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September 2025 | A-09-23-03003

By Requiring Emergency Preparedness Plans for Independent Labs, CMS Could Better Ensure That Medicare Enrollees Have Access to Infectious-Disease Diagnostic Testing During a Public Health Emergency

REPORT HIGHLIGHTS

September 2025 | A-09-23-03003

By Requiring Emergency Preparedness Plans for Independent Labs, CMS Could Better Ensure That Medicare Enrollees Have Access to Infectious-Disease Diagnostic Testing During a Public Health Emergency

Why OIG Did This Audit

- A report published by the Pandemic Response Accountability Committee identified that Medicare paid more than $551 million for almost 8 million diagnostic tests for an emerging infectious disease at the beginning of a public health emergency (PHE) from February through August 2020. Almost 50 percent of these tests were performed at independent laboratories (labs). The report stated that various issues affected Medicare enrollees' access to this diagnostic testing, including availability of tests and shortages in medical supplies used to administer tests.
- CMS established national emergency preparedness requirements for certain provider types to ensure adequate planning for natural and human-caused disasters, facility emergencies, and emerging infectious diseases. Independent labs are not one of these provider types.
- This audit assessed whether CMS should require independent labs to have emergency preparedness plans to ensure that diagnostic tests related to the cause of a PHE are available to enrollees.

What OIG Found

- By requiring emergency preparedness plans for independent labs, CMS could better ensure that enrollees have access to diagnostic testing related to an emerging infectious disease or a biological toxin that is the cause of a PHE.
- During the first 3 years of the PHE, independent labs performed the majority of enrollees' diagnostic tests related to the emerging infectious disease, and some independent labs experienced testing process and staffing issues that may have affected enrollees' access to tests.
- CMS does not have an emergency preparedness plan requirement for independent labs but has such a requirement for certain provider types that participate in Medicare.

What OIG Recommends

We recommend that CMS consider requiring independent labs that participate in Medicare to have emergency preparedness plans to better ensure that Medicare enrollees have access to diagnostic testing related to an emerging infectious disease or a biological toxin in the event of a future PHE.

CMS did not state whether it concurred with our recommendation but stated that it would take our findings and recommendations into consideration.

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INTRODUCTION

WHY WE DID THIS AUDIT

A public health emergency (PHE) is the occurrence or imminent threat of an illness or a health condition caused by an epidemic or pandemic disease, bioterrorism, or a novel and highly fatal infectious agent or biological toxin that poses a substantial risk of a significant number of human fatalities or incidents or permanent or long-term disability.[1] Diagnostic testing is critical to help slow and contain the spread of an emerging infectious disease during a PHE. A report published by the Pandemic Response Accountability Committee (PRAC) identified that Medicare paid more than $551 million for almost 8 million diagnostic tests for an emerging infectious disease at the beginning of a PHE from February through August 2020.[2, 3] Almost 50 percent of these tests were performed at independent laboratories (labs).[4] The report stated that several issues—such as the availability of diagnostic tests for the emerging infectious disease, evolving Centers for Disease Control and Prevention guidance on whom should be tested, and shortages in medical supplies used to administer tests—affected access to diagnostic testing for people enrolled in Medicare (enrollees) and the nationwide population.

In 2016, the Centers for Medicare & Medicaid Services (CMS) published its Emergency Preparedness Rule (EP Rule). The EP Rule established national emergency preparedness requirements for certain provider types to ensure adequate planning for natural and human-caused disasters, facility emergencies, and emerging infectious diseases. According to CMS, sound, timely planning provides the foundation for effective emergency management. However, CMS does not have requirements for independent labs to have emergency preparedness plans; independent labs are not one of the provider types to which CMS's EP Rule applies. We conducted this audit to assess whether CMS should require independent labs to have emergency preparedness plans.

[1] National Institutes of Health, "Global health security and universal health coverage: Understanding convergences and divergences for a synergistic response." Accessed on Mar. 25, 2025.

