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COVID-19 Testing: Frequently Asked Questions

Updated September 16, 2021

Congressional Research Service
https://crsreports.congress.gov
R46481

CRS REPORT
Prepared for Members and
Committees of Congress

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SUMMARY

R46481

September 16, 2021

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COVID-19 Testing: Frequently Asked Questions

The United States has at times reported some of the highest numbers of cases and deaths from the Coronavirus Disease 2019 (COVID-19) pandemic globally, and the disease has affected and continues to affect communities nationwide. In response, federal, state, and local governments have undertaken containment and mitigation efforts to increase the efficacy of isolation and quarantine policies, reduce the impact of COVID-19 related hospitalizations, and support targeted mitigation efforts while the vaccine rollout continues. The highly transmissible Delta variant is challenging progress made in containing the pandemic, and the public health community is taking steps to respond to and attempt to limit the spread of this variant, which currently accounts for almost all new COVID-19 cases in the United States.

Diagnostic testing is a critical part of the clinical management of COVID-19, which is caused by the SARS-CoV-2 virus. Testing for public health purposes is also an important factor in responding to and managing the pandemic. Although demand for testing has generally decreased since vaccines became widely available, testing continues to be part of efforts to monitor the prevalence of COVID-19, as well as community-level outbreaks; to identify and track the emergence of new COVID-19 variants of concern; and to help guide mitigation measures and support a safe return to work and school as vaccine administration continues. The use of testing for public health purposes rather than for the clinical diagnosis and management of individuals poses legal and policy complications, because regulation and payment policies can differ based on how the test is used.

COVID-19 testing in the United States is provided in a number of health care and community-based settings. Insurance coverage and payment for a given COVID-19 test can depend on a number of factors, including the entity administering the test or processing test results, and the reason for which the test is administered. Congress, through several coronavirus legislative packages, has enacted various insurance coverage requirements along with other funding mechanisms to help pay for testing.

This CRS report provides answers to numerous questions related to COVID-19 testing, including

- types of testing available and their reliability;
- testing capacity and infrastructure;
- delivery of testing, including the settings where testing is available;
- payment for testing, including the provision by federally operated health systems and payment by federal and private payors and payment sources available for people who are uninsured;
- federal funding for testing infrastructure and for the clinical provision of COVID-19 testing; and
- reporting of test results.

This report concludes with several appendices: **Appendix A** identifies acronyms used in this report, **Appendix B** lists CRS experts on the various testing topics discussed, and **Appendix C** provides testing-related resources.

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Introduction

The United States has at times reported some of the highest numbers of cases and deaths from the Coronavirus Disease 2019 (COVID-19) pandemic globally, and the disease has affected and continues to affect communities nationwide. In response, federal, state, and local governments have undertaken containment and mitigation efforts to increase the efficacy of isolation and quarantine policies, reduce the impact of COVID-19 related hospitalizations, and support targeted mitigation efforts while the vaccine rollout continues. The highly transmissible Delta variant—which currently accounts for nearly all new U.S. cases of COVID-19—is challenging progress made in containing the pandemic, and the public health community is taking steps to learn about, respond to, and attempt to limit the spread of this variant.[1]

Diagnostic testing is a critical part of the clinical management of COVID-19, which is caused by the SARS-CoV-2 virus. Testing for public health purposes is also an important factor in responding to and managing the pandemic. With the rapid development, authorization, and administration of several highly effective vaccines, demand for testing has generally decreased, but it remains key to managing the pandemic broadly and to guiding clinical management of the disease. Although demand for testing has generally decreased since vaccines have become widely available, testing continues to be part of efforts to monitor the prevalence of COVID-19, as well as community-level outbreaks; to identify and track the emergence of new COVID-19 variants of concern; and to help guide mitigation measures and support a safe return to work and school as vaccine administration continues. In addition, testing may be used to identify breakthrough infections in the vaccinated population, to identify and isolate positive cases of COVID-19 in individuals who are asymptomatic, and as part of contact tracing efforts. The use of testing for public health purposes rather than for the clinical diagnosis and management of individuals poses legal and policy complications, because regulation and payment policies can differ based on how the test is used.

Further, COVID-19 testing in the United States is provided in a number of health care and community-based settings. Insurance coverage and payment for a given COVID-19 test can depend on a number of factors, including the entity administering the test or processing test results, and the reason for which the test is administered. These factors can determine whether a certain funding source or payment mechanism may be used to pay for a given test. Congress, through several coronavirus legislative packages[2], has enacted various insurance coverage requirements along with other funding mechanisms to help pay for testing.

This report provides answers to numerous questions related to COVID-19 testing. These include, among others, questions about the types of tests and their uses, where individuals can access testing, funding for testing-related efforts, and how different payers will reimburse providers for testing. As testing for various purposes is now widely available, questions continue to arise about the settings where people can access testing, and how payment for such testing and accompanying services occurs. **Appendix C** provides a list of testing-related resources; it will be updated as additional information becomes available or additional issues arise.

This report does not address issues related to the development and regulation of COVID-19 tests. For information about those issues, see

- CRS In Focus IF11389, *FDA Regulation of Laboratory-Developed Tests (LDTs)*;

[1] CDC, "Monitoring Variant Proportions," https://covid.cdc.gov/covid-data-tracker/#variant-proportions.

[2] These laws are P.L. 116-123, P.L. 116-127, P.L. 116-136, P.L. 116-139, P.L. 116-260, and P.L. 117-2.

- CRS Insight IN11548, *HHS Announcement on FDA Premarket Review of Laboratory-Developed Tests (LDTs)*;
- CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*;
- CRS In Focus IF11789, *COVID-19 Variants: Vaccines, Diagnostics, and Therapeutics*;
- CRS Report R46261, *Early Development and Regulation of Diagnostic Testing for COVID-19: Frequently Asked Questions*
- CRS In Focus IF11516, *COVID-19 Testing: Key Issues*; and
- CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

Although this report addresses public and private payment for testing, it does not address payment or other issues related to COVID-19 treatment or vaccination. For information about those issues, see

- CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*;
- CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)*;
- CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions*;
- CRS Report R46340, *Federal Response to COVID-19: Department of Veterans Affairs*;
- CRS Insight IN11273, *COVID-19: The Basics of Domestic Defense Response*;
- CRS Insight IN11333, *COVID-19 and the Indian Health Service*;
- CRS Insight IN11367, *Federal Health Centers and COVID-19*;
- CRS Insight IN11438, *The COVID-19 Health Care Provider Relief Fund*;
- CRS Insight IN11609, *COVID-19 Vaccine: Financing for Its Administration*;
- CRS Report R46715, *FEMA Assistance for Vaccine Administration and Distribution: In Brief*;
- CRS Insight IN11617, *Unauthorized Immigrants' Access to COVID-19 Vaccines*;
- CRS Report R46711, *U.S. Public Health Service: COVID-19 Supplemental Appropriations in the 116th Congress*;
- CRS Report R46777, *American Rescue Plan Act of 2021 (P.L. 117-2): Private Health Insurance, Medicaid, CHIP, and Medicare Provisions*; and
- CRS Report R46834, *American Rescue Plan Act of 2021 (P.L. 117-2): Public Health, Medical Supply Chain, Health Services, and Related Provisions*

Other CRS products on COVID-19 are available at https://www.crs.gov/resources/coronavirus-disease-2019.

COVID-19 Testing Overview

COVID-19 testing—including its development, regulation, and availability—has been a central and ongoing issue throughout the COVID-19 public health emergency. Early efforts to develop a national test, led by the Centers for Disease Control and Prevention (CDC), encountered challenges.[3] Actions taken by the Food and Drug Administration (FDA) to increase the flexibility of COVID-19 in vitro diagnostics (IVDs) regulation[4] facilitated access to testing, but also created an environment of uncertainty for commercial manufacturers and clinical laboratories, as well as for health care providers and patients.[5] Issues have arisen around the accuracy of tests, their uses, and the settings in which they may be used for clinical purposes, as well as for nondiagnostic purposes such as screening. In addition, considerations regarding these issues may vary based on whether a test is diagnostic, and specifically a molecular or an antigen test, or serologic.

What Are the Different Types of COVID-19 Tests?

Generally, coronavirus diagnostics (IVDs) may be molecular, serological, or antigen tests.[6] From a technical perspective, tests are characterized by their methods, as well as by the substance they directly identify: antigens,[7] antibodies,[8] or viral nucleic acid. Initially in the pandemic, development of COVID-19 tests was largely focused on molecular tests, and specifically tests using a technique called Polymerase Chain Reaction (PCR), and secondarily on serology tests, those tests that identify the presence of antibodies to the SARS-CoV-2 virus. As FDA shifted to prioritize the review of point-of-care tests, which are usually antigen tests, in order to increase the scale of testing and also to focus on screening, numerous such tests have been authorized by the FDA.[9] This type of test directly identifies the presence of a SARS-CoV-2 antigen, or protein, through the use of SARS-CoV-2 antibodies which preferentially bind to the SARS-CoV-2 antigen.

From a clinical perspective, tests may be used to diagnose an active infection (by detecting the virus directly) or a prior infection (by detecting antibodies to the virus). Molecular and antigen tests are used to diagnose current infection, whereas serology tests are used to determine prior infection.[10] **Table 1** provides a summary of the types of tests, their uses, and accuracy.

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[3] See CRS Report R46261, *Early Development and Regulation of Diagnostic Testing for COVID-19: Frequently Asked Questions*.

[4] See CRS In Focus IF11516, *COVID-19 Testing: Key Issues*.

[5] Medium, "Regulatory uncertainty made COVID responses difficult," April 6, 2020, https://medium.com/cgo-benchmark/regulatory-uncertainty-made-covid-responses-difficult-c7e6e5e8f7c3.

[6] FDA, "Coronavirus Testing Basics," https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics.

[7] An antigen is defined by the National Cancer Institute (NCI) as follows: "Any substance that causes the body to make an immune response against that substance. Antigens include toxins, chemicals, bacteria, viruses, or other substances that come from outside the body," https://www.cancer.gov/publications/dictionaries/cancer-terms/def/antigen.

[8] An antibody is defined by NCI as follows: "A protein made by plasma cells (a type of white blood cell) in response to an antigen (a substance that causes the body to make a specific immune response). Each antibody can bind to only one specific antigen. The purpose of this binding is to help destroy the antigen," https://www.cancer.gov/publications/dictionaries/cancer-terms/def/antibody.

[9] Food and Drug Administration (FDA), "In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2. [An EUA is an emergency use authorization.]

[10] FDA, "Serology/Antibody Tests: FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/serologyantibody-tests-faqs-testing-sars-cov-2.

Molecular Diagnostic Testing

Molecular diagnostic testing for COVID-19 generally relies on nucleic acid amplification techniques (NAATs), such as PCR, to detect viral genetic material. These tests identify viral nucleic acid in samples taken from individuals' noses or throats using swabs and are technically complex but well characterized, generally requiring both specific instruments and highly trained laboratory personnel. PCR-based testing involves sample collection (usually a swab, as noted), viral nucleic acid extraction, and direct testing to identify the presence of the SARS-CoV-2 viral nucleic acid through reverse transcription, amplification, and detection techniques. PCR tests may be high-throughput, whereby many samples may be run simultaneously in a central laboratory; in that case, the run time is generally several hours. PCR or other NAAT-based tests may also be point-of-care tests, which are typically faster and simpler to run, but often run only a single or a few samples at one time. Molecular tests may use other technologies to identify viral nucleic acid, including for example, CRISPR, a gene-editing technology that is starting to be used in diagnostics.[11]

Antigen Testing

An antigen test uses antibodies to a specific antigen (e.g., SARS-CoV-2 virus) to identify the virus in a patient's sample. Unlike a COVID-19 serology test, which can determine prior infection, an antigen test can determine an active infection. This difference is accounted for by the fact that a serology test identifies antibodies, a product of the immune response whose generation lags infection, whereas an antigen test directly identifies the virus. Rapid antigen tests—numerous of which have been authorized for use in the United States for COVID-19[12]—can detect viral antigens, generally in a throat or nose swab. These tests, used for diagnostic purposes, are usually point-of-care, relatively low-cost, and easy to manufacture and use. Because of these characteristics, this type of test is considered a good candidate for screening in asymptomatic individuals who are not suspected of being infected, in addition to clinical diagnosis. However, they tend to be less accurate than molecular diagnostic tests.

Serology Testing

A COVID-19 serology test identifies antibodies to the SARS-CoV-2 virus, usually in an individual blood sample. Antibodies are proteins generated by the immune system in response to an antigen, or foreign substance, and their generation lags infection by a week or more. An antigen may be a pathogenic virus or bacteria, for example, or generally any substance recognized by the immune system as both foreign and harmful. Serology tests for SARS-CoV-2 indicate exposure to and recovery from prior infection with the virus. The FDA has stated that such tests are not authorized to be used alone for the diagnosis of COVID-19.[13] However, serology testing may be used to identify individuals who can donate convalescent plasma[14] as a possible

[11] FDA, "Coronavirus (COVID-19) Update: Daily Roundup May 7, 2020," May 7, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-may-7-2020; Also see CRS Report R44824, *Advanced Gene Editing: CRISPR-Cas9*.

[12] Food and Drug Administration (FDA), "In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2.

[13] FDA, "Serology/Antibody Tests: FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/serologyantibody-tests-faqs-testing-sars-cov-2.

[14] *Convalescent plasma* refers to blood plasma that is collected from an individual who has recovered (i.e., "convalesced") from a disease, in this case COVID-19, and then administered to a patient actively sick with COVID-19

therapeutic, to help guide development of a vaccine, and to determine the extent and spread of COVID-19 in the general population, as well as the true infection fatality rate. In addition, as scientists learn more about the extent and duration of immunity that antibodies may confer after natural infection, serology testing could be informative about a given individual's immunity. The FDA issued a safety communication in May 2021 noting that currently, serology testing is *not* recommended to assess immunity in individuals who have received a vaccination, for several reasons including, for example, that not all authorized serology tests identify the specific antibodies that are generated in response to a vaccination.[15]

For What Purposes Is COVID-19 Testing Used?

Broadly, testing may be used for surveillance, screening, or diagnosis.[16] *Surveillance* may be used to provide information at a population or community level; it does not generally guide decisions at the individual level, nor are results of surveillance testing generally returned to the individual as samples are anonymized. Surveillance testing may guide decisions, for example, about population-level public health mitigation or other measures. Such testing may employ serology testing to help determine the proportion of a given population or subpopulation that has had and recovered from coronavirus infection, or it may use diagnostic testing to provide early indicators of emerging outbreaks or population-level estimates of the number of individuals with current COVID-19 infections.

