide awareness of these issues.

OTHER MATTERS

During our audit, we focused on identifying improvements that CMS could make in the CDLT rate setting process during a future PHE. Although it was outside the scope of our audit, based on our discussions with laboratory associations, we were informed of potential changes that CMS could make. These potential changes could lead to increased testing capacity during a PHE, improve the timeliness of reporting laboratory testing results during a PHE, and uniformity of laboratory reporting systems across States and other jurisdictions.

FUNDING FOR CAPITAL EQUIPMENT PURCHASES

During our interviews, one laboratory association suggested that capital equipment purchases, such as those for high-throughput-testing platforms, could be encouraged by providing the laboratories with access to grants. The laboratory association noted that after the pandemic, laboratories would still need to continue to pay for the operation and maintenance of any equipment they purchased. Even with the increased payment rates, laboratories would still face uncertainty regarding whether they would be able to conduct enough testing over the course of a PHE to recoup the cost of the investment in the high-throughput equipment and the associated maintenance costs.

USE OF LOCAL LABORATORIES IN RURAL AREAS

The adoption of high-throughput technology may not have been necessary or beneficial in rural areas, where the use of local laboratories that had the ability to use standard testing technology may have provided faster results for individuals in their areas than sending samples to laboratories with high-throughput technology. One laboratory association stated that it would have been better for more laboratories to conduct proximal testing using standard testing technology that was closer to rural patients than relying on centralized, distant testing in laboratories with high-throughput technology. It also noted that difficulties, such as the time it takes to transport samples from isolated areas to centralized testing locations, could lead to delays. The overreliance on high-throughput testing may have prevented some of the smaller laboratories from expanding COVID-19 testing capacity through the use of available standard testing technology because they did not have the capital needed to invest in new machinery that they may not have had a use for once the pandemic concluded.

LABORATORY TEST RESULTS REPORTING

One stakeholder suggested promoting a uniform laboratory test result reporting system across States and other jurisdictions. Inconsistency in testing and reporting standards can add manual tasks to laboratories' administrative burdens leading to increased costs and reporting time.

Also, it may not be possible to hire and train additional employees to perform these administrative duties in a timely manner during a PHE.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed applicable laws and regulations effective as of January 2018 related to CMS setting rates for new CDLTs. In addition, we reviewed those principles in the *Standards for Internal Controls in the Federal Government* (Green Book) that we determined were relevant to our audit objective. We also conducted interviews with CMS and the MACs' pricing coordinators to obtain an understanding of the rate setting process that occurred from February 2020 through January 2021. We conducted interviews with officials from two laboratory associations, which are trade associations that represent clinical laboratories, to obtain an understanding of the communication they had with CMS and MACs during the PHE rate setting process. We also asked CMS, MACs, and the laboratory associations to provide us with input on how the rate setting process could be improved for future PHEs.

We did not assess the overall internal control structure of CMS. Rather, we limited our review of internal controls to those related to our audit objective. We assessed CMS's control activities and information and communication as they related to the rate setting process for new CDLTs during a PHE. This included assessing CMS's policies and procedures and interviewing key stakeholders in the CDLT rate setting process.

We conducted our fieldwork from June 2021 to November 2023, which included contacting CMS, National Government Services, First Coast Services Options and Novitas Solutions, Palmetto GBA's MolDX Program, the American Clinical Laboratory Association, and the National Independent Laboratory Association.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws and regulations,
- reviewed CMS policies and procedures for setting new CDLT rates,
- interviewed CMS officials to obtain an understanding of the rate setting process and the events that occurred early in the pandemic to set COVID-19 viral test rates,
- interviewed MAC officials to obtain an understanding of the processes used to set new CDLT rates and their involvement in setting the COVID-19 viral interim test rates,
- interviewed officials from laboratory associations and laboratory providers to obtain an understanding of their involvement in the rate setting process for COVID-19 viral tests, and

- provided the results of our audit to 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: January 19, 2024

TO: Amy J. Frontz
Deputy Inspector General for Audit Services
Office of Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS Could Improve Its Procedures for Setting Medicare Clinical Diagnostic Laboratory Test Rates Under the Clinical Laboratory Fee Schedule for Future Public Health Emergencies (A-01-21-00506)