[2] A PHE was declared on Jan. 31, 2020, and renewed by the Secretary of Health and Human Services on multiple dates in 2020, 2021, 2022, and 2023. This PHE expired at the end of the day on May 11, 2023 (referred to as "the PHE" in this report).

[3] PRAC, *Federal COVID-19 Testing Report: Data Insights From Six Federal Health Care Programs*, Jan. 14, 2021. The Department of Health and Human Services (HHS), Office of Inspector General's findings on Medicare payments for COVID-19 diagnostic testing constituted one section of the PRAC report, which had findings for health care programs at six Federal agencies.

[4] Independent labs are stand-alone lab testing sites that are not associated with an institution or a physician's office.

OBJECTIVE

Our objective was to determine whether CMS should require emergency preparedness plans for independent labs to ensure that diagnostic tests related to the cause of a PHE are available to enrollees.

BACKGROUND

Medicare Program

The Medicare program, established by Title XVIII of the Social Security Act, provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. CMS administers the Medicare program. CMS ensures that program enrollees are aware of the services for which they are eligible and that those services are accessible and of high quality. CMS also develops health and safety standards for providers of health care services authorized by Medicare legislation.

Medicare Part B provides insurance for preventive and medically necessary services, including clinical lab tests (such as diagnostic tests).

Public Health Emergencies

Under Section 319 of the Public Health Service Act (42 U.S.C. § 247d), the Secretary of Health and Human Services can declare a PHE if it is determined that: (1) a disease or disorder presents a PHE; or (2) a PHE, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists.

A PHE was declared on January 31, 2020, and lasted through May 11, 2023.[5] Older adults and people with certain chronic medical conditions, such as heart or lung disease or diabetes, were at higher risk for getting very sick or dying from the infectious disease that was the cause of the PHE.

Diagnostic Tests for Identifying Infectious Diseases

Clinical lab tests, when used appropriately, are important because they provide health care providers with information for prevention, early detection, diagnosis, treatment, and

[5] See footnote 2.

management of disease.[6] During a PHE, diagnostic tests play a critical role in the effort to contain the spread of an infectious disease by helping individuals to make informed decisions about their health.[7] Diagnostic tests enable cases to be identified, allowing infected individuals to seek treatment or to isolate themselves to prevent the spread of a disease.[8] Samples (e.g., nasal swabs) may be collected from an individual at a testing site or at home using a home collection kit. At the beginning of a PHE, samples are sent to labs for testing. Later, self-tests that provide rapid results at home may become available. However, self-tests may be less likely to detect an infectious disease than tests performed by labs.

CMS's Emergency Preparedness Rule

In September 2016, CMS published the EP Rule for 17 provider types participating in Medicare.[9] The rule established emergency preparedness regulations through these 17 provider types' existing conditions of participation and conditions for coverage, and required an all-hazards approach to emergency preparedness.[10] CMS published the EP Rule because CMS had found that the existing emergency preparedness requirements had not gone far enough to address the complexities of actual emergencies. In addition, in the event of a disaster, health care facilities did not have the necessary emergency planning and preparation in place to adequately protect the health and safety of those they served. Because emergencies and disasters could

What Is CMS's Definition of an All-Hazards Approach?

An all-hazards approach is an integrated approach to emergency preparedness that focuses on identifying hazards and developing emergency preparedness capacities and capabilities that can address those identified hazards as well as a wide spectrum of emergencies or disasters. This approach includes preparedness for natural and human-caused disasters, facility emergencies, and emerging infectious diseases.

[6] To perform diagnostic testing, a lab must be certified under the Clinical Laboratory Improvement Amendments (CLIA) Program (i.e., must be CLIA-certified) and meet applicable regulatory requirements. The CLIA Program generally regulates lab testing performed on human specimens in the U.S. and ensures that labs provide accurate, reliable, and timely patient test results no matter where a test is performed. Three agencies within HHS—CMS, the Centers for Disease Control and Prevention, and the Food and Drug Administration—work together to administer the CLIA Program. Although all labs must be CLIA-certified to receive Medicare payments, CLIA has no direct Medicare program responsibilities.