Screening is typically carried out in individuals who are asymptomatic and who have no reason to believe that they are currently infected (e.g., due to recent exposure or travel history). Screening can identify individuals who are infected but have no symptoms (asymptomatic) or those individuals who are infected but are not *yet* showing symptoms (presymptomatic). This type of testing is generally done in groups of individuals, such as students at a school or employees in a workplace, as a way to preempt and prevent the spread of disease to others rather than to inform treatment for an individual. Although screening in the case of COVID-19 in a setting such as a workplace or a school can guide decisions about individuals—for example, whether they should stay home or self-isolate for a period of time—it does not necessarily guide *clinical* decisions about an individual's care. Screening may use molecular- or antigen-based tests to directly detect the presence of the virus, and this type of testing would generally be confirmed with additional testing were an individual to begin to show symptoms.

Finally, *diagnosis* involves a molecular or antigen test to directly test for the presence of the virus, either in the presence of signs or symptoms, or with a reason to suspect that an individual may be actively infected with SARS-CoV-2 (e.g., a recent exposure to a confirmed case). Such testing would guide clinical decisions and disease management at the individual level. Serology tests are not currently used for clinical diagnostic purposes or to establish the exclusion of infection, per relevant FDA guidance on diagnostic testing for COVID-19 during the COVID-19 emergency period.[17]

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for treatment. See CRS Report R46375, *The U.S. Blood Supply and the COVID-19 Response: In Brief*.

[15] FDA, "Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination: FDA Safety Communication," May 19, 2021, https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety.

[16] For a high-level overview of these three types of testing, see FDA, "COVID-19 Test Uses: FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-uses-faqs-testing-sars-cov-2.

[17] FDA, "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)," May 11, 2020,

When Is COVID-19 Testing Clinically Useful?

The answer to this question depends on the type of test and the circumstances of the testing. Serology testing at the current time is not generally clinically useful for the treatment or management of COVID-19 at an individual level.[18] Moreover, serology testing does not provide reliable information about an active, current infection, nor does it currently provide information about immunity to reinfection. The mechanism of the immune response to infection with SARS-CoV-2—whether antibodies provide immunity and, if so, for what duration, and what level of antibody might be required for this effect—is largely unknown at this time.[19] In certain fact-specific cases, serology testing results may inform clinical treatment or management, but these cases are not the norm.

Molecular diagnostic or rapid antigen testing is clinically useful *in the presence of signs or symptoms, or in the context of a known or suspected exposure*. This type of testing in the absence of any reason to suspect infection, or in the absence of signs or symptoms of illness, is generally not clinically useful. Individuals who receive a positive result in this case may be either *asymptomatic* (meaning they are infected but are not exhibiting symptoms of the disease) or *presymptomatic* (meaning they are infected but have not yet begun to show clinical signs or symptoms of the disease). In the case of an asymptomatic case, no clinical treatment will be needed, so the test result is not clinically useful for that individual. In the case of a presymptomatic case, once the tested individual begins to exhibit symptoms, clinical treatment may become necessary, but testing would likely be repeated at that time to confirm the diagnosis. At this time, there is an authorized therapeutic option for individuals who have been exposed to a confirmed positive COVID-19 case, but are asymptomatic or presymptomatic (post-exposure prophylaxis).[20] In this context, screening tests could potentially be used to guide the clinical decision to give an exposed individual treatment to prevent further COVID-19 transmission to others and/or severe health outcomes.

Do New Variants Affect COVID-19 Diagnostic Testing?

Currently, the Delta variant is the dominant variant of the SARS-CoV-2 virus circulating in the country.[21] This variant is more transmissible than previous variants, and is currently accounting for almost all new COVID-19 cases. COVID-19 diagnostic testing focuses on detecting the *presence or absence* of infection with the SARS-CoV-2 virus, including detecting the absence or presence of infection with variants of the virus.

Diagnostic testing generally does not identify the *specific variant* of the virus causing infection, such as the Delta variant. That distinction requires sequencing of the viral genome, which is not part of most authorized COVID-19 tests, nor is it relevant to clinical treatment of patients.

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.

[18] See for example, the American Medical Association, "Serological testing for SARS-CoV-2 antibodies," May 14, 2020, https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies.

[19] FDA, "Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/antibody-serology-testing-covid-19-information-patients-and-consumers.

[20] FDA, "FDA authorizes REGEN-COV monoclonal antibody therapy for post-exposure prophylaxis (prevention) for COVID-19," https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-regen-cov-monoclonal-antibody-therapy-post-exposure-prophylaxis-prevention-covid-19, August 10, 2021.

[21] CDC, "Monitoring Variant Proportions," https://covid.cdc.gov/covid-data-tracker/#variant-proportions.

Genomic surveillance, which is used to identify and type specific variants, is carried out by sequencing a specific subset of tested positive patient samples. The Food and Drug Administration (FDA) monitors relevant EUA-authorized COVID-19 tests to ensure that they continue to perform accurately when challenged with new virus variants.[22]

How Accurate Are Diagnostic and Serology Tests?

The accuracy of diagnostic testing is primarily determined by assessing two test performance characteristics: (1) the ability of the test to identify true positives (people with disease) and (2) the ability of the test to identify true negatives (people without the disease). These are referred to as *sensitivity*—the ability to detect a true positive—and *specificity*—the ability to detect a true negative.[23] A test with high sensitivity will have a low rate of false negatives, whereas a test with high specificity will have a low rate of false positives. A test's reliability in clinical diagnosis will be affected by the prevalence of the disease in the population or community, and specifically, in lower prevalence settings, tests return higher rates of false positives, and in higher prevalence settings, tests return higher rates of false negatives, even if the test has relatively high sensitivity and specificity.[24] The test is performing as expected in these circumstances, but clinicians and others weigh these considerations when interpreting results. These distinctions have different implications in the context of an infectious disease; specifically, a false negative may result in the unknowing transmission of the disease to others, whereas a false positive may result in incorrect therapeutic treatment decisions or unnecessary use of Personal Protective Equipment (PPE), among other things.

Accuracy concerns have arisen with respect to both diagnostic and serological COVID-19 testing.[25] With respect to molecular diagnostic testing for COVID-19, tests are generally highly specific (i.e., false positives are unlikely) but problems can occur with respect to sensitivity, or false negatives. Relevant research indicates that the false negative rate for PCR tests varies based on the timing of the test, with the most accurate testing occurring approximately three days after the onset of symptoms.[26] Although no diagnostic test performs with perfect accuracy, certain issues may result in lower accuracy. PCR-based tests are usually accurate and will generally reliably identify viral nucleic acid, if it is present in amounts above the limit of detection for a given diagnostic. However, problems can occur with sampling technique, storage, and transport of the sample (e.g., over-dilution, temperature maintenance).[27] In addition, viral load varies during the course of an infection by site (e.g., throat, nose), thereby affecting the amount of virus present in a collected sample, which can in turn affect the test results.

In terms of accuracy, serology tests may have issues with specificity and the return of false positive results. This inaccuracy may occur because cross-reactivity with antibodies from

[22] For more information, see CRS In Focus IF11789, *COVID-19 Variants: Vaccines, Diagnostics, and Therapeutics*.

[23] Cochrane UK, "Sensitivity and specificity explained: A Cochrane UK Trainees blog," https://uk.cochrane.org/news/sensitivity-and-specificity-explained-cochrane-uk-trainees-blog.

[24] Takashi Asai, "COVID-19: accurate interpretation of diagnostic tests—a statistical point of view," *Journal of Anesthesia*, December 11, 2020, https://link.springer.com/article/10.1007/s00540-020-02875-8.

[25] S. Woloshin et al., "False Negative Tests for SARS-CoV-2 Infection—Challenges and Implications," *New England Journal of Medicine*, 383(6), August 6, 2020, https://www.nejm.org/doi/full/10.1056/NEJMp2015897.

[26] LM Kucirka et al., "Variation in False-Negative Rate of Reverse Transcriptase Polymerase Chain Reaction–Based SARS-CoV-2 Tests by Time Since Exposure," *Annals of Internal Medicine*, May 13, 2020, https://www.acpjournals.org/doi/10.7326/M20-1495.

[27] FDA, "Coronavirus Testing Basics (Molecular Tests)," https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics.

commonly circulating coronaviruses or other viruses can return false positives (the result is not specific enough to SARS-CoV-2).[28] Beginning in early 2020, serology tests were allowed to be marketed and used without an Emergency Use Authorization (EUA),[29] which contributed to uncertainty about how well these tests performed initially.[30] In response to this early experience, the FDA began working with other federal agencies (e.g., the National Institutes of Health (NIH)) to provide independent validation for these tests,[31] and it modified its guidance to require manufacturers to receive authorization for commercially manufactured and marketed serology tests.[32]

Table 1. Summary of COVID-19 Testing Types, Uses, and Accuracy

Type of test	What it tests for	Approval status	Appropriate for			Accuracy issues
			Diagnosis	Screening	Surveillance	
Molecular	Detects viral genetic material	More than 250 EUA authorized tests	Yes	Yes (e.g., workplace or school testing)	Yes (for outbreaks)	False negatives may occur where samples have low amounts of virus
Serological	Detects serum antibodies	More than 80 EUA authorized tests	No	No	Yes (for prevalence estimates)	False positives may occur from cross-reactivity of antibodies from non-SARS-CoV-2 common coronaviruses
Antigen	Detects viral antigen	About 30 EUA authorized tests	Yes	Yes (e.g., workplace or school testing)	Yes (for outbreaks)	Rates of false negatives tend to be higher than for molecular diagnostics

Sources: CRS Analysis of "What Are the Different Types of COVID-19 Tests?," and FDA, "In Vitro Diagnostics EUAs," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

Note: EUA = emergency use authorization.

[28] FDA, "Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts," April 18, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts.

[29] An EUA is an authorization granted by the FDA when certain conditions are met (e.g., a public health emergency) that allows an unapproved medical product to be marketed and used clinically. For more information about the EUA mechanism, see CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*.

[30] FDA, "Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy," May 4, 2020, https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy.

[31] FDA, "Serology/Antibody Tests: FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/serologyantibody-tests-faqs-testing-sars-cov-2.

[32] FDA, "Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff," May 11, 2020, https://www.fda.gov/media/135659/download.

Testing Capacity and Infrastructure

For much of the pandemic, prior to availability of vaccines and multiple types of EUA authorized COVID-19 tests, demand for testing for COVID-19—including for diagnostic, screening and surveillance purposes—placed significant strain on both the clinical laboratory infrastructure in the United States and on the testing supply chain.[33] This stress continued as late as early spring 2021, and has recently reemerged as the Delta variant spreads and case counts rise again.[34] During the pandemic, clinical laboratories reported that the supply chain was stressed at almost every point, and that access to testing and testing turn-around time varied across the country, with excess capacity in some areas and excess demand in others.[35]

Clinical diagnostic testing is carried out by a network of private and public laboratories, as well as at the point of care by health care providers in health care settings. Clinical laboratories include large commercial reference laboratories (e.g., Quest); academic and university laboratories (e.g., University of Washington Medicine Virology Laboratory[36]); and hospital and other clinical laboratories. Testing is also carried out by CDC and other federal laboratories and the U.S. network of state and local public health laboratories, including some Department of Defense (DOD) and international laboratories.[37] Tests authorized for use at the point of care may be used in health care or other settings that have appropriate CLIA certification, an option which has helped ease strain on the clinical laboratory infrastructure.

In April 2020, the Trump Administration released the *Testing Blueprint: Opening Up America Again*; this report outlined three core areas which aimed to "enable State and local officials to quickly isolate cases, respond to local outbreaks, and create confidence that citizens are safe to engage in social and business activities," including Diagnostic Testing Plans, Timely Monitoring Systems and Rapid Response Programs.[38] In late May 2020, and again in August and November of 2020, the Department of Health and Human Services (HHS) released a national testing strategy report compiling certain testing-related information pursuant to a requirement in the Paycheck Protection Program and Healthcare Enhancement Act (PPPHCEA, P.L. 116-139).[39] These reports were not required to be, nor were they, released publicly by HHS.[40] The May 2020 HHS plan deferred to states to develop testing programs and implement testing in their states.[41] States and

[33] American Association for Clinical Chemistry (AACC), "COVID-19 Survey Results," https://www.aacc.org/science-and-research/covid-19-resources/aacc-covid-19-testing-survey/full-survey-results.

[34] AACC, "New Coronavirus Testing Protocol Could Help Labs Keep Up With Rising Testing Demands as Delta Variant Spreads," July 21, 2021, https://www.aacc.org/media/press-release-archive/2021/07-jul/new-coronavirus-testing-protocol-could-help-labs-keep-up-with-spread-of-delta-variant.

[35] See for example, Association of Molecular Pathology, "SARS-CoV-2 Molecular Testing, Summary of Recent SARS-CoV-2 Molecular Testing Survey," https://www.amp.org/AMP/assets/AMP_SARS-CoV-2_Survey_Report_FINAL.pdf?pass=28.

[36] University of Washington Medicine, "UW Virology COVID-19 Dashboard," http://depts.washington.edu/labmed/covid19/.

[37] See CDC, "Introduction to Public Health Laboratories," https://www.cdc.gov/publichealth101/laboratories.html.

[38] Homeland Security Digital Library, "Testing Blueprint: Opening America Up Again," https://www.hsdl.org/c/testing-blueprint-opening-america-up-again/.

[39] P.L. 116-139, Division B "Additional Emergency Appropriations for Coronavirus Response," Title I, "Department of Health and Human Services," 134 STAT. 627-628.

[40] GAO, "COVID-19 Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention (GAO-21-265)," January 28, 2021, https://www.gao.gov/assets/gao-21-265.pdf, p. 88.

[41] Department of Health and Human Services (HHS), "COVID Strategic Testing Plan," May 24, 2020. "The role of the Federal government is to enable innovation, help scale supplies, and provide strategic guidance. States, territories, and

jurisdictions developed strategies to test their populations, specifically with respect to the types and amount of tests needed, as well as their capacity and plans for overall testing, including for diagnosis, contact tracing, surveillance, testing in congregate or high-risk health care and employment settings, and general workplace and school-based screening.[42]

What Is Point-of-Care vs. Centralized Testing?

