Report in Brief
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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.