[7] Diagnostic tests are clinical lab tests that can be used to identify current infection with a virus that causes an infectious disease.

[8] Diagnostic tests may be developed by a lab or a commercial manufacturer. A lab-developed test is designed, manufactured, and used within a single lab. A commercial manufacturer-developed test is distributed for use in labs or other settings, such as a physician's office or an individual's home.

[9] 81 Fed. Reg. 63860 (Sept. 16, 2016). Revisions were made to this final rule at 84 Fed. Reg. 51732 (Sept. 30, 2019).

[10] CMS develops conditions of participation and conditions for coverage that health care organizations must meet to begin and continue participating in the Medicare and Medicaid programs. The conditions of participation and conditions for coverage are requirements established by the Secretary of Health and Human Services as necessary to protect the health and safety of patients.

disrupt the health care environment and change the demand for health care services, it was important that health care facilities integrate emergency management into their daily functions.

The provider types covered under the EP Rule included, among others, hospitals, home health agencies, community mental health centers, and organ procurement organizations.[11] (See Appendix B for the list of 17 provider types that were required to have emergency preparedness plans.[12]) However, independent labs are not one of the provider types to which the EP Rule applies.

The EP Rule established national emergency preparedness requirements for Medicare-participating health care providers and suppliers to: (1) plan adequately for both natural and human-caused disasters and (2) coordinate with Federal, State, Tribal, and regional and local emergency preparedness systems. Specifically, the EP Rule required providers to: (1) develop an emergency preparedness plan based on a risk assessment,[13] (2) develop and implement policies and procedures based on the emergency plan and risk assessment, (3) develop a communication plan that complies with both Federal and State laws, and (4) develop and maintain training and testing programs. The requirements were focused on three key elements that CMS considered necessary to maintain access to health care during disasters or emergencies: safeguarding human resources, maintaining business continuity, and protecting physical resources. (See Appendix C for an example of some of the emergency planning elements from a provider type covered under CMS's EP Rule: communications, staffing, buildings and equipment, technology, safety, and supplies.)

[11] According to CMS officials, if any of the covered provider types have an in-house lab, the provider type's EP Rule applies to the in-house lab.

[12] CMS published its EP Rule for 17 provider types in September 2016. On Nov. 23, 2022, CMS published a final rule establishing rural emergency hospitals (REHs) as a new Medicare provider type, effective Jan. 1, 2023 (after our audit period, which covered calendar years 2020 through 2022), and promulgating emergency preparedness requirements for REHs that are generally consistent with the emergency preparedness requirements for other Medicare-participating provider types (87 Fed. Reg. 71748, 72305–06 (Nov. 23, 2022) (adding the REH emergency preparedness condition of participation at 42 CFR § 485.542)). Thus, after our audit period, CMS had emergency preparedness requirements for 18 provider types.

[13] An emergency preparedness plan is one part of a facility's emergency preparedness program and provides a framework that includes conducting facility-based and community-based risk assessments that will assist a facility in addressing patient needs along with the continuity of business operations. Additionally, a plan will support, guide, and ensure a facility's ability to collaborate with local emergency preparedness officials.

On February 1, 2019, CMS added "emerging infectious diseases" to the definition of the all-hazards approach in the EP Rule because it "determined it was critical for facilities to include planning for infectious diseases within their emergency preparedness program."[14] On March 26, 2021, CMS expanded the Emergency Preparedness Interpretive Guidelines to further expand on best practices, lessons learned, and planning considerations for emerging infectious diseases.[15]

What Is an Emerging Infectious Disease?

An emerging infectious disease is a serious public health threat that either has appeared and affected a population for the first time, or has existed previously but is rapidly spreading, either in terms of the number of people getting infected, or to new geographical areas (World Health Organization).