Clinical testing may be *centralized*, in which a sample is collected and sent to a central laboratory for testing, or *decentralized*, in which the testing occurs entirely at or near the patient or point of care (POC), commonly referred to as point-of-care testing. The FDA notes that "point of care" includes patient care settings such as "hospitals, physician offices, urgent care, outreach clinics, pharmacies, and temporary patient care settings that have appropriately trained personnel to perform the test and are operating under a CLIA Certificate of Waiver or Certificate of Compliance."[43] In addition, the agency notes that, in general, "point of care" does not apply to at-home testing or at-home sample collection.[44] The FDA has authorized a number of molecular diagnostic point-of-care tests (e.g., Abbott IDNow) and about 25 antigen point-of-care tests to date (the majority of authorized antigen tests are authorized for use at the POC), although the majority of all EUA-authorized tests are not authorized for use in a point-of-care setting.[45]

POC tests are particularly important in cases where an individual is seriously ill and a test result is needed quickly to care for the individual and conserve PPE, as well as in places that are far away from centralized laboratories—particularly rural and remote areas. POC tests are generally noted for being faster, less expensive, less technically complex to run, and simpler to manufacture.[46] However, these tests are also often less accurate and, in particular, may be less sensitive, meaning they return more false negatives than a comparable non-POC molecular diagnostic would.[47] In addition, while most antigen tests are available at the point of care, they also generally are less sensitive than molecular diagnostic tests (both laboratory-based or POC molecular tests).

There were accuracy issues with at least one FDA-authorized POC molecular diagnostic, which led the FDA to require confirmation of negative results with an authorized high-sensitivity

tribes are responsible for formulating and implementing testing plans; and the private sector will continue to develop and produce technologies, supplies, and services to meet the needs of the States," pp. 7, https://delauro.house.gov/sites/delauro.house.gov/files/HHS_COVID_Testing_Report.pdf.

[42] HHS, "HHS Releases July - December COVID-19 State Testing Plans," https://public3.pagefreezer.com/browse/HHS%20%E2%80%93%C2%A0About%20News/20-01-2021T12:29/https://www.hhs.gov/about/news/2020/08/10/hhs-releases-july-december-covid-19-state-testing-plans.html.

[43] CLIA refers to the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578), a law that regulates all clinical laboratories in the United States. For more information, see https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA.

[44] FDA, "COVID-19 Test Settings: FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-settings-faqs-testing-sars-cov-2.

[45] FDA, "In Vitro Diagnostics EUAs," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

[46] National Academy of Sciences, "Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic (April 8, 2020)," https://www.nap.edu/catalog/25775/rapid-expert-consultation-on-sars-cov-2-laboratory-testing-for-the-covid-19-pandemic-april-8-2020.

[47] See for example Office of the Assistant Secretary for Health, "Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19)," https://www.cdc.gov/coronavirus/2019-ncov/downloads/OASH-COVID-19-guidance-testing-platforms.pdf.

molecular diagnostic.[48] This highlighted the fact that the speed and cost-effectiveness associated with POC tests may potentially be offset if additional steps are needed to mitigate accuracy issues. However, POC diagnostics' sensitivity can be weighed against their turnaround time and frequency, particularly in the context of screening and surveillance. Specifically, research suggests that frequent testing with a faster turnaround time is more important than test sensitivity to effective control of virus spread. Relevant research notes that "[t]esting frequency was found to be the primary driver of population-level epidemic control, with only a small margin of improvement provided by using a more sensitive test."[49] A June 2021 NIH-funded study adds to this knowledge base, finding that antigen tests perform on par with molecular tests when taken frequently (specifically, every three days, in this study).[50]

Is There a National COVID-19 Testing Plan or Strategy?

Since early in the pandemic, there has been ongoing discussion about how to coordinate and organize COVID-19 testing efforts in the United States. Numerous experts in public health and medicine have weighed in on this issue, with several preparing model testing strategies and recommending various approaches to a coordinated national plan.[51] Many experts have called for a national strategy coordinated and led by the federal government;[52] however, the states have generally carried out their own testing programs and strategies, with strategic guidance from the federal government.

In April 2020, the Trump Administration released its *Testing Blueprint: Opening America Up Again*, which "describes the roles and responsibilities, as well as core objectives, for the robust State testing plans and rapid response programs needed by States to safely reopen."[53] Other

[48] FDA notes that "negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests." See Abbott IDNow Letter of Authorization, updated September 17, 2020, https://www.fda.gov/media/136522/download.

[49] Daniel B. Larremore et al., "Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance," medRxiv, June 27, 2020, https://www.medrxiv.org/content/10.1101/2020.06.22.20136309v2.full.pdf.

[50] NIH, "NIH-funded screening study builds case for frequent COVID-19 antigen testing," June 30, 2021, https://www.nih.gov/news-events/news-releases/nih-funded-screening-study-builds-case-frequent-covid-19-antigen-testing.

[51] See for example: (1) Rockefeller Foundation, "National Covid-19 Testing & Tracing Action Plan," July 2020, https://www.rockefellerfoundation.org/national-covid-19-testing-and-tracing-action-plan/; (2) Harvard Center for Ethics, "ROADMAP TO PANDEMIC RESILIENCE: Massive Scale Testing, Tracing, and Supported Isolation (TTSI) as the Path to Pandemic Resilience for a Free Society," April 20, 2020, https://ethics.harvard.edu/files/center-for-ethics/files/roadmaptopandemicresilience_updated_4.20.20.pdf; (3) American Enterprise Institute, "National coronavirus response: A road map to reopening," March 29, 2020, https://www.aei.org/research-products/report/national-coronavirus-response-a-road-map-to-reopening/; and (4) AAMC, "AAMC Recommendations for COVID-19 Testing: The Current State and The Way Forward," October 22, 2020, https://www.aamc.org/covidroadmap/testing.

[52] See, for example, STAT News, "The U.S. needs a national Covid-19 testing strategy, not a state-by-state patchwork," October 1, 2020, https://www.statnews.com/2020/10/01/national-covid-19-testing-strategy-not-state-by-state-patchwork/; Families USA, "CALLING FOR A TRUE NATIONAL TESTING STRATEGY FOR COVID-19," June 11, 2020, https://familiesusa.org/resources/calling-for-a-true-national-testing-strategy-for-covid-19/; and American Society for Clinical Pathology, "The United States Must Develop a National COVID-19 Diagnostic Testing and Support Strategy," April 14, 2020, https://www.ascp.org/content/news-archive/news-detail/2020/04/14/the-american-society-for-clinical-pathology-calls-on-the-federal-government-to-develop-a-national-covid-19-diagnostic-testing-and-support-strategy.

[53] Trump White House, "President Donald J. Trump Is Ensuring States Have The Testing Capacity Needed To Safely Open Up America Again, April 27, 2020, https://trumpwhitehouse.archives.gov/briefings-statements/president-donald-j-trump-ensuring-states-testing-capacity-needed-safely-open-america/.

efforts were started in response to the perceived lack of national guidance on testing. For example, in July 2020, HHS announced the launch of the National COVID-19 Testing Implementation Forum, described as "a new program to capture feedback between federal officials and the private sector."[54] Information about the initiative was limited. Stated goals included gathering private sector input on end-to-end supply chain issues and implementation of a national surveillance strategy. In addition, several states formed a bipartisan purchasing compact in August 2020 to procure rapid antigen tests directly from the tests' manufacturers, bypassing the federal government and using their combined leverage to ensure manufacturers of demand for their product.[55]

PPPHCEA, enacted in late April 2020, required HHS to develop and submit to Congress a COVID-19 strategic testing plan not later than 30 days after its enactment, and required the plan be updated every 90 days until funds were expended.[56] The plan was required to help states understand the types of testing available for COVID-19, provide guidelines for testing and estimates of testing production, and outline how the HHS Secretary would increase testing capacity and testing supplies. This strategic testing plan was first submitted to designated congressional committees on May 24, 2020. That report detailed background on the types of COVID-19 tests, as well as an overview of the types of laboratories carrying out testing (the testing "ecosystem"), among other things, but it did not provide a comprehensive national testing strategy. Additional reports were sent to Congress in August and November of 2020 in fulfillment of the PPPHCEA statutory requirement, although they were not released publicly.[57]

The PPPHCEA also required states and other jurisdictions receiving funding pursuant to the act to submit testing plans that included the following information: the number of tests needed; estimates of laboratory and testing capacity, including related to workforce, equipment and supplies, and available tests; and a description of how the state, locality, territory, tribe, or tribal organization will use its resources for testing, including how such use relates to easing any COVID-19 community mitigation policies.[58] According to the May 2020 COVID-19 strategic testing plan submitted by HHS to Congress, "States are requested to detail how a minimum of two percent of the State's population will be tested each month beginning immediately; as well as plans to increase that number by the fall of 2020."[59] The state plans were initially required to be submitted to HHS 30 days post-enactment, but states were given an extension to May 30 for plans covering May and June, and until June 15 for plans covering the remainder of 2020. In late June 2020, Representative Frank Pallone, Chairman of the House Committee on Energy and Commerce, sent a letter to HHS requesting the public release of the state testing plans.[60] Although

[54] HHS, "HHS Announces National COVID-19 Testing Implementation Forum," July 21 2020, https://www.hhs.gov/about/news/2020/07/21/hhs-announces-national-covid-19-testing-implementation-forum.html.

[55] *Washington Post*, "There's no national testing strategy for coronavirus. These states banded together to make one." August 4, 2020, https://www.washingtonpost.com/coronavirus/coronavirus-state-testing-compact/2020/08/04/8b73bed8-d66f-11ea-9c3b-dfc394c03988_story.html.

[56] P.L. 116-139, Division B, "Additional Emergency Appropriations for Coronavirus Response," Title I, Department of Health and Human Services, 134 STAT. 627-628.

[57] GAO, "COVID-19 Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention (GAO-21-265)," January 28, 2021, https://www.gao.gov/assets/gao-21-265.pdf, p. 82.

[58] P.L. 116-139, Division B, "Additional Emergency Appropriations for Coronavirus Response," Title I, Department of Health and Human Services, 134 STAT. 627-628.

[59] HHS, "Report to Congress: COVID-19 Strategic Testing Plan," May 24, 2020, pp. 71-81, https://delauro.house.gov/sites/delauro.house.gov/files/HHS_COVID_Testing_Report.pdf (hereinafter, HHS, "COVID-19 Strategic Testing Plan").

[60] 360dx.com, "US Congressman Requests State COVID-19 Testing Plans From HHS," June 26, 2020,

these state plans were not required to be released publicly, HHS made them publicly available on July 10, 2020.[61]

In late January 2021, the Government Accountability Office (GAO) released a report recommending that "HHS develop and make publicly available a comprehensive national COVID-19 testing strategy that incorporates all characteristics of an effective national strategy."[62] President Biden's Pandemic Relief Strategy notes that widespread, accessible testing will lead to better public health outcomes.[63] He further issued an executive order on January 20, 2021, tasking the coordination of the federal government's approach to COVID-19 testing to a newly created position within the Executive Office.[64] The Biden Administration has not released a national testing strategy,[65] although in September 2021, the Administration released a COVID-19 Action Plan, which includes several actions to increase and improve access to testing, and specifically to at-home and POC testing.[66]

How Have Supply Chain-Related Issues Affected COVID-19 Testing?

Earlier in the pandemic, there were widespread reports of supply chain issues affecting access to COVID-19 diagnostic testing nationally.[67] As vaccines were administered across the country and case counts declined, the demand and need for testing decreased, which eased many of the supply chain stressors experienced in the beginning of the pandemic.[68] In response, some manufacturers decreased production of their tests. However, the emergence of the highly transmissible Delta variant over the summer—combined with eased mitigation measures and reopening of schools and workplaces—has again increased demand for testing, placing new strain on the supply of some tests.[69] Specifically, the supply of COVID-19 at-home tests and POC tests is under some

https://www.360dx.com/infectious-disease/us-congressman-requests-state-covid-19-testing-plans-hhs#.XxY7EJ5Kg4k.

[61] HHS, "HHS Releases July - December COVID-19 State Testing Plans," https://public3.pagefreezer.com/browse/HHS%20%E2%80%93%C2%A0About%20News/20-01-2021T12:29/https://www.hhs.gov/about/news/2020/08/10/hhs-releases-july-december-covid-19-state-testing-plans.html.

[62] GAO, "COVID-19 Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention (GAO-21-265)," January 28, 2021, https://www.gao.gov/assets/gao-21-265.pdf.

[63] White House, "National Strategy For the Covid-19 Response and Pandemic Preparedness" January, 2021, available at https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf.

[64] Executive Order 12987, "Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID-19 and To Provide United States Leadership on Global Health and Security," 86 *Federal Register* 7019-7021, January 20, 2021.

[65] Roll Call, "Lack of national COVID testing strategy drives confusion," April 20, 2021, https://www.rollcall.com/2021/04/20/lack-of-national-covid-testing-strategy-drives-confusion/.

[66] The White House, "Path out of the Pandemic: President Biden's COVID-19 Action Plan," https://www.whitehouse.gov/covidplan/#testing-masking%C2%A0.

[67] See for example McKinsey & Company, "COVID-19: Overcoming supply shortages for diagnostic testing," July 15, 2020, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/covid-19-overcoming-supply-shortages-for-diagnostic-testing#.

[68] Pew, "U.S. COVID-19 Testing Has Dropped Dramatically," March 22, 2021, https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/03/22/us-covid-19-testing-has-dropped-dramatically.

[69] Reuters, "U.S. COVID-19 tests again in short supply as infections soar, schools reopen," August 27, 2021, https://www.reuters.com/world/us/us-covid-19-tests-again-short-supply-infections-soar-schools-reopen-2021-08-27/.

stress due in part to increased demand for these products generated by increasing cases and surveillance testing in schools, among other things.

The supply chain for molecular diagnostics, a complex and relatively slow type of testing, is not streamlined and has not developed to support the high-volume, rapid sample-to-answer testing required during the pandemic. The testing industry has been described as "bespoke,"[70] meaning it has generally focused on developing tailor- or custom-made products, rather than mass production of a uniform product. It is not centrally coordinated; is composed of multiple entities; and relies on a wide variety of platforms and instruments that are largely not interoperable. As a result, most laboratories' supply chains rely on a unique combination of inputs from various manufacturers, which can be difficult to characterize and optimize.