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

Medicare Part B items and services that are clinical diagnostic laboratory tests (CDLTs) generally are paid for under the Clinical Laboratory Fee Schedule (CLFS) in accordance with section 1833(h) and section 1834A of the Social Security Act (the Act). These sections in the Act (1833(h) and 1834A) do not currently include emergency rate-setting procedures for new CDLTs during public health emergencies (PHEs). However, CMS's current procedures allow for tests to be priced quickly. CMS follows the CLFS public consultation procedures in 42 C.F.R. § 414.506 prior to establishing the basis of payment (crosswalking or gapfilling) for new CDLTs that are not advanced diagnostic laboratory tests (ADLTs) and determining the amount of payment based on the crosswalking and gapfilling payment methodologies in 42 C.F.R. § 414.508(b). However, before CMS has undertaken the public consultation process, the agency's longstanding policy is for the Medicare Administrative Contractors (MACs) to set payment amounts for the new test codes in their respective jurisdictions and pay those amounts until Medicare establishes the CLFS payment rates. This is the process that was followed when setting the initial payment amounts for COVID-19 laboratory tests. CMS publicly announced the payment amounts for the initial set of COVID-19 laboratory tests in each MAC jurisdiction on March 12, 2020.

CMS was committed to expanding Medicare coverage and payment for COVID-19 laboratory testing throughout the PHE for COVID-19 to ensure availability and timeliness of testing. CMS monitored the ongoing situation and engaged with stakeholders to identify and address barriers and/or needs in order to achieve these goals. For example, CMS maintained the current emergencies website which included various resources, including a section on clinical and technical guidance for laboratories.[1] CMS also hosted a variety of stakeholder calls, including Office Hours sessions where we often discussed laboratory questions.[2] CMS also participated in Clinical Laboratory COVID-19 Response Calls with the Centers for Disease Control and

[1] The CMS current emergencies website may be accessed at: https://www.cms.gov/about-cms/what-we-do/emergency-response/current-emergencies.
[2] Transcripts and audio recordings from the stakeholder calls are available online at: https://www.cms.gov/training-education/open-door-forums/about/odf-podcast-and-transcripts.

Prevention (CDC).[3] Additionally, CMS met directly with laboratories, laboratory associations, and other stakeholders during the PHE. Lastly, CMS convened multiple annual laboratory public meetings and Medicare Advisory Panel on CDLTs (Panel) meetings throughout the duration of the PHE which provided feedback to aid CMS in establishing the basis and amounts of payment for COVID-19 laboratory tests.

Generally, Healthcare Common Procedure Coding System (HCPCS) codes describe the type of laboratory test that is being performed, without detail regarding the technology or machinery that is being utilized to perform the test. Through stakeholder interactions, CMS became aware of the multiple operational and implementation challenges that clinical diagnostic laboratories faced in order to respond to the COVID-19 PHE, as well as mounting pressure and an increase in resources required to perform large quantities of molecular genomic COVID-19 CDLTs and report the results as quickly as possible, by making use of high throughput technology. As a result of general awareness of resource costs associated with meeting these demands, CMS established a separate payment rate for high throughput COVID-19 tests. That is, to acknowledge the value in the use of high throughput technology during the unprecedented PHE situation, along with the need to establish a uniform rate quickly to incentivize its use, CMS established a separate payment rate for high throughput COVID-19 tests. CMS issued Ruling CMS-2020-1-R on April 14, 2020 in order to better align payment with the presumed increase in laboratories' resource costs. As data emerged with the progression of the COVID-19 pandemic, CMS re-assessed the resources involved in performing COVID-19 laboratory tests and operating high throughput technologies and issued Ruling CMS-2020-1-R2 on January 1, 2021. This ruling adjusted the payment amount for CDLTs making use of high throughput technologies for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 from $100 to $75. CMS found that the initial assumptions used as the basis of the payment amount did not account for laboratories' potential ability to lower their resource costs by allowing greater lag time between when the specimen was collected and when the CDLT was completed. Consequently, CMS refined payment for the use of high throughput technology and established a policy that would encourage quicker turnaround times differently from those with slower turnaround times by adding a new HCPCS code with differential payment for laboratories to use (U0005) when a test was performed in under 2 days. When tests were performed in under 2 days, laboratories received an additional $25 per test.

CMS Rulings are decisions of the CMS Administrator that serve as precedent final opinion and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.[4] They are published under the authority of the Administrator of CMS. CMS Rulings are binding on all CMS components, on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration (SSA) to the extent that components of the SSA adjudicate matters under the jurisdiction of CMS.

Given the extraordinary circumstances, CMS Rulings were the quickest way to uniformly increase the payment amount for those tests to account for the additional resources needed, which could lead to increased testing capacity, faster results, and more effective means of combating the spread of the virus.