HOW WE CONDUCTED THIS AUDIT

For our audit period, from calendar years (CYs) 2020 through 2022 (i.e., approximately the first 3 years of the PHE that lasted from January 31, 2020, through May 11, 2023), Medicare Part B paid $2.4 billion for 29.2 million selected diagnostic tests specific to the infectious disease that was the cause of the PHE; these diagnostic tests were received by 8.3 million enrollees nationwide. These diagnostic tests included tests performed by various providers, including independent labs and internal medicine and family practice providers. We calculated the portion of testing performed by independent labs.

To obtain an understanding of the experiences of independent labs that performed diagnostic testing during the PHE, we conducted interviews with: (1) representatives from 11 independent labs[16] and (2) a representative from the American Clinical Laboratory Association (ACLA).[17] We identified how these labs' experiences during the PHE may have affected enrollees' access to diagnostic testing for the emerging infectious disease.

To obtain an understanding of CMS's emergency preparedness plan requirements for providers, we reviewed CMS's EP Rule for provider types participating in Medicare. We reviewed two emergency preparedness plans for two different provider types to identify sample elements of such plans. We interviewed CMS officials and obtained written responses from CMS to understand the EP Rule.

[14] CMS Memorandum to State Survey Agency Directors, QSO-19-06-All (Feb. 1, 2019).

[15] CMS Memorandum to State Survey Agency Directors, QSO-21-15-All (Mar. 26, 2021).

[16] We selected 11 American Clinical Laboratory Association (ACLA) member labs. At the time of our interviews, ACLA member labs were performing the majority of the diagnostic testing in the United States for the emerging infectious disease during the PHE. Some labs we interviewed were performing testing nationally, while some labs were focused on local needs.

[17] We submitted questions to the ACLA representative and received written responses. ACLA is a national not-for-profit association representing leading clinical and anatomic pathology labs, including national, regional, specialty, hospital, end-stage renal disease, and nursing home labs.

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

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

FINDINGS

By requiring emergency preparedness plans for independent labs, CMS could better ensure that enrollees have access to diagnostic testing related to an emerging infectious disease or a biological toxin that is the cause of a PHE.

From CYs 2020 through 2022, independent labs performed the majority (i.e., more than 95 percent) of enrollees' diagnostic tests nationwide that were paid under Medicare Part B and related to the emerging infectious disease that was the cause of the PHE that lasted from January 31, 2020, through May 11, 2023. Some independent labs shared that they experienced testing process and staffing issues that affected their ability to perform diagnostic testing for the emerging infectious disease. These issues may have affected enrollees' access to diagnostic tests for the emerging infectious disease.

CMS does not have an emergency preparedness plan requirement for independent labs, but during our audit period it had such a requirement for 17 other provider types that participate in Medicare. Without a CMS requirement for independent labs to have emergency preparedness plans, enrollees' access to diagnostic testing for an emerging infectious disease or a biological toxin may be impacted in a future PHE. Having an emergency preparedness plan that addresses elements such as supplies and staffing could potentially help improve access to testing during a PHE.

BY REQUIRING EMERGENCY PREPAREDNESS PLANS FOR INDEPENDENT LABS, CMS COULD BETTER ENSURE THAT ENROLLEES HAVE ACCESS TO DIAGNOSTIC TESTING RELATED TO AN EMERGING INFECTIOUS DISEASE OR A BIOLOGICAL TOXIN THAT IS THE CAUSE OF A PUBLIC HEALTH EMERGENCY

During the First 3 Years of the Public Health Emergency, Independent Labs Performed the Majority of Enrollees' Diagnostic Tests Related to the Emerging Infectious Disease, and Some Independent Labs Experienced Issues That May Have Affected Enrollees' Access to Tests

From CYs 2020 through 2022 (i.e., approximately the first 3 years of the PHE that lasted from January 31, 2020, through May 11, 2023), independent labs performed more than 95 percent of enrollees' diagnostic tests nationwide that were paid under Medicare Part B and related to the emerging infectious disease that was the cause of the PHE (27.9 million of 29.2 million total

diagnostic tests). In addition, independent labs performed diagnostic tests for almost 94 percent of all enrollees tested during the PHE (7.8 million of 8.3 million enrollees).