As the FDA was granting EUAs for more laboratory-developed tests (LDTs) and test kits to meet increasing demand and testing volume increased, laboratories across the country reported shortages of virtually all necessary supplies for testing. A survey of clinical laboratories across the country conducted in December 2020 through January 2021 found that 50% of responding labs reported challenges obtaining necessary supplies, including test kits, reagents and swabs.[71] PCR-based molecular diagnostic testing involves sample collection, nucleic acid extraction, and testing to identify the presence of the SARS-CoV-2 virus. Since testing began, there have been shortages of the supplies needed for each of these steps: swabs needed for sample collection; viral transport media needed to stabilize and store the samples after collection and during transport; ribonucleic acid (RNA)[72] extraction kits and reagents needed to extract viral RNA from the samples prior to testing; test kits and testing reagents needed to amplify and detect viral nucleic acid; and instruments needed to run tests. PPE needed during sample collection has similarly been in short supply, as has laboratory space and trained personnel needed to run the tests, as well as common laboratory consumables (e.g., pipette tips).[73]

Private efforts, spearheaded by the American Society for Microbiology (ASM) and the Association for Supply Chain Management (ASCM), nationally monitored and publicly reported on inventory and supply shortages experienced by clinical laboratories in late 2020. The most recent data from these efforts indicated that clinical laboratories were operating at 40% of their capacity, that key supply shortages continued (e.g., test kits, consumables), and that supplies for non-COVID-19 testing were being affected.[74] The Biden Administration's *National Strategy for the COVID-19 Response and Pandemic Preparedness* notes that the "federal government will identify, inventory, and monitor the need, availability, and manufacturing capacity of critical supplies," including for testing and PPE.[75]

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[70] Andrew Slavitt, "Here's How The US Can Start Testing More People for Covid-19," May 5, 2020. https://coronavirus.medium.com/heres-how-the-us-can-start-testing-more-people-for-covid-19-ed3f10bb9952.

[71] AACC, "COVID-19 Survey Results," https://www.aacc.org/science-and-research/covid-19-resources/aacc-covid-19-testing-survey/full-survey-results.

[72] RNA (ribonucleic acid) is defined as a "complex compound of high molecular weight that functions in cellular protein synthesis and replaces DNA (deoxyribonucleic acid) as a carrier of genetic codes in some viruses." https://www.britannica.com/science/RNA.

[73] For more information, see CRS In Focus IF11774, *COVID-19 Testing Supply Chain*.

[74] American Society for Microbiology, "Supply Shortages Impacting COVID-19 and Non-COVID Testing," January 19, 2021, https://asm.org/Articles/2020/September/Clinical-Microbiology-Supply-Shortage-Collecti-1.

[75] Biden White House, "National Strategy for the COVID-19 Response and Pandemic Preparedness," January 21, 2021, https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf.

Which Federal Agencies Are Involved in the Testing Supply Chain?

The FDA has worked with industry to identify and mitigate shortages by modifying test EUAs to allow for the use of alternate supplies when carrying out a test and by providing information for manufacturers and laboratories relating to testing supply substitution strategies.[76] However, throughout much of the pandemic, shortages persisted due to global demand and the unprecedented level of testing, as well as a lack of coordinated ascertainment, production, and allocation of supplies. The FDA does not have the authority to allocate or distribute supplies.

By virtue of the national emergency, Federal Emergency Management Agency (FEMA) has played a key federal role in procuring and distributing testing supplies (see the "What Is FEMA's Role in Distributing Testing Materials to Providers?" section of this report), and the Defense Production Act (DPA) is an available mechanism for compelling production of testing supplies.[77] For example, President Trump invoked the DPA for the production of nasal swabs, and the Department of Defense announced $75 million in DPA investments to increase nasal swab production.[78] The Assistant Secretary for Preparedness and Response (ASPR) at HHS also has a significant role in supply chain issues for medical countermeasures in public health emergencies, including, for example, through the management of the Strategic National Stockpile.[79]

What Is FEMA's Role in Distributing Testing Materials to Providers?

During the early pandemic response, FEMA procured and distributed testing materials directly to states, tribes, territories, local governments, and nonprofit medical facilities to expand testing capacity.[80] In the first half of 2020, FEMA and HHS also led the Laboratory Diagnostics Task Force, which supports testing efforts undertaken by state and local governments, health care providers, and public health labs.[81] In June 2020, this task force was reorganized under HHS oversight.[82]

Generally, FEMA may provide personnel, supplies, and operational support for urgent response work to states, tribes, territories, local governments, and eligible private nonprofit organizations (Applicants) authorized to receive Public Assistance (PA) under a Stafford Act declaration; this assistance is referred to as Direct Federal Assistance.[83] When warranted, FEMA tasks its own personnel or other federal agencies, such as HHS and CDC, to perform work or provide supplies

[76] FDA, "COVID-19 Testing Supplies: FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-testing-supplies-faqs-testing-sars-cov-2.

[77] For more information about the Defense Production Act, see CRS Insight IN11387, *COVID-19: Defense Production Act (DPA) Developments and Issues for Congress*.

[78] Department of Defense (DOD), "DOD Details $75 Million Defense Production Act Title 3 Puritan Contract," April 29, 2020, https://www.defense.gov/Newsroom/Releases/Release/Article/2170355/dod-details-75-million-defense-production-act-title-3-puritan-contract/.

[79] See "HHS Office of the Assistant Secretary for Preparedness and Response," https://www.phe.gov/about/aspr/Pages/default.aspx.

[80] Federal Emergency Management Agency (FEMA), "Federal Support to Expand National Testing Capabilities," May 5, 2020, https://www.fema.gov/fact-sheet/federal-support-expand-national-testing-capabilities (hereinafter FEMA, "Federal Support to Expand National Testing Capabilities").

[81] Ibid.

[82] FEMA, Pandemic Response to Coronavirus Disease 2019 (COVID-19): Initial Assessment Report FEMA Operations January through September 2020, January 2021, p. 5, https://www.fema.gov/sites/default/files/documents/fema_covid-19-initial-assessment-report_2021.pdf.

[83] Authorized in Stafford Act Sections 402, 403, 418, 419, and 502; 42 U.S.C. §§5170a, 5170b, 5185, 5186, and 5192. See also 44 C.F.R. §206.208.

eligible for PA on behalf of the requesting Applicants. According to FEMA, the agency exercised this authority to procure and distribute testing supplies and services directly to states, tribes, territories, local governments, and eligible nonprofits during the early phase of the federal pandemic response.[84]

Beginning in early May 2020, FEMA announced that the agency would begin delivering a limited amount of testing materials to states, tribes, and territories to support each government's own testing plan, in accordance with the Trump Administration's *Testing Blueprint*.[85] FEMA Administrator Peter Gaynor explained that each government would begin receiving testing swabs and transport media from FEMA by May 14, 2020, and would continue to receive weekly distributions through the end of June 2020.[86] In June 2020, FEMA reported that the agency planned to conclude its testing supply procurement and distribution operation in early July 2020.[87] FEMA confirmed this timeline in April 2021.[88]

These activities were provided as a form of Direct Federal Assistance authorized under the Stafford Act, and also through authorities established in an interagency agreement with ASPR of HHS.[89] States, tribes, and territories were responsible for determining a distribution strategy to meet the needs of their own populations.[90] While supplies purchased through FEMA's interagency agreement with ASPR were free to applicants, supplies provided as Direct Federal Assistance were initially subject to a 25% nonfederal cost share.[91] However, President Biden has subsequently waived the cost share for testing supplies purchased or supplied directly to applicants between January 20, 2020 and September 30, 2021.[92]

Some nonfederal stakeholders praised FEMA's testing supply distribution effort.[93] However, some Members of Congress and nonfederal stakeholders raised concerns related to FEMA's procurement and distribution of testing supplies, following reports that some distributed supplies

[84] Email from FEMA Office of Congressional and Legislative Affairs to CRS, June 19, 2020.

[85] FEMA, "Federal Support to Expand National Testing Capabilities"; HHS, "COVID-19 Strategic Testing Plan," pp. 20-21.

[86] Testimony of FEMA Administrator Peter Gaynor and Rear Admiral John Polowczyk, in U.S. Congress, Senate Homeland Security and Governmental Affairs Committee, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic*, hearing, 116th Cong., 2nd sess., June 9, 2020, p. 11, at https://www.hsgac.senate.gov/imo/media/doc/Testimony-Gaynor%20&%20Polowczyk-2020-06-09.pdf.

[87] FEMA Office of Congressional and Legislative Affairs email to CRS, June 23, 2020.

[88] FEMA Office of Congressional and Legislative Affairs email to CRS, April 16, 2021.

[89] FEMA and HHS, "Memorandum of Understanding Between the Federal Emergency Management Agency and the Department of Health and Human Services, Office of Assistance Secretary of Preparedness Response," executed April 5, 2020, provided to CRS by FEMA Office of Congressional and Legislative Affairs; FEMA, "Coronavirus Pandemic Response: Summary of Cost Share by Shared Resources," September 17, 2020, https://www2.illinois.gov/iema/LocalEMA/Documents/PAforms/COVID-19-CostShare.pdf.

[90] FEMA, "Federal Support to Expand National Testing Capabilities."

[91] FEMA, "Coronavirus Pandemic Response: Summary of Cost Share by Shared Resources," September 17, 2020, available at https://www2.illinois.gov/iema/LocalEMA/Documents/PAforms/COVID-19-CostShare.pdf.

[92] FEMA, "FEMA Statement on 100% Cost Share," February 3, 2021, https://www.fema.gov/press-release/20210203/fema-statement-100-cost-share.

[93] See, for example, Director, Office of Emergency Services, Governor's Office of California Ghilarducci, who testified that "this is a huge one-time increase in rapid point-of-care testing for the State and will be immensely helpful." U.S. Congress, House Subcommittee on Oversight, Management, and Accountability and House Subcommittee on Emergency Preparedness, Response, and Recovery, *Reviewing Federal and State Pandemic Supply Preparedness and Response*, 116th Cong,. 2nd sess., July 14, 2020, No. 116-76, p. 18.

were faulty and that agency efforts did not resolve testing supply gaps.[94] GAO has issued several recommendations relevant to FEMA's distribution of testing supplies, including the following:

- HHS, in coordination with FEMA, develop and communicate to stakeholders plans outlining specific federal government actions that will be taken to help mitigate medical supply gaps for the remainder of the pandemic.[95]
- HHS, in coordination with FEMA, document roles and responsibilities for supply chain management functions that were transitioning to HHS.[96]
- HHS, in coordination with FEMA, devise solutions to help states, tribes, territories, and local governments track supply requests.[97]

FEMA and HHS initially disagreed with these recommendations from GAO, noting their ongoing work to manage the medical supply chain.[98] The recommendations remain open as of March 2021.[99]

Delivery of Testing for COVID-19

This set of questions addresses issues related to individuals accessing testing, including (1) who can receive testing, (2) the settings where testing is available, and (3) the settings where testing is available for individuals who are unable to pay for the full costs of testing.

What Is CDC's Role in Setting Testing Guidelines?

States and other jurisdictions (e.g., tribal, territorial) are primarily responsible for setting prioritization criteria and other jurisdiction-specific policies for COVID-19 testing. At an individual level, testing recommendations may rely on clinician judgement.[100] State approaches may differ depending on their respective testing capacities and the level of COVID-19 transmission in their communities.[101] The federal government, particularly through CDC, can

[94] Ibid. See also, for example Chairman James E. Clyburn, Chairman, Select Subcommittee on the Coronavirus Crisis, et al., Letter to Department of Homeland Security Secretary Mayorkas and FEMA Acting Administrator Robert Fenton, March 30, 2021, pp. 1, 10-11, https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2021-03-30.Select%20Sub%20to%20Mayorkas%20Fenton%20re%20DHS%20FEMA%20.pdf; Senators Elizabeth Warren, Tina Smith, et al., Letter to Vice President Pence, April 10, 2020, https://www.warren.senate.gov/imo/media/doc/LTO.20-04-09.Diagnostic%20Testing%20Inventory.pdf; and Ryan Gabrielson and J. David McSwane, "FEMA Ordered $10.2 Million in COVID-19 Testing Kits It's Now Warning States Not to Use," *ProPublica*, June 26, 2020, https://www.propublica.org/article/fema-ordered-10-2-million-in-covid-19-testing-kits-its-now-warning-states-not-to-use.

[95] This recommendation, first issued in GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions*, GAO-20-701, September 2020 (hereinafter GAO, *COVID-19: Federal Efforts)*, p. 1, https://www.gao.gov/products/gao-20-701, was reiterated in GAO, *COVID-19: Sustained Federal Action is Crucial as Pandemic Enters Its Second Year*, GAO-21-387, pp. 80, 88, 177-178, 455-56 (hereinafter GAO, *COVID-19: Sustained Federal Action)*, https://www.gao.gov/assets/gao-21-387.pdf.

[96] This recommendation, first issued in GAO's September 2020 report, GAO, COVID-19: *Federal Efforts*, p. 1, was reiterated in GAO, *COVID-19: Sustained Federal Action*, pp. 80, 177-178, and 455-56.

[97] Ibid.

[98] GAO, *COVID-19: Sustained Federal Action*, pp. 177-178.

[99] GAO, *COVID-19: Sustained Federal Action*, pp. 455-456.

[100] CDC, "Testing for COVID-19," last updated June 24, 2020, https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html.

[101] Bill McBride, *Memorandum: Capacity for COVID-19 Testing- Current Status*, National Governors Association,

inform these criteria by issuing guidance. As the federal government's lead public health agency, CDC develops and maintains expertise on the science and best practices for testing as a part of public health responses and ongoing disease mitigation.[102]

These guidance documents are generally advisory in nature, unless specifically promulgated by regulation or executive order.[103] CDC has generally opted to inform clinical practice through guidance, rather than regulation. While these advisory guidelines are not binding, they can serve to establish best practices in a given field.[104] These best practices can have broad implications for a variety of entities, including local jurisdictions and medical licensing agencies. A local jurisdiction may consider a nonbinding CDC issued guidance a new threshold that must be met for achieving best practices, whereas a medical licensing agency may consider the same guidance as evidence for the standard of practice against which licensees should be measured.

CDC has issued a number of guidance documents throughout the COVID-19 pandemic related to testing practices that have evolved with testing supply, availability of different test types, testing priorities, and levels of disease transmission in different locations and communities, among other factors. Early testing guidance focused on how to prioritize the use of limited testing supply (see next question). As the pandemic has evolved, various guidance documents have provided standards and technical assistance for state and local health departments in a variety of situations, for example, testing individuals at homeless service provider sites or how and when health care providers, laboratories, and public health staff should use antibody tests.[105] CDC has also recently updated testing guidance for students, teachers, and staff in K-12 education settings.[106] CDC has additionally issued further guidance on expanded availability and use of screening tests and information on testing vaccinated individuals.[107] These guidance documents are often updated or replaced as new information is found, which then can trigger the downstream change in standard of practice mentioned previously.