[3] Transcripts and audio recordings from these meetings are available online at: https://www.cdc.gov/locs/clcr-call-archive/2020.html.
[4] A list of CMS Rulings is available at: https://www.cms.gov/medicare/regulations-guidance/cms-rulemaking/rulings/cms.

CMS notes that OIG's report frequently refers to the adequacy of payment rates. However, OIG did not assess the adequacy of the CLFS rates set by CMS, the payment amounts set by the MACs, or otherwise review documentation to objectively determine the costs associated with performing COVID-19 CDLTs using high throughput technology as part of the methodology for this audit.

Additionally, the OIG's report includes an "other matters" section that references potential changes that CMS could make. CMS notes that funding for capital equipment purchases, use of local laboratories in rural areas, and implementation of a uniform laboratory test reporting system are outside the scope and authority of the agency. We continue to encourage OIG to engage with the agencies within the Department of Health and Human Services charged with overseeing these topics to best understand the policies and processes that are in place.

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

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services establish procedures to improve communication among all stakeholders involved in setting new CDLT rates during a PHE.

CMS Response

As stated above, CMS monitored the ongoing situation and engaged with stakeholders to identify and address barriers and/or needs in order to ensure availability and timeliness of testing throughout the COVID-19 PHE. Specifically, newly established COVID-19 test codes, with the exception of those established by the Ruling CMS-2020-1-R, were discussed at the annual Laboratory Public Meetings, depending on when each code was created. The Medicare Advisory Panel on CDLTs discussed each code and made payment recommendations to CMS. There were also several public comment periods during which the public could provide input on payment rates. Therefore, in summary, CMS considered public comments shared during the annual Laboratory Public Meetings, the expertise and recommendations from the Medicare Advisory Panel on CDLTs, and public comments submitted during the comment period after posting of the preliminary determinations for newly established COVID-19 test codes undergoing the annual payment determinations process under the CLFS. Lastly, CMS notes that the test codes developed under the Rulings were terminated with the end of the PHE. However, CMS will take OIG's findings and recommendation into consideration for future PHEs.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services improve its procedures, which may require seeking legislative authority, for setting and adjusting rates for new CDLTs during a PHE by providing the MACs with the flexibility needed to set and adjust payment rates that would cover the laboratory costs of providing services when responding to a PHE.

CMS Response

As evidenced by agency's actions during the COVID-19 PHE, CMS's current procedures allow for tests to be priced quickly. Following typical and established procedures, MACs had the ability to set payment amounts for new test codes in their respective jurisdictions and pay those amounts until Medicare established the CLFS payment rates. CMS Rulings are used periodically by the agency to provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions related to Medicare. The COVID-19 PHE was unprecedented and forced the agency to be flexible, and act quickly and decisively in order to ensure beneficiaries had access to these important tests. During the COVID-19 PHE, Ruling CMS-2020-1-R and Ruling

CMS-2020-1-R2 were used to set payment for new COVID-19 tests due to the need to address the use of high throughput technology. This technology is highly sophisticated equipment that requires more intensive technician training and a more time-intensive process to assure quality. The results of these tests were used for critical treatment and public health purposes, for example, to diagnose and quarantine suspected COVID-19 infected patients. Timelier results enabled more effective contact tracing, since less time would have passed between the identified contact and notification of individuals of possible exposure, thereby reducing the overall number of persons that may be exposed. After it became clear that laboratories were able to lower their resource cost by allowing greater lag time when the specimen is collected and when the test is performed, CMS issued Ruling CMS-2020-1-R2 to pay a different amount for tests with quick turnaround times than those with slower turnaround times.

Rulings CMS-2020-1-R and CMS-2020-1-R2 were used to increase resources for laboratories making use of high throughput platforms when performing COVID-19 tests. As a result, this encouraged more laboratories to invest in technology that could keep up with the high demand of COVID-19 testing until faster and simpler tests could be developed. CMS notes that the MACs also demonstrated flexibility when setting the initial payment rates, as the initial payment rates for COVID-19 tests established by the MACs were 2.5x higher than other similar tests to account for resources during the PHE.

As demonstrated by the actions taken above, CMS was able to set payment rates during the PHE in a timely manner and that reflected feedback from the laboratory stakeholders regarding the needed resources for high throughput COVID-19 tests. A public health emergency, particularly regarding an emerging infections disease, poses complex and sometimes unforeseen challenges. CMS will take OIG's findings and recommendation into consideration for future PHEs. It should be noted that any procedures or changes to authority regarding emergency rate setting during future pandemics or public health emergencies must ensure the flexibility to meet the needs of, and be responsive to, the given situation.