Representatives from some independent labs and the ACLA representative that we interviewed shared testing process and staffing issues they experienced that affected their ability to perform diagnostic testing during the months at the beginning of the PHE. These issues may have affected enrollees' access to diagnostic tests.

The independent lab representatives and the ACLA representative shared that the independent labs and ACLA member labs, respectively, faced shortages of supplies related to the testing process for the emerging infectious disease, including shortages of specimen collection materials, swabs, transport media, and reagents.[18] Labs stated that because of the lack of supplies, testing was running at below capacity. Labs reported being in competition for supplies with other labs and with government agencies for limited supplies. Labs also shared that they faced staffing shortages due to labor reductions and furloughs resulting from the decline in requests for testing services that were not related to the PHE.

The issues that the independent labs experienced may have affected enrollees' access to diagnostic tests. Testing enables individuals to know whether they have an infectious disease and to make informed health decisions (such as whether to seek treatment or to isolate themselves). Supply and staffing shortages may have resulted in: (1) tests being prioritized or reserved for certain populations, i.e., symptomatic individuals; (2) people not getting tests; (3) testing backlogs and extended wait times for test results that rendered test results useless; and (4) delayed testing and treatment. An emergency preparedness plan that addresses elements such as supplies and staffing could potentially help improve access to testing during a PHE. The EP Rule states that it is commonly understood that health care facilities that do not have an emergency plan are at heightened risk for health care delivery and service disruptions.[19] Vulnerable populations are at greatest risk for negative consequences from health care disruptions.[20]

CMS Does Not Have an Emergency Preparedness Plan Requirement for Independent Labs but Has Such a Requirement for Certain Medicare-Participating Provider Types

CMS does not have an emergency preparedness plan requirement for independent labs. Specifically, independent labs are not one of the provider types covered under CMS's EP Rule.[21]

[18] Supply shortages can affect access to testing. Shortages of such things as swabs and reagents limit labs' ability to perform testing.

[19] 81 Fed. Reg. 63860, 64008 (Sept. 16, 2016).

[20] 81 Fed. Reg. 63860, 64017 (Sept. 16, 2016).

[21] See footnote 12.

Emergency preparedness regulations in CMS's EP Rule require facilities to have an emergency preparedness program that includes an emergency plan that takes into account an all-hazards approach to emergency preparedness, including planning for emerging infectious diseases. The approach is specific to the location of the facility, considering the types of hazards most likely to occur in the area.

CMS's EP Rule provides comprehensive, consistent, and flexible emergency preparedness requirements for certain Medicare-participating provider types. The EP Rule encompasses four core elements: (1) risk assessment and emergency planning, (2) policies and procedures, (3) communication plans, and (4) training and testing. The EP Rule addresses the need for advance preparation, effective policies and procedures, and sufficient training and testing before an emergency.

Appendix C lists some examples of emergency planning elements from a provider type covered under CMS's EP Rule. Emergency preparedness plan elements include, among other things, identifying key suppliers and alternative sources for supplies and ensuring adequate staffing to maintain the operational functions of the facility.

Facilities that do not have emergency preparedness plans established before an emergency or a disaster may face difficulties providing continuity of care for their patients. In addition, without proper training, health care workers may find it difficult to implement emergency preparedness plans during an emergency or a disaster.

Without a CMS Requirement for Independent Labs To Have Emergency Preparedness Plans, Enrollees' Access to Diagnostic Testing for an Emerging Infectious Disease or a Biological Toxin May Be Impacted in a Future Public Health Emergency

Without a CMS requirement for independent labs to have emergency preparedness plans, independent labs could face supply and staffing shortages and other issues affecting the testing process that could affect their ability to provide diagnostic testing for an emerging infectious disease or a biological toxin in a future PHE. As a result, enrollees' access to related diagnostic testing may be impacted.