At times, changes in CDC guidelines have caused confusion, and in some cases, observers have raised concerns about their scientific validity.[108] In addition, frequent changes to published guidance can impose an additional burden on state and local entities that may adjust operations to meet the new standard established by the guidance. A November 2020 GAO report evaluated

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May 14, 2020, https://www.nga.org/wp-content/uploads/2020/04/Testing-Memo-Update-5-13-20.pdf.

[102] CDC, "CDC in Action: Working 24/7 to Stop the Threat of COVID-19," February 4, 2021, https://www.cdc.gov/budget/documents/covid-19/CDC-247-Response-to-COVID-19-fact-sheet.pdf.

[103] For a further detailed discussion on how guidance documents may affect policy, see CRS Report R44468, *General Policy Statements: Legal Overview*, by Jared P. Cole and Todd Garvey.

[104] See, for example, CDC, "About the CDC Guidelines for Infection Control in Dental Health Care-2003," updated November 26, 2019, https://www.cdc.gov/oralhealth/infectioncontrol/faqs/about-the-cdc-guidelines.html (stating that "CDC develops guidelines and recommendations to improve the effectiveness and impact of public health interventions and inform key audiences, such as clinicians, public health practitioners, and the public").

[105] CDC, "Guidance for COVID-19," https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Aasc&Topic=Disease%20Information%20%3E%20Testing.

[106] CDC, "Guidance for COVID-19," https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Aasc&Topic=Disease%20Information%20%3E%20Testing.

[107] CDC, "Testing Overview," https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html#previous.

[108] See, for example, Apoorva Mandavilli, "C.D.C. Testing Guidance Was Published Against Scientists' Objections," *New York Times*, November 19, 2020; Carl O'Donnell, Vishwadha Chander, and Manojna Maddipatla, "Exclusive: Most U.S. States Reject Trump Administration's New COVID-19 Testing Guidance," *Reuters*, August 28, 2020; and National Academy of Sciences and National Academy of Medicine, "NAS and NAM Presidents Alarmed By Political Interference in Science Amid Pandemic," press release, September 24, 2020, https://www.nationalacademies.org/news/2020/09/nas-and-nam-presidents-alarmed-by-political-interference-in-science-amid-pandemic.

issues around CDC's testing guideline. GAO noted confusion and misunderstandings around the guidelines for rapid antigen testing, and lack of coordination around guidelines and requirements for such tests from FDA, CMS, and CDC. GAO also noted that CDC testing guideline changes were not always transparently communicated and recommended that the CDC clearly disclose the scientific rationale for any change to the testing guidelines at the time the changes are made.[109]

How Has Testing Been Prioritized?

As the pandemic has evolved, CDC has issued guidance to identify populations prioritized for various types of tests. In the early stages of the pandemic, CDC guidance recommended limiting COVID-19 diagnostic testing mostly to individuals with relevant travel or exposure history, as a means of conserving limited testing supply.[110] As of March 17, 2021, CDC guidance includes considerations for the uses of diagnostic and serologic testing, testing symptomatic and asymptomatic individuals, and the testing of vaccinated individuals. In previous iterations, CDC had recommended that diagnostic tests be prioritized for the following four populations:

- individuals with signs or symptoms consistent with COVID-19;
- asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission;
- asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings (e.g., congregate living settings); and
- individuals being tested for purposes of public health surveillance for SARS-CoV-2.[111]

As testing supply has increased, CDC has begun issuing broad guidance documents for COVID-19 testing in a variety of populations, including non-health care workplaces, schools, and other congregate settings.[112] The latest iterations of CDC testing guidance (i.e., March 17, 2021 guidance) reflect a greater focus on equity considerations in both urban and rural areas, such as testing access and availability.[113] CDC has also developed more specific guidance related to testing certain populations or testing programs in specific settings.[114]

Where Can Individuals Get a COVID-19 Test?

Testing availability may vary by state and by the type of test sought. Generally, a range of both ambulatory and inpatient *health care settings* and providers (e.g., hospitals, doctors' offices, urgent care centers) provide testing, and some congregate living sites (e.g., nursing homes) may provide testing to their residents. In addition, many jurisdictions have established testing

[109] U.S. Government Accountability Office, *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response*, GAO-21-191, November 2020, p. 84-85, https://www.gao.gov/assets/gao-21-191.pdf.

[110] CRS Report R46219, *Overview of U.S. Domestic Response to Coronavirus Disease 2019 (COVID-19)*.

[111] CDC, "Coronavirus Disease 2019 (COVID-19): Testing Overview," Updated July 2, 2020, https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Fclinical-criteria.html.

[112] CDC, "Guidance for COVID-19," https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Aasc&Topic=Disease%20Information%20%3E%20Testing.

[113] CDC, "Testing Overview," https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html#previous.

[114] For example, CDC has issued testing guidelines for nursing homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html, and for high-density critical infrastructure workplaces: https://www.cdc.gov/coronavirus/2019-ncov/community/worker-safety-support/hd-testing.html.

programs in *community-based settings*, such as walk-up or drive-through testing sites, public health departments, and those at retail pharmacies. A number of settings provide free or reduced-cost tests to the general population using another source of payment (see the "Where Are Free or Reduced Cost Tests Available?" section of this report).

Generally, state law governs who may order a test, which in turn may affect the settings where testing is available. For example, not all states permit nurse practitioners to order tests, so in those states a person would need to see a physician to have a test ordered.[115] Some states have expanded the roles of health professionals during the period of the state's emergency declaration. In some cases, this expanded authority is to expire at the end of the state declared emergency. Given this, who may order a test may change over time.[116] Two factors inform whether a complete test is available directly from a provider or if a central laboratory must be involved in its processing: (1) the settings that are able to provide tests (e.g., whether testing is available at a pharmacy), which may be affected by both state law and CLIA (Clinical Laboratory Improvement Amendments of 1988) requirements and (2) where a test is FDA-authorized to be provided (e.g., a waived or point-of-care setting). Test availability may also differ based on the locations where a given payor may pay for testing. For example, some payors may require the provider to be recognized as meeting federal (and sometimes state) conditions of participation requirements (e.g., Medicaid participating provider) in order to pay for a test that a program enrollee receives from that provider.

Where Are Free or Reduced Cost Tests Available?

A number of types of health care and other settings may administer COVID-19 tests; however, few types of facilities have requirements to provide care to all individuals regardless of their ability to pay. As such, not all testing sites provide free testing nor do all types of facilities test uninsured individuals.

Public Health Department Testing Programs

Throughout the pandemic, state, local, territorial, and tribal (SLTT) health departments have operated diagnostic testing programs, though activities have varied by jurisdiction. For example, some local health departments have operated temporary testing sites (e.g., drive-through testing sites), or so-called "mobile strike teams," to provide targeted testing in outbreak areas or for certain populations, such as uninsured or high-risk individuals.[117] Some of the community-based testing sites have been operated jointly by FEMA and/or HHS with health departments, while others have been operated in partnership with health care provider organizations or commercial partners such as retail pharmacies (e.g., CVS).[118] In the early stages of the pandemic, many of the

[115] National Alliance of State Pharmacy Associations, "COVID-19 Testing," https://naspa.us/resource/covid-19-testing/. On April 8, 2020, HHS released guidance authorizing pharmacists to order testing and providing immunity to do so. See HHS, "Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act," https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf.

[116] For state provider licensure changes during the COVID-19 emergency period, see Federation of State Medical Boards, *U.S. States Modifying Requirements for Telehealth in Response to COVID-19*, March 6, 2021, https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf.

[117] National Association of City and County Health Officials (NACCHO), *Local Health Departments Standing Strong on the Frontlines of COVID-19 Response*, April 9, 2020, https://www.naccho.org/uploads/downloadable-resources/Press-Release-NPHW-2020-Role-of-LHDs-in-COVID-19-Response_4.9.20.pdf.

[118] Bill McBride, *Memorandum: Capacity for COVID-19 Testing- Current Status*, National Governors Association,

health department testing programs were focused on target populations, such as health care workers and first responders.[119] Some health department testing programs then expanded to become more broadly available in some jurisdictions, though the availability of testing and the populations that can access such testing has varied by jurisdiction. Moving forward, it is unclear to what extent the public health sector will remain responsible for ongoing diagnostic testing programs. Traditionally, clinical diagnosis activities are largely conducted within the clinical sector, while public health is responsible for outbreak response, surveillance, and some efforts to protect at-risk populations.[120]

Testing provided by or in partnership with health departments is often available free of charge to individuals, though testing is often limited to residents of a certain jurisdiction and some programs may seek to bill private health insurance plans or public payors (e.g., Medicaid) for individuals with applicable coverage or to charge certain individuals for testing.[121] CDC and other grant funding provided through several coronavirus supplemental appropriations measures have supported testing programs run by health departments.[122] In particular, to date, over $40 billion has been awarded to jurisdictions as Epidemiology and Laboratory Capacity (ELC) grants[123] that can be used to support public health department testing programs; allowable items in this funding stream include most costs associated with standing up, operating, and demobilizing testing sites.[124] In addition, the American Rescue Plan Act of 2021 (ARPA) provided $47.8 billion available until expended for testing, contact tracing, and mitigation activities related to monitoring and reducing the spread of COVID-19.

In late 2020-early 2021, SLTT health jurisdictions focused their efforts on providing testing opportunities in underserved areas and populations. This includes establishing testing sites, facilitating partnerships with local leaders, and building communication networks with populations who have limited access to testing. For example, the state of California funded over 100 testing sites in communities of color, while other jurisdictions, such as Hamilton County Tennessee, built partnerships with the faith-based community to establish testing sites in predominately Black communities.[125]

May 14, 2020, https://www.nga.org/wp-content/uploads/2020/04/Testing-Memo-Update-5-13-20.pdf.

[119] Association of State and Territorial Health Officials, *16 Key Considerations for Drive-Through or Mobile Testing*, March 19, 2020, https://astho.org/StatePublicHealth/16-Key-Considerations-for-Drive-Through-or-Mobile-Testing/03-19-20/.

[120] Association of Public Health Laboratories (APHL), "Smart Testing for Optimizing Pandemic Response," January 2021, https://www.aphl.org/aboutAPHL/publications/Documents/ID-2021-Smart-Testing-for-Optimizing-Pandemic-Response.pdf.

[121] For example, the District of Columbia (DC) operates free testing sites for DC residents who do not have individual providers experiencing any COVID-19 symptoms or with known exposures. Although individuals with insurance will be asked to provide their information, testing will be provided to residents at no cost; see https://coronavirus.dc.gov/testing. The Texas Department of State Health Services states "unless otherwise stated, deductible, co-pay, or co-insurance may apply." Public health testing programs vary by local jurisdiction in Texas. See https://dshs.texas.gov/coronavirus/testing.aspx.

[122] GAO, *COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year*, GAO-21-387, March 31, 2021, https://files.gao.gov/reports/GAO-21-387/index.html#appendix7.

[123] HHS, "COVID-19 Funding ELC Enhancing Detection Expansion," https://www.hhs.gov/sites/default/files/covid-19-funding-elc-enhacing-detection-expansion.pdf.

[124] CDC, "ELC Enhancing Detection Expansion Questions & Answers," March 15, 2021, https://www.cdc.gov/ncezid/dpei/pdf/elc-enhancing-detection-expansion-faq-508.pdf.

Karen DeSalvo, Bob Hughes, and Mary Bassett, *Public Health COVID-19 Impact Assessment: Lessons Learned and Compelling Needs*. National Academy of Medicine. April 7, 2021. https://nam.edu/public-health-covid-19-impact-assessment-lessons-learned-and-compelling-needs/.

As local health departments have taken on a significant role in distributing and administering COVID-19 vaccines to their communities, testing remains a core function of preventing the spread of COVID-19. While distinct appropriations from recent COVID-19 relief acts have been made for both vaccine and testing capabilities, local health jurisdictions may have limited capacity in terms of public health workforce for all functions of the COVID-19 response.[126] Another area of concern is that most local health jurisdiction surge staff were hired on as temporary, term-limited contract workers, which may lead to a decrease in staffing at the end of the fiscal year. Until funding streams are fully implemented and SLTT health jurisdictions are able to hire appropriate staff, jurisdictions may need to divert staff and resources from testing initiatives in order to meet vaccination demand and goals.

It is difficult to predict how long such expanded testing and contact tracing efforts within the public health sector will last. The CDC recommends surging testing and contact tracing capacity as the number of cases in a jurisdiction rises.[127] Continued testing may be required to monitor community spread of COVID-19, even with ongoing vaccinations. As more individuals are vaccinated, experts expect the severity and prevalence of disease to decrease, but are aware that community transmission of COVID-19 may still occur. Additional federal awards made with funding from ARPA may facilitate increasing the capacity of public health infrastructure to maintain a consistent level of testing, even when community transmission is relatively low due to increased vaccination.[128]

Moving forward, public health departments and laboratories may focus their efforts on surveillance and screening testing, instead of clinical diagnostic testing. Public health surveillance testing gathers and monitors population or community level data on disease outbreaks, which allows health jurisdictions to characterize disease incidence and prevalence.[129] Public health departments also play a significant role in the Biden Administration's efforts to establish screening testing programs in schools and other settings.[130]

Emergency Departments

Hospitals with emergency departments are required to provide an appropriate medical screening examination and stabilization care regardless of a patient's eligibility to participate in Medicare. This obligation is required under the Emergency Medical Treatment and Active Labor Act (EMTALA),[131] and it generally extends to individuals who come to the emergency department and are suspected to have COVID-19.[132] EMTALA does permit hospitals to bill individuals for

[126] See, for example, a discussion on how the Biden Administration is prioritizing bolstering the public health workforce. Steven Findlay, *As Pandemic Surged, Contact Tracing Struggled; Biden Looks to Boost It*, Kaiser Health News, February 10, 2021, https://khn.org/news/article/as-pandemic-surged-contact-tracing-struggled-biden-looks-to-boost-it/.

[127] CDC, "Prioritizing Case Investigations and Contact Tracing for COVID-19 in High Burden Jurisdiction," https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/prioritization.html

[128] P.L. 117-2 Section 2401.

[129] CDC, "Testing Strategies for SARS-CoV-2," updated May 27, 2021, https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/sars-cov2-testing-strategies.html. See "Public Health Surveillance Testing"

[130] HHS, "Biden Administration to Invest More Than $12 Billion to Expand COVID-19 Testing," press release, March 17, 2021, https://www.hhs.gov/about/news/2021/03/17/biden-administration-invest-more-than-12-billion-expand-covid-19-testing.html.