During the PHE, widespread diagnostic testing was critical to contain the spread of the emerging infectious disease. The Medicare population was particularly vulnerable to the infectious disease that was the cause of the PHE because that population generally consisted of older adults and people with chronic medical conditions. CMS plays a crucial role in ensuring the health and safety of enrollees. Therefore, it is important for CMS to protect the health of enrollees from the effects of an emerging infectious disease and keep enrollees safe from uncontrolled community spread by helping to ensure access to diagnostic testing in the event of a future PHE.

CONCLUSION

Diagnostic testing is vital for diagnosing infected individuals and understanding disease spread during an infectious disease emergency. From CYs 2020 through 2022, independent labs performed more than 95 percent of enrollees' diagnostic tests nationwide that were paid under Medicare Part B and related to the emerging infectious disease that was the cause of the PHE that lasted from January 31, 2020, through May 11, 2023. Some independent labs shared that they experienced testing process and staffing issues that affected their ability to perform diagnostic testing for the emerging infectious disease. These issues may have affected enrollees' access to diagnostic tests for the emerging infectious disease. Having an emergency preparedness plan that addresses elements such as supplies and staffing could potentially help improve access to testing during a PHE.

CMS does not have a requirement for independent labs to have emergency preparedness plans, but during our audit period it had such a requirement for certain Medicare-participating provider types. An independent lab's emergency preparedness plan could include elements such as identifying key suppliers and alternative sources for supplies and ensuring adequate staffing to maintain the operational functions of the facility. CMS plays a crucial role in ensuring the health and safety of Medicare enrollees, and establishing emergency preparedness plan requirements for independent labs could help CMS better protect the health and safety of enrollees by helping to ensure access to diagnostic tests in the event of future emergencies.

RECOMMENDATION

We recommend that the Centers for Medicare & Medicaid Services consider requiring independent labs that participate in Medicare to have emergency preparedness plans to better ensure that Medicare enrollees have access to diagnostic testing related to an emerging infectious disease or a biological toxin in the event of a future PHE.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS did not state whether it concurred with our recommendation but stated that it would take our findings and recommendations into consideration. CMS also noted that requiring independent labs that participate in Medicare to have emergency preparedness plans may require notice and comment rulemaking. After reviewing CMS's comments, we maintain that our recommendation is valid. Establishing emergency preparedness plan requirements for independent labs could help CMS better protect the health and safety of enrollees by helping to ensure access to diagnostic tests in the event of future emergencies.

In addition to addressing our recommendation, CMS provided information on its actions taken during a recent PHE to promote beneficiary access to important diagnostic tests. CMS stated that throughout the PHE, it was committed to expanding Medicare coverage and payment for

lab testing to promote availability and timeliness of testing and frequently engaged with stakeholders to identify barriers or needs that needed to be addressed. CMS also stated that its regulations and policies related to the CLIA do not dictate how a lab should manage supply issues or shortages, but within its authority CMS published a memo with guidance for the lab community on applicable requirements and exercised enforcement discretion related to supplies.

CMS also provided technical comments on our draft report, which we addressed. CMS's comments, excluding the technical comments, are included as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

From CYs 2020 through 2022s (i.e., approximately the first 3 years of the PHE that lasted from January 31, 2020, through May 11, 2023), Medicare Part B paid $2.4 billion for 29.2 million selected diagnostic tests specific to the infectious disease that was the cause of the PHE; these diagnostic tests were received by 8.3 million enrollees nationwide.[22] These diagnostic tests included tests performed by various providers, including independent labs and internal medicine and family practice providers. We calculated the portion of testing performed by independent labs.

To obtain an understanding of the experiences of independent labs that performed diagnostic testing during the PHE, we conducted interviews with: (1) representatives from 11 independent labs[23] and (2) a representative from ACLA.[24] We identified how these labs' experiences during the PHE may have affected enrollees' access to diagnostic testing for the emerging infectious disease. The information shared by the representatives from ACLA and the 11 independent labs represented experiences encountered as of that point in time. This information may not represent experiences that all independent labs encountered during the PHE, and we did not independently verify the information shared.

We did not review CMS's or the independent labs' overall internal control structures because we determined that they were not significant to our audit objective. This audit is not an assessment of CMS's or independent labs' responses to the PHE.