[131] 42 U.S.C. §1395dd.

[132] HHS, Center for Medicare and Medicaid Services (CMS), "Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19)," memorandum, March 9, 2020, at https://www.cms.gov/files/document/qso-20-15-emtala-requirements-and-coronavirus-0311-updated-003pdf.pdf-1.

services provided pursuant to their EMTALA obligation. Although some individuals may pay for these services, hospitals that provide care pursuant to their EMTALA obligation may seek payment from the uninsured testing fund discussed below. As mentioned above, some community-based and facility-specific testing may be available to individuals who do not have a source of payment. In addition, the federal government has created an uninsured fund to reimburse facilities for testing provided to uninsured individuals. Congress has enacted legislation that has expanded Medicaid eligibility so that Medicaid funds may be available for testing for some individuals who are otherwise ineligible for Medicaid (see the "How Can Facilities That Provide Testing for Uninsured Individuals Be Reimbursed?" section of this report).

Health Centers

Federal health centers (also called federally qualified health centers or FQHCs) are outpatient facilities that receive federal grants to provide primary care and other services. They must be located in medically underserved areas and provide care to all individuals regardless of their ability to pay. They may bill patients with public or private insurance coverage for the services provided, and they are required to use a sliding scale fee schedule for individuals who do not have coverage.[133] Health centers have received more than $9.6 billion in supplemental funding to provide COVID-19 testing and related care. Of that amount, $600 million was explicitly appropriated for testing in PPHCEA; however, all of the funds appropriated to health centers were to prevent, prepare for, and respond to COVID-19, which includes testing.[134] The Health Resources and Services Administration (HRSA), which administers the health center program, surveyed health centers on the impact of COVID-19 on their operations. The survey found that more than 90% of responding health centers were offering testing, in some states nearly all health centers offered walk-up or drive up testing, though the availability varied by state and territory.[135]

Federally Qualified Health Center Look-Alikes

Federally Qualified Health Center Look-Alikes (called Look-Alikes) are outpatient centers similar to the health centers described above, but Look-Alikes do not receive a health center grant. Like health centers, these entities serve an underserved population, must be located in medically underserved areas, and are required to provide care to all individuals regardless of their ability to pay. As such, Look-Alikes are a setting where uninsured individuals may receive COVID-19 testing. The majority (93.3%) of Look-Alikes reported to HRSA that they have COVID-19 testing capacity, with nearly two-thirds providing walk-up or drive-up testing.[136]

Look-alikes were eligible to receive funds appropriated for testing in PPPHCEA and were eligible to receive funds under the $7.6 billion appropriated for health centers and community care in ARPA.P.L. 117-2). ARPA funds were made available for a number of COVID-19 preparation and response activities, which includes testing. In addition, these funds may be used for expenses that were incurred since the beginning of the PHE. Specific uses of these funds by look-alikes is not known.

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[133] CRS Report R43937, *Federal Health Centers: An Overview*.

[134] CRS Insight IN11367, *Federal Health Centers and COVID-19*; CRS Report R46711, *U.S. Public Health Service: COVID-19 Supplemental Appropriations in the 116th Congress*; and Section 2601 of P.L. 117-2.

[135] HHS, Health Resources and Services Administration (HRSA), "Health Center Covid-19 Survey: Operational Capacity" https://data.hrsa.gov/topics/health-centers/covid-operational-capacity, accessed March 26, 2021.

[136] HHS, HRSA, "Health Center Program Look-Alike COVID-19 Survey National Summary Report," latest data from April 2, 2021.

Federal Community-Based Testing Sites

During the initial months of FEMA's coordination of pandemic response efforts, FEMA collaborated with HHS to establish and staff community-based testing sites (CBTS) in partnership with state and local governments.[137] In March 2020, FEMA and HHS helped establish 41 CBTS throughout the country.[138] Initially, local staff at each site were supplemented by one federal physician and by U.S. Public Health Service personnel.[139] The federal government also provided assistance with contracts, logistics, lab processing, and patient notification. The sites initially focused on testing for certain health care facility workers and first responders, though later they expanded access to a broader population.[140]

In early April 2020, FEMA announced the option for CBTS to transition to full state management, with states assuming responsibilities such as staffing, procurement, and testing.[141] These sites continued to receive direct assistance (e.g., supplies) and reimbursement for eligible costs (e.g., staff overtime, testing supplies) through the FEMA Public Assistance Program. In late June 2020, FEMA reported to CRS that most community-based testing sites had closed or transitioned to state management. The 13 remaining federally run sites were due to close or transition to full state management by June 30, 2020, though sites would remain eligible for financial support and supplies through the Public Assistance program.[142] Subsequently, several sites in Texas continued to receive federal operational support in response to requests by the Office of the Governor.[143]

In May 2020, FEMA announced that the federal government, led by HHS, would build upon the first publicly run CBTS model to expand testing nationwide through a public-private partnership.[144] Under CBTS 2.0, or the "community-based sites public-private partnership," the federal government provided a flat fee for each test administered by pharmacy and retail companies at hundreds of sites throughout the country.[145] According to the GAO, participants

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[137] GAO, *COVID-19: Opportunities to Improve Federal Response and Recovery Efforts,* June 2020, GAO-20-625, p. 91 (hereinafter GAO, *COVID-19: Opportunities),* https://www.gao.gov/assets/gao-20-625.pdf.

[138] FEMA, "Weekly Update: Coronavirus Pandemic Whole-of-America Response," June 18, 2020, p. 2, provided by FEMA Congressional and Legislative Affairs. FEMA, "Coronavirus (COVID-19) Pandemic Whole-of-Government Response," Wednesday, March 25, 2020, p. 3; FEMA, "Option to Transition Federal Community-Based Testing Sites to State Management," advisory, April 9, 2020, (hereinafter FEMA, "Community-Based Testing Sites"), https://www.fema.gov/news-release/20200726/option-transition-federal-community-based-testing-sites-state-management.

[139] HHS, "COVID-19 Strategic Testing Plan," p. 24.

[140] FEMA, "Community-Based Testing Sites."

[141] Ibid.

[142] A FEMA Office of Congressional and Legislative Affairs email to CRS, June 23, 2020, noted that all sites were due to close or transition by June 30, 2020. FEMA guidance indicated that community-based testing sites under state management continued to remain eligible for Public Assistance. FEMA, "Community-Based Testing Sites."

[143] HHS, "Assistant Secretary for Health Admiral Brett P. Giroir, M.D., Statement on Texas Community-Based Testing Sites 1.0 Extension," June 26, 2020, https://www.hhs.gov/about/news/2020/06/26/assistant-secretary-for-health-admiral-brett-p-giroir-md-statement-on-texas-community-based-testing-sites-1-0-extension.html; Office of Texas Governor, "Governor Abbott Announces Additional Extension Of Community Based COVID-19 Testing Sites In Houston, Harris County," December 30, 2020, https://gov.texas.gov/news/post/governor-abbott-announces-additional-extension-of-community-based-covid-19-testing-sites-in-houston-harris-county.

[144] FEMA, "Federal Support to Expand National Testing Capabilities"; Testimony of the Office of the Assistant Secretary for Health, U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *COVID-19: An Update on the Federal Response,* 116th Cong., 2nd sess., Sept. 23, 2020 (hereinafter *COVID-19: Updated Federal Response),* https://www.cdc.gov/washington/testimony/2020/t20200923.htm.

[145] FEMA, "Federal Support to Expand National Testing Capabilities"; HHS, "COVID-19 Strategic Testing Plan," pp.

(i.e., pharmacies and retail companies) could submit claims to cover expenses after federal payments end to private insurers, Medicare, Medicaid, and the COVID-19 Uninsured Program (the program is ongoing as of August 2021).[146] HHS reported that the private sector partners are responsible for coordinating the full testing process, including registration, scheduling, provider order, patient notifications, medical supplies, equipment, and lab testing.[147]

In January 2021, HHS reported that 3,300 sites established through the public-private partnership were operating in 50 states, Washington, DC, and Puerto Rico, and had processed more than 5.6 million samples since the program's initiation.[148] HHS reported that the majority of the sites were located in areas with "moderate to high social vulnerability."[149] The HHS-operated Community Based Testing Sites website lists retail partners by state.[150] HHS further announced that the partnership would continue to operate through April 2021, as a result of a $550 million funding extension.[151]

Concerns from some Members of Congress, federal officials, and nonfederal stakeholders regarding the community-based sites' public-private partnership, include the following:

- how sites were selected and the duration of federal site management, particularly amid concerns over insufficient numbers of sites and premature cessation of federal support for testing sites;[152]
- the closure of testing sites damaged during episodes of civil unrest;[153]

24-25; HHS, "HHS Extends COVID-19 Testing Public-Private Partnership," June 30, 2020, https://www.hhs.gov/about/news/2020/06/30/hhs-extends-covid-19-testing-public-private-partnership.html.

[146] GAO, *COVID-19: Federal Efforts,* p. 27, note 56. See also Testimony of the Office of the Assistant Secretary for Health, *COVID-19: Updated Federal Response.*

[147] HHS, "HHS Extends COVID-19 Testing Public-Private Partnership," June 30, 2020, https://www.hhs.gov/about/news/2020/06/30/hhs-extends-covid-19-testing-public-private-partnership.html.

[148] HHS, "HHS Continues Community Based Testing Sites for COVID-19," release, January 7, 2021, https://www.hhs.gov/about/news/2021/01/07/hhs-continues-community-based-testing-sites-covid-19.html.

[149] Ibid. and HHS, "COVID-19 Strategic Testing Plan," p. 25. Submitted testimony of HHS Assistant Secretary for Health Brett Giroir, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic,* hearings, 116th Cong., 2nd sess., June 9, 2020, p. 7, https://www.hsgac.senate.gov/evaluating-the-federal-governments-procurement-and-distribution-strategies-in-response-to-the-covid-19-pandemic. "Moderate to high social vulnerability" is defined according to CDC's Social Vulnerability Index. See CDC/ATSDR, "CDC/ATSDR Social Vulnerability Index," April 28, 2021, https://www.atsdr.cdc.gov/placeandhealth/svi/index.html. For related discussion, see Garth Graham, "Addressing the Disproportionate Impact of COVID-19 on Communities of Color," *Journal of Racial and Ethnic Health Disparities,* vol. 8, no. 2 (2021), pp. 280-282.

[150] HHS, "Community-Based Testing Sites for COVID-19," https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html.

[151] HHS, "HHS Continues Community Based Testing Sites for COVID-19," release, January 7, 2021, https://www.hhs.gov/about/news/2021/01/07/hhs-continues-community-based-testing-sites-covid-19.html.

[152] See statement of Rep. Sheila Jackson Lee, U.S. Congress, House Committee on Homeland Security, *Examining the National Response to the Worsening Coronavirus Pandemic: Part II,* 116th Cong., 2nd sess., July 22, 2020, pp. 22-23, https://media.proquest.com/cdn/media/hms/PFT/1/aYXeI?_tm=1618328042836&_cfs=eX1rlF3bzplI58zyDehVFVRPShXsQnFz0oQ5GLsXpNk%3D; Jessica Boehm, "Phoenix Mayor Kate Gallego says federal government denied requests for COVID-19 testing help," *Arizona Republic,* July 6, 2020, https://www.azcentral.com/story/news/local/phoenix/2020/07/06/phoenix-mayor-gallego-fema-denied-coronavirus-testing/3286326001/; Statements by Rep. Andy Kim, U.S. Congress, House Select Subcommittee on the Coronavirus Crisis, Committee on Oversight and Reform, *The Administration's Efforts to Procure, Stockpile, and Distribute*, hearing, 116th Cong., 2nd sess., July 2, 2020, No. 116-101, p. 35.

[153] Amy Goldstein, "Scores of testing sites forced to close because of vandalism in civil unrest," *Washington Post,* June 3, 2020, https://www.washingtonpost.com/health/scores-of-testing-sites-forced-to-close-because-of-vandalism-in-civil-unrest/2020/06/03/e6d9fa54-a4e6-11ea-b473-04905b1af82b_story.html.

- lack of availability of tests for young children at participating sites;[154]
- insufficient testing access among people of color;[155]
- the small scale of the community-based testing sites models relative to testing demands;[156]
- difficulties encountered by independent pharmacies seeking to participate in the public-private partnership;[157] and
- insufficient clarity regarding payment for testing by third-party payers, the federal government, or other entities.[158]

Can COVID-19 Testing Be Done at Home?

There has been significant interest in, and some confusion around, at-home testing for COVID-19. Testing at home has benefits—including increased access to testing and decreased use of PPE and decreased risk of illness transmission because of the ability to avoid going in person to a health care facility—however, this type of testing requires more rigorous FDA oversight to ensure that the lay user conducting the test can do so safely and with accurate results. Although this type of testing has traditionally been termed "at-home" by the FDA, this type of test may actually be carried out in any non-laboratory setting, including and especially relevant for COVID-19, schools, daycares, workplaces, or high-risk settings. The "at-home" designation means that the test may be conducted outside of a CLIA-regulated environment, and FDA has termed these tests "non-laboratory" tests.[159]

Testing for COVID-19 in a home environment can involve either (1) a sample being self-collected at home using a kit and sent to a central laboratory for processing, or (2) a complete test, including sampling, testing, and interpretation, being conducted in the home. Complete home testing may involve telehealth visits with a health care provider to supervise the sample collection

[154] See letters to participating retailers from Senators Elizabeth Warren and Tina Smith, October 7, 2020, https://www.warren.senate.gov/newsroom/press-releases/warren-smith-question-top-retail-testing-providers-companies-on-lack-of-pediatric-testing-at-their-covid-19-testing-sites; Senators Elizabeth Warren and Tina Smith, Letter to then HHS Secretary Alex M. Azar, December 7, 2020, https://www.warren.senate.gov/imo/media/doc/2020.12.07%20Letter%20to%20HHS%20re%20testing%20investigations_updated1.pdf.

[155] Ibid. U.S. Congress, House Select Subcommittee on the Coronavirus Crisis of the Committee on Oversight and Reform, *The Urgent Need for a National Plan to Contain the Coronavirus*, hearing, 116th Cong., 2nd sess., July 31, 2020, No. 116-109, pp. 57-59.

[156] Kate Sheridan, "This Tiny Texas Company is Running Most of the Drive-Thru COVID-19 Testing in the U.S.," August 3, 2020, https://www.statnews.com/2020/08/03/etruenorth-tiny-company-running-covid-19-company/; S. Lawrence Kocot, "Expand COVID-19 Testing With Real-Time Processing Through Community Pharmacies," *Health Affairs*, July 1, 2020, https://www.healthaffairs.org/do/10.1377/hblog20200629.567658//; Statement of Rep. Jackson Lee, U.S. Congress, House Committee on Homeland Security, *Examining the National Response to the Worsening Coronavirus Pandemic*, 116th Cong., 2nd sess., July 8, 2020, No. 116-73, p. 8.

[157] Letter from Karry K. La Violette, National Community Pharmacists Association, to Senators Warren and Smith, October 20, 2020, p. 4, https://www.warren.senate.gov/imo/media/doc/2020.12.07%20Letter%20to%20HHS%20re%20testing%20investigations_updated1.pdf; S. Lawrence Kocot, "Expand COVID-19 Testing With Real-Time Processing Through Community Pharmacies," *Health Affairs*, July 1, 2020, https://www.healthaffairs.org/do/10.1377/hblog20200629.567658//.

[158] Senators Elizabeth Warren and Tina Smith, Letter to then HHS Secretary Alex M. Azar, December 7, 2020, pp. 3 and 5, https://www.warren.senate.gov/imo/media/doc/2020.12.07%20Letter%20to%20HHS%20re%20testing%20investigations_updated1.pdf.

[159] FDA, "COVID-19 Test Settings: FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-settings-faqs-testing-sars-cov-2.

and help interpret the test result and develop a treatment plan, if indicated. Complete at-home testing generally requires a prescription or order from a health care provider, although the FDA does also allow at-home tests to be offered over-the-counter (OTC), or without a prescription. Although test developers have been free to pursue this option, it requires additional data and studies to determine that its use would be simple and safe, and would not result in harm to the lay user, which may serve as a barrier for test developers seeking this type of authorization.[160] Advantages to OTC at-home tests are increased access and the ability to access a test and results entirely outside of the health care setting (with no prescription or interaction with a health care provider necessary).

The FDA must approve or authorize for marketing all at-home COVID-19 tests, at-home sample self-collection kits, or modifications to existing EUAs for tests to specifically allow for at-home sample collection methods. To date, the agency has authorized several at-home tests, available both by prescription and OTC, and including multiple antigen tests and a handful of molecular diagnostic tests.[161] With the authorization particularly of OTC at-home tests, and federal support for their manufacture, these tests have become more readily available across the country. Numerous at-home sample collection kits have also been approved and EUAs have been modified to allow for use of at-home sample collection.[162] The agency has noted that it continues to be open to this type of testing and encourages submission of EUAs, as long as the submission contains accompanying data "demonstrating the ability of a lay user to collect their specimen, run the test, and interpret their results accurately."[163] Flexibilities in the EUA process granted for many commercial and laboratory-developed COVID-19 tests do not apply to at-home testing or sample collection, and an EUA is required prior to clinical use or commercial distribution of these tests in any case.[164]

What Disparities Have Arisen in COVID-19 Testing and What Has the Federal Government Done to Address Them?

Access to reliable and convenient COVID-19 testing sites and resources, as well as other disparities in testing, have been noted as an issue throughout the pandemic response. A specific area of concern is "testing deserts." These are geographical locations where residents have to travel at least 10 miles to access a test.[165] According to national data on testing site locations compiled by a health technology firm, testing deserts were disproportionately located in more

[160] See for example, FDA, "Over-the-Counter Diagnostic Tests for the Detection of Pathogens Causing Infectious Diseases," August 2016, https://www.fda.gov/media/99903/download.

[161] FDA, "In Vitro Diagnostic EUAs," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

[162] See for example, FDA, "Coronavirus (COVID-19) Update: FDA Authorizes First Test for Patient At-Home Sample Collection," April 21, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-patient-home-sample-collection.

[163] FDA, "COVID-19 Test Settings: FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19-test-settings-faqs-testing-sars-cov-2.

[164] FDA, "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)," May 11, 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.

[165] Heath, Sara, "Patients Face Geographic Barriers to COVID-19 Testing Access," *Patient Engagement Hit: Patient Care Access News,* August 24, 2020, https://patientengagementhit.com/news/patients-face-geographic-barriers-to-covid-19-testing-access; and Tori and Marsh, "Over 67 Million Americans Lack Access to COVID-19 Testing: Where Are These 'Testing Deserts'?," *GoodRx,* August 20, 2020.

rural areas and had populations with comparatively lower average incomes in comparison to other areas with more reliable access.[166] Another national study similarly found that counties with a travel time of more than 20 minutes to a COVID-19 testing site had a higher percentage of the population that were from racial and ethnic minority groups, were uninsured, and had lower population density (i.e., rural).[167] Further, media analyses found that, as of June 18, 2020, testing sites in neighborhoods with disproportionately higher nonwhite populations faced higher demand (though noted some data limitations in fully accounting for testing capacity at these sites).[168]

In addition, some academic studies have found testing disparities in specific locations. For example, a study of New York City found that a number of tests conducted in a given zip code was positively associated with the proportion of residents who identified as white.[169] Other studies showed similar racial disparities in West Virginia and Missouri.[170] Some analyses have also noted additional factors that could cause certain racial and ethnic minority communities to disproportionately forgo needed testing, including distrust of the health care system, occupational factors such as long work hours, or lack of health care coverage.[171] While the increase in vaccine uptake has significantly decreased the number of individuals seeking out COVID-19 testing,[172] some states and localities are still experiencing testing disparities.[173]

Analyses of testing disparities have been hindered by incomplete reporting of demographic data for all tests conducted, including race/ethnicity. To date, eight states, plus the District of Columbia, report race and ethnicity data for all testing data. Most other states report race and ethnicity data for confirmed positive cases of COVID-19 only. Limitations in testing data, therefore, have limited the ability to analyze and understand disparities in access to testing and, in turn, may also limit understanding of disparities in disease transmission and acquisition rates, especially for those who do not require medical treatment.[174] Despite the data limitations, some available evidence show testing disparities, as summarized above.

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[166] See also Sarah Krouse, Brianna Abbott, and Daniela Hernandez, "Covid-19 Tests Are Still Hard to Get in Many Communities," *The Wall Street Journal*, January 22, 2021, https://www.wsj.com/articles/covid-19-testing-challenges-remain-for-many-urban-rural-communities-11611320400.

[167] CDC, "COVID-19 Racial and Ethnic Health Disparities: Risk of Exposure to COVID-19," December 10, 2020, https://www.cdc.gov/2019-ncov/community/health-equity/racial-ethnic-disparities/increased-risk-exposure.html and

[168] Matthew Vann, Soo Rin Kim, and Laura Bronner, "White Neighborhoods have more Access to COVID-19 Testing Sites: ANALYSIS," *ABC News*, June 22, 2020.

[169] Wil Lieberman-Cribbin, Stephanie Tuminello, Raja M. Flores, et al., "Disparities in COVID-19 Testing and Positivity in New York City," *American Journal of Preventive Medicine*, vol. 59, no. 3 (September 2020), pp. 326-332.

[170] Brian Hendricks, Rajib Paul, Cassie Smith, et al., "Coronavirus Testing Disparities Associated with Community Level Deprivation, Racial Inequalities, and Food Insecurity in West Virginia," *Annals of Epidemiology*, vol. 59 (July 2021), pp. 44-49; and Aaloke Mody, Kristin Pfeifauf, Cory Bradley, et al., "Understanding Drivers of Coronavirus Disease 2019 (COVID-19) Racial Disparities: A Population-Level Analysis of COVID-19 Testing Among Black and White Populations," *Clinical Infectious Diseases*, December 14, 2020.

[171] Georges C. Benjamin, *Covid-19 Testing: Removing Barriers to Ensure Equitable Access*, American Public Health Association, April 22, 2020, https://www.covid19conversations.org/-/media/Files/PDF/COVID19/Georges_Benjamin_Equity.ashx.

[172] Michael Ollove, "U.S. COVID-19 Testing Has Dropped Dramatically," *PEW Charitable Trusts*, March 22, 2021, https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2021/03/22/us-covid-19-testing-has-dropped-dramatically.

[173] See example, Lauren Peace, "Research confirms major racial disparities in West Virginia COVID testing," *Mountain State Spotlight*, May 27, 2021, https://mountainstatespotlight.org/2021/05/27/racial-disparities-wv-covid-testing/.

[174] Johns Hopkins Coronavirus Resource Center, "Racial Data Transparency," https://coronavirus.jhu.edu/data/racial-data-transparency.

To facilitate equity in testing access, various federal programs and initiatives have sought to address disparities in testing access, alongside general efforts to boost testing capacity. HHS, under the Trump Administration, sought to boost access to testing as a part of its efforts to address the COVID-19 racial health disparities. Its primary strategies included (1) expanding testing at federally qualified health centers (see "Health Centers"), (2) supporting community-based retail testing in areas with high social vulnerability,[175] and (3) supporting state and local public health capacity for testing programs through funding (see "Public Health Department Testing Programs").[176] Several additional HHS programs have sought to address health disparities. For example, through its Rapid Acceleration of Diagnostics (RADx) program, NIH funded $500 million for a community-based research effort to develop and evaluate strategies for testing programs in underserved communities, including populations such as racial and ethnic minority populations or those living in nursing homes, jails, and rural areas.[177] In addition, in summer 2020, CDC released its *COVID-19 Response Heath Equity Strategy*,[178] which aimed to reduce COVID-19 health disparities and increase testing, contact tracing, and other public health measures for specific target populations, including racial and ethnic minorities, people with disabilities, those experiencing homelessness, people living in rural areas, and other vulnerable populations. The CDC provided action steps for local health jurisdictions and community partners to take to reduce inequities in access to testing and other public health prevention measures, including establishing partnerships with critical community partners and developing culturally and linguistically responsible communication materials to boost testing access and uptake.

Independent analyses have found ongoing challenges with federal and other efforts to expand testing access and address disparities during the Trump Administration. For example, the National Academy of Medicine noted, in an April 2021 impact assessment, that many of the federal retail testing sites were not located in communities of color, citing a Vox media report.[179] GAO also noted that CDC's health equity strategy lacked key elements of an effective national strategy. For example, its stated goal to increase access to testing for populations at increased risk for COVID-19 did not identify specific agency actions to achieve its stated goal.[180]

More recently, President Biden's National Strategy for the COVID-19 Response and Pandemic Preparedness calls for expanding testing for schools and congregate living centers, ramping up manufacturing of testing supplies and materials, and increasing genomic sequencing efforts.[181] In addition, his executive order to establish a Pandemic Testing Board highlights reducing disparities

[175] As defined using CDC's Social Vulnerability Index. See CDC/ATSDR, "CDC/ATSDR Social Vulnerability Index," April 28, 2021, https://www.atsdr.cdc.gov/placeandhealth/svi/index.html.

[176] HHS, "HHS Initiatives to Address the Disparate Impact of COVID-19 on African Americans and Other Racial and Ethnic Minorities," https://www.hhs.gov/sites/default/files/hhs-fact-sheet-addressing-disparities-in-covid-19-impact-on-minorities.pdf.

[177] NIH, "NIH to Assess and Expand COVID-19 Testing for Underserved Communities," September 30, 2020, https://www.nih.gov.

[178] CDC, "CDC COVID-19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID-19 Disparities and Achieving Health Equity," updated August 21, 2020, https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.

[179] Karen DeSalvo, Bob Hughes, and Mary Bassett, *Public Health COVID-19 Impact Assessment: Lessons Learned and Compelling Needs*, National Academy of Medicine, April 7, 2021, https://nam.edu/public-health-covid-19-impact-assessment-lessons-learned-and-compelling-needs/ and

[180] GAO, *COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters its Second Year*, March 31 2021, pp. 79-90, https://www.gao.gov/assets/gao-21-265.pdf.

[181] National Strategy for the COVID-19 Response and Pandemic Preparedness, January 2020, https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf.

in access to testing as a key goal.[182] The Biden Administration has also made several funding announcements aimed at expanding testing access. For example, of the $12 billion that President Biden had announced on March 17, 2021 for expansion of COVID-19 testing, $2.25 billion will be administered as CDC grants to SLTT public health departments to "improve testing and contact tracing capabilities; develop innovative mitigation and prevention resources and services; and, improve data collection and reporting to advance health equity and address social determinants of health as they relate to COVID-19."[183] In addition, HHS directed almost $1 billion from ARPA to be designated for strengthening the COVID-19 response in rural communities, including expansion of testing and other preventive services,[184] and more than $32 million to health centers that serve under-resourced communities for expanded COVID-19 testing, treatment, and vaccinations.[185]

There are currently limited evaluations of the Biden Administration's testing efforts. Some studies show that jurisdictions continue to note disparities among marginalized populations in regard to access to testing. Some analyses have continued to find that in certain locations, communities of color (including Hispanic and Black/African American populations) and rural populations have had more limited access to testing than White and urban populations.[186] Even with disparities in access to testing, certain racial and ethnic minority communities, including Black/African American and Hispanic groups, have experienced a disproportionate rate of positive COVID-19 cases.[187]

Private Health Insurance Coverage of Testing

Private health insurance is the predominant source of health insurance coverage in the United States. Private health insurance includes both the group market (largely made up of employer-sponsored insurance) and the nongroup market (commonly referred to as the individual market, which includes plans directly purchased from an insurer both on and off health insurance exchanges).[188] The federal government may regulate private health insurance plans, including by requiring plans to cover certain benefits. Federal requirements may vary by coverage type.

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[182] Executive Order 13996, "Establishing the COVID–19 Pandemic Testing Board and, establishment, and efforts to ensure sustainable public health workforce for COVID-19 and other biological threats," January 21, 2021.

[183] HHS, "Biden Administration to Invest More Than $112 Billion to Expand COVID-19 Testing," March 17, 2021, https://www.hhs.gov/about/news/2021/03/17/biden-administration-invest-more-than-12-billion-expand-covid-19-testing.html.

[184] HHS, "HHS Announces Nearly $1 billion from American Rescue Plan for Rural COVID-19 Response," May 4, 2021, https://www.hhs.gov/about/news/2021/05/04/hhs-announces-nearly-1-billion-from-american-rescue-plan-for-rural-covid-19-response.html.

[185] HHS, "HHS Awards Over $32 Million in American Rescue Plan Funding to Expand COVID-19 Training and Support for Health Centers," April 29, 2021, https://www.hhs.gov/about/news/2021/04/29/hhs-awards-over-32-million-american-rescue-plan-funding-expand-covid-19-training-support-health-centers.html.