We conducted our audit from February 2023 through June 2025.

[22] We reviewed COVID-19 diagnostic tests billed with Healthcare Common Procedure Coding System (HCPCS) codes U0003 and U0004. HCPCS is the approved coding system for reporting outpatient procedures, items, and services (42 CFR §§ 424.32(a)(1) and (b) and 45 CFR §§ 162.1002(c)(1) and (a)(5)(iv)). Tests that Medicare Part B enrollees received through other programs, such as community testing efforts, were not included in our audit unless they were paid for by Medicare Part B.

[23] See footnote 16.

[24] See footnote 17.

METHODOLOGY

To accomplish our objective, we:

- obtained from CMS's National Claims History file the Medicare Part B claims data for diagnostic tests billed with Healthcare Common Procedure Coding System (HCPCS) codes U0003 or U0004 that had dates of service from CYs 2020 through 2022;[25, 26]

- reviewed the claims data to identify diagnostic tests performed by independent labs and calculated: (1) the amount and percentage of enrollees' diagnostic tests nationwide paid under Medicare Part B that were performed by independent labs and (2) the amount and percentage of enrollees who received these diagnostic tests performed by independent labs;[27]

- interviewed representatives from 11 nonstatistically selected independent labs and a lab association (i.e., ACLA) to obtain information on their experiences during the PHE that lasted from January 31, 2020, through May 11, 2023;

- identified how the selected independent labs' experiences may have affected enrollees' access to diagnostic testing;

- interviewed CMS officials, reviewed applicable websites, and reviewed written responses from CMS to obtain an understanding of CMS's emergency preparedness plan requirements for certain Medicare-participating provider types covered under the EP Rule;[28]

- reviewed 2 emergency preparedness plans for 2 different provider types that are covered under the EP Rule to identify sample elements of such plans; and

- discussed the results of our audit with CMS officials.

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

[25] As of the end of the PHE that lasted from January 31, 2020, through May 11, 2023, these two HCPCS codes for COVID-19 diagnostic tests (i.e., U0003 and U0004) had been terminated and were no longer payable for dates of service on or after May 12, 2023.

[26] We reviewed only paid Medicare Part B claims (i.e., claims that were paid greater than $0).

[27] To identify independent labs, we identified code 69 reported in the provider specialty code field on each claim.

[28] See footnote 12.

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: PROVIDER TYPES REQUIRED TO HAVE EMERGENCY PREPAREDNESS PLANS

During our audit period, the following were the 17 provider types that were required to have emergency preparedness plans under CMS's EP Rule:[29, 30]

- hospitals;
- religious nonmedical health care institutions;
- ambulatory surgical centers;
- hospices;
- psychiatric residential treatment facilities;
- programs of all-inclusive care for the elderly;
- transplant centers;
- long-term care facilities;
- intermediate care facilities for individuals with intellectual disabilities;
- home health agencies;
- comprehensive outpatient rehabilitation facilities;
- critical access hospitals;
- clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services;
- community mental health centers;
- organ procurement organizations;
- rural health clinics and federally qualified health centers; and
- end-stage renal disease facilities.

[29] According to CMS officials, if any of these provider types have an in-house lab, the provider type's EP Rule applies to the in-house lab.

[30] See footnote 12.

APPENDIX C: SAMPLE ELEMENTS OF AN EMERGENCY PREPAREDNESS PLAN[31]

Communications	**Staffing**
☐ Assign a primary contact with national, State, or local emergency response teams ☐ Ensure timely and appropriate communications with regulatory agencies (Food and Drug Administration, CMS, HHS) and industry or accrediting organizations ☐ Ensure adequate clinical supplies, equipment, and services are available through appropriate communication and coordination with suppliers	☐ Ensure adequate staffing to maintain the operational functions of the facility ☐ Identify which staff would assume specific roles in another's absence through succession planning and delegations of authority
Buildings and Equipment	**Technology**
☐ Ensure adequate emergency workspace ☐ Identify processes and procedures to obtain equipment needed to address surge capabilities or equipment failure	☐ Ensure appropriate technological capabilities
Safety	**Supplies**
☐ Provide guidance for staff safety while working	☐ Identify key suppliers and partners ☐ Identify alternative sources for supplies ☐ Provide alternatives and replacements to unavailable products

[31] We summarized information from the emergency preparedness plan for a hospital and an organ procurement organization. These two provider types are covered under CMS's EP Rule.