[186] See example, Katerina Brandt et al., "SARS-CoV-2 testing in North Carolina: Racial, ethnic, and geographic disparities," *Health & Place*, vol. 69, May 2021, https://www.sciencedirect.com/science/article/pii/S1353829221000721?via%3Dihub; and Brian Hendricks et al., "Coronavirus Testing Disparities Associated with Community Level Deprivation, Racial Inequalities, and Food Insecurity in West Virginia," *Annals of Epidemiology*, vol. 59 (July 2021).

[187] Katherine Mackey et al., "Racial and Ethnic Disparities in COVID-19-Related Infections, Hospitalizations, and Deaths: A Systemic Review," *Annals of Internal Medicine*, December 1, 2020, https://www.ncbi.nlm.nih.gov/research/coronavirus/publication/33253040.

[188] The CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions* has additional background information on private health insurance and types of plans. Also see "What Types of Plans Are

The questions below address federal requirements related to private health insurance coverage of COVID-19 testing, including types of tests that must be covered, coverage of related items and services, coverage of testing for public health surveillance and employment purposes, and coverage of testing conducted by out-of-network providers. The questions address the types of plans subject to federal COVID-19 testing coverage requirements, and whether states may impose their own coverage requirements.

Are Private Health Insurance Plans Required to Cover Testing, and Does That Differ by Type of Test?

Prior to the enactment of the Families First Coronavirus Response Act (FFCRA, P.L. 116-127), no federal requirements specifically mandated private health insurance coverage of items or services related to COVID-19 testing.

Section 6001 of the FFCRA, as amended, requires most private health insurance plans to cover COVID-19 testing, including administration of the test, and related items and services, as defined in the act. The coverage must be provided without consumer cost-sharing, including deductibles, copayments, or coinsurance.[189] Prior authorization or other medical management requirements are prohibited. These coverage requirements are discussed in more detail below.

FFCRA Section 6001(a)(1), as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES, P.L. 116-136) Section 3201, describes the types of tests that must be covered, along with the administration of such tests. In addition, the Department of Labor (DOL), HHS, and the Treasury issued FAQ documents on April 11, 2020,[190] June 23, 2020,[191] and February 26, 2021[192] (hereinafter, "Tri-Agency FAQ 42," "Tri-Agency FAQ 43," and "Tri-Agency FAQ 44," respectively), on the private health insurance coverage requirements in FFCRA and the CARES Act.[193]

The acts together require coverage of in vitro diagnostics, as defined in FDA regulation,[194] that detect SARS-CoV-2 or diagnose the virus that causes COVID-19 and that are approved, cleared, or authorized for marketing by the agency or being marketed or clinically used pursuant to an allowed flexibility in FDA guidance. The acts didn't explicitly state whether this included

Subject to the FFCRA and CARES Act Requirements?" in this report.

[189] A *deductible* is the amount an insured consumer pays for covered health care services before coverage begins (with exceptions). *Coinsurance* is the share of costs, figured in percentage form, an insured consumer pays for a covered health service. A *copayment* is the fixed dollar amount an insured consumer pays for a covered health service.

[190] Department of Labor (DOL), HHS, and the Treasury, "FAQS ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 42," April 11, 2020, at https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf. Hereinafter referred to as "Tri-Agency FAQ 42."

[191] DOL, HHS, and the Treasury, "FAQS ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 43," June 23, 2020, at https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf. Hereinafter referred to as "Tri-Agency FAQ 43."

[192] DOL, HHS, and Treasury, "FAQS ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 44," February 26, 2021, at https://www.cms.gov/files/document/faqs-part-44.pdf. Hereinafter referred to as "Tri-Agency FAQ 44."

[193] For a discussion of the agencies' implementation authority and the force of law of these documents, see the "Are Plans Required to Cover Testing for Public Health Surveillance or Employment Purposes?" section of this report.

[194] 21 C.F.R. §809.3(a).

serology testing.[195] The Tri-Agency FAQ 42 interpreted the coverage requirement as applying to diagnostic (i.e., molecular and antigen) and serological (i.e., antibody) tests.

Together, the acts, as interpreted by the agencies through guidance, also require coverage without cost-sharing of

> items and services furnished to an individual during [specified types of visits; discussed below] that result in an order for or administration of [an applicable COVID-19 test; see above], but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product.[196]

Per an example provided in guidance,

> if the individual's attending provider determines that other tests (e.g., influenza tests, blood tests, etc.) should be performed during a visit ... to determine the need of such individual for COVID-19 diagnostic testing, and the visit results in an order for, or administration of, COVID-19 diagnostic testing, the plan or issuer must provide coverage for the related tests under section 6001(a) of the FFCRA.[197]

In addition, consumers must not face cost-sharing for "facility fees" or other fees, to the extent they are related to COVID-19 testing or related items and services that are required to be covered under FFCRA Section 6001.[198]

The coverage requirements do not apply to any services or items furnished at a testing visit that are not related to COVID-19 (e.g., if someone received testing or treatment for an unrelated condition at the same visit). In addition, the law and guidance do not explicitly address coverage and cost-sharing for the testing-"related" items and services discussed above, if the individual does not ultimately receive the test.[199] The coverage requirements also do not encompass treatment for illnesses associated with COVID-19.[200]

Per FFCRA Section 6001(a)(2), the coverage requirements apply to the specified items and services, discussed above, when furnished at visits including to health care provider offices (including in-person and telehealth visits), urgent care centers, and emergency rooms. Per the Tri-Agency FAQ 42, the requirements also apply at "nontraditional" settings, "including drive-through screening and testing sites where licensed healthcare providers are administering COVID-19 diagnostic testing."[201] Also see, in this section, "Are Plans Required to Cover Testing for Public Health Surveillance or Employment Purposes?"

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[195] Although both serology tests and molecular and antigen diagnostic tests meet the regulatory definition of "in vitro diagnostic," applicability to serology testing was not clear based only on the statutory language, as it refers to detection and identification of the virus. Serology testing does not detect or identify the virus; rather, it detects antibodies. (See the "What Are the Different Types of COVID-19 Tests?" section of this report for more information.)

[196] FFCRA §6001(a)(2). Also see the Tri-Agency FAQ 42, including questions five, six, and eight.

[197] Tri-Agency FAQ 42, question five. Also see Tri-Agency FAQ 44, question five.

[198] For more information, see the Tri-Agency FAQ 43, question seven, including its footnote 16.

[199] Per the Tri-Agency FAQ 42, question five, the coverage of related items and services is required when "the visit results in an order for, or administration of, COVID-19 diagnostic testing." This language also appears in FFCRA Section 6001(a)(2). The statute and guidance do not explicitly address whether the coverage requirements apply if an individual receives the related items and services, even for purposes of determining the need for COVID-19 testing, but does not actually receive a COVID-19 test. Other federal and/or state requirements could be applicable.

[200] For more information on private health insurance coverage of COVID-19 treatment, see CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions*.

[201] See Tri-Agency FAQ 42, question eight regarding "nontraditional" visits. Also see question 13 for more information

In addition, guidance indicates that the coverage requirements apply to at-home COVID-19 tests, including at-home swab kits that may be sent to a lab for processing, when such tests are "ordered by an attending health care provider who has determined that the test is medically appropriate for the individual," as specified in guidance.[202]

These coverage requirements apply only to the specified items and services furnished during the COVID-19 public health emergency period described in FFCRA, as of the date the FFCRA was enacted (March 18, 2020).[203]

What Types of Plans Are Subject to the FFCRA and CARES Act Requirements?

These requirements apply to individual health insurance coverage, fully insured small- and large-group coverage, and self-insured group plans.[204] The individual and small-group markets include plans sold on and off the individual and small-group health insurance exchanges, respectively.

This includes grandfathered individual or group plans, which are exempt from certain other federal private health insurance requirements. Per the definition of individual health insurance coverage cited in FFCRA, the coverage requirements do not apply to short-term, limited duration insurance (STLDI). The Tri-Agency FAQ 42 specifies other types of private health insurance coverage that are, or are not, subject to the COVID-19 testing coverage requirements.

This section of this report focuses mainly on coverage requirements for private sector plans stemming from Section 6001 of the FFCRA and other federal provisions. Section 6006 of the FFCRA separately addresses the Federal Employees Health Benefits Program (FEHB), which provides health insurance to federal employees, retirees, and their dependents. That section requires that no federal civil servants enrolled in a health benefits plan or FEHB enrollees may be required to pay a copayment or other cost-sharing related to COVID-19 testing, administration of the test, or related items and services for visits during the emergency period.[205]

about telehealth visits.

[202] Tri-Agency FAQ 43, question four. Also see question three regarding "attending providers."

[203] Some FFCRA and CARES Act coverage requirements are contingent upon the declaration of the COVID-19 public health emergency. This was declared by the HHS Secretary on January 31, 2020, effective as of January 27, pursuant to Section 319 of the Public Health Service Act (PHSA). Hence, the emergency period began on January 27, 2020, and remains in effect as long as the declaration, or any renewal of it, is in effect. See "Duration of Emergency Period" in CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*; and HHS, Assistant Secretary for Preparedness and Response, "Public Health Emergency Declarations," at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

[204] The requirements are technically applicable to group health plans and health insurers offering individual and group health insurance coverage. In this section, references to "plans" include applicable plans and insurers. More information on the types of plans discussed in this paragraph, and the applicability of FFCRA and CARES Act requirements to them, is available in CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions*.

[205] For more information, see CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

Are Plans Required to Cover Testing for Public Health Surveillance or Employment Purposes?

As discussed above, Section 6001 of the FFCRA, as amended by the CARES Act, generally requires plans to cover specified testing for the detection or diagnosis of COVID-19 and administration of such tests, without cost-sharing, during the COVID-19 emergency period.[206] Following enactment of this provision, questions arose about the range of covered testing, including whether plans must pay for testing that is not mainly intended for the clinical or treatment needs of individual patients.[207] These questions centered on whether Section 6001 compels plans to cover testing for other reasons, such as public health surveillance or workplace health purposes.[208]

Although the statutory language of Section 6001 does not articulate the precise circumstances under which testing must be covered, it generally restricts the ability of plans to limit coverage of COVID-19 testing. More specifically, this Section indicates that plans cannot "impose prior authorization or other medical management requirements" with respect to required COVID-19 testing coverage.[209] Although the term is not defined for purposes of Section 6001, medical management requirements commonly refer to standards or processes that plans follow to determine medically appropriate coverage parameters (e.g., limits on the frequency of covered treatments, or the health care setting for a specific item or service).[210] While this Section makes clear that plans cannot use such techniques to restrict coverage of COVID-19 testing, the scope of covered testing, and whether the provision compels plans to cover testing in all instances, have been the subject of debate.[211]

Section 6001 authorizes the Secretaries of HHS, Labor, and the Treasury to implement the provision "through sub-regulatory guidance, program instruction or otherwise" and the agencies have issued FAQ documents that address the provision's implementation.[212] As the agencies have

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[206] See Families First Coronavirus Response Act, P.L. 116-127, §6001, 134 Stat. 201 (2020); Coronavirus Aid, Relief, and Economic Security Act, P.L. 116-136, §3201, 134 Stat. 366 (2020) codified at 42 U.S.C. §1320b-5 note. For more information on the definition of "emergency period" see "Duration of Emergency Period" in CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

[207] See, for example, Letter from the National Association of Insurance Commissioners and the Center for Insurance Policy and Research, to Alex Azar, Secretary of Health and Human Services, and Seema Verma, Administrator, Centers for Medicare & Medicaid Services, at https://www.naic.org/documents/government_relations_letter_to_azar.pdf..

[208] See, for example, id.

[209] 42 U.S.C. §1320b-5 note.

[210] Although not expressly applicable to Section 6001, other federal statutes and regulations use the term "medical management." See, for example, Consolidated Appropriations Act, 2021 (P.L. 116-260), Section 111 of Division BB, adding Section 2799A-1(f)(1)(F) to the Public Health Service Act (in the context of surprise medical billing, "medical management techniques" include concurrent review and prior authorization); 45 C.F.R. §147.130(a)(4) (clarifying that with respect to coverage of certain preventive health services, nothing prohibits a health plan or insurer from "using reasonable medical management techniques to determine the frequency, method, treatment, or setting" for the required coverage). See also, Amy B. Monahan, *The Regulatory Failure to Define Essential Health Benefits*, 44 AM. J. L. & MED. 529, 544 (2018).

[211] See, for example, Katie Thomas, "Testing Nursing Home Workers Can Help Stop Coronavirus. But Who Should Pay?," *New York Times* (June 9, 2020), https://www.nytimes.com/2020/06/09/health/testing-coronavirus-nursing-homes-workers.html. Also see Blake Farmer, *Insurers May Only Pay For Coronavirus Tests When They're 'Medically Necessary,'* National Public Radio (June 19, 2020), https://www.npr.org/sections/health-shots/2020/06/19/880543755/insurers-may-only-pay-for-coronavirus-tests-when-theyre-medically-necessary.

[212] 42 U.S.C. §1320b-5 note; Tri-Agency FAQs 42, 43, and 44.

noted in these documents, the FAQs do not carry the force of law, but they may inform regulated parties about the agencies' enforcement priorities.[213] In June 2020, the agencies issued their FAQ 43 guidance document that addresses coverage of COVID-19 testing for surveillance or employment purposes.[214] In this guidance, the agencies specified that testing "conducted to screen for general workplace health and safety (such as employee 'return-to-work' programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section 6001 of the FFCRA."[215]

The most recent Tri-Agency FAQ 44 (issued in February 2021) reiterates that plans are not required to provide coverage of COVID-19 testing for public health surveillance or employment purposes, but that plans could offer such coverage voluntarily.[216] Some Members of Congress have expressed a different view regarding Section 6001, indicating that FFCRA "makes clear that health plans are required to cover, without any conditions or limitations, the specified items and services related to diagnostic tests for the detection of COVID-19."[217] As of the date of this report, it appears that the statutory text of Section 6001 has not been examined by a court.

Are Plans Required to Cover Multiple Tests and/or Tests for Asymptomatic Individuals?

In addition to the debate described above, there have been other questions about coverage for testing, including for asymptomatic individuals.

Per the Tri-Agency FAQs 43 and 44, coverage of testing is required for asymptomatic individuals, whether or not they have had known or suspected recent exposure to SARS-CoV-2.[218] The coverage requirements also apply each time an individual receives a diagnostic test for COVID-19, "provided that the tests are diagnostic and medically appropriate for the individual, as determined by an attending health care provider in accordance with current accepted standards of medical practice."[219] FAQ 43 suggests that providers "consult guidance issued by the CDC, as well as