APPENDIX D: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: July 17, 2025

TO: Carla J. Lewis
Acting Deputy Inspector General for Audit Services
Office of Inspector General

FROM: Dr. Mehmet Oz DR
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: By Requiring Emergency Preparedness Plans for Independent Labs, CMS Could Better Ensure That Medicare Enrollees Have Access to Infectious-Disease Diagnostic Testing During a Public Health Emergency (A-09-23-03003)

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

The COVID-19 Public Health Emergency (PHE) was unprecedented and forced the Agency to be flexible and act quickly and decisively to promote beneficiary access to important diagnostic tests as they were developed. CMS was committed to expanding Medicare coverage and payment for COVID-19 laboratory testing throughout the COVID-19 PHE to promote availability and timeliness of testing. CMS monitored the evolving situation and frequently engaged with stakeholders to identify barriers or needs that needed to be addressed to achieve these goals. For example, CMS maintained the "Current Emergencies" webpage on CMS's website which included helpful resources during the COVID-19 PHE, including a section on clinical and technical guidance for laboratories.[1] CMS also hosted a variety of COVID-19 stakeholder calls, including Office Hours sessions where we often discussed questions received from CLIA-certified laboratories.[2] CMS also participated in Clinical Laboratory COVID-19 Response Calls with the Centers for Disease Control and 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 Clinical Diagnostic Laboratory Tests (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.

The OIG's report states that independent lab representatives and an American Clinical Laboratory Association (ACLA) representative shared that they faced shortages of supplies related to the testing process for the emerging infectious disease, including shortages of specimen collection materials, swabs, transport media, and reagents. CMS regulations and

[1] The CMS Current Emergencies webpage 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.
[3] Transcripts and audio recordings from these meetings are available online at: https://www.cdc.gov/locs/clcr-call-archive/2020.html.

policies related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) do not dictate how a laboratory should manage supply issues or shortages. However, within our authority, CMS published a memo that provided the laboratory community with guidance on the applicable requirements if a laboratory modifies manufacturer's instructions by using alternative collection devices and transport media and provided the Food and Drug Administration (FDA) resources to further support use of alternative media.[4] Additionally, CMS exercised enforcement discretion as announced in the Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency, which stated "*During the COVID-19 public health emergency, in order to address the concern over COVID-19 reagent and swab supply problems, CMS will allow laboratories to use expired COVID-19 test kits, reagents, and swabs. If doing so deviates from the test manufacturer's authorized instructions for use, the use would not be authorized under the EUA and should not be represented as such… Thus, laboratories may use expired supplies until non-expired supplies become available provided that they put policies and procedures in place to ensure the reagents are performing as expected (e.g., ensuring that any expired supplies pass quality control tests with each assay run).*"[5]

The OIG's recommendation and CMS' response are below.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services consider requiring independent labs that participate in Medicare to have emergency preparedness plans to better ensure that Medicare enrollees have access to diagnostic testing related to an emerging infectious disease or a biological toxin in the event of a future PHE.

CMS Response

CMS will take OIG's findings and recommendation into consideration. Please note that requiring independent labs that participate in Medicare to have emergency preparedness plans may require notice and comment rulemaking.

[4] CMS published QSO-20-21-CLIA on 3/26/2020. This memo is available at: https://www.cms.gov/files/document/qso-20-21-clia.pdf-0.

[5] The full text of the FAQ is available at: https://www.cms.gov/files/document/frequently-asked-questions-faqs-clia-guidance-during-covid-19-emergency-updated-12-17-2020.pdf, see item 27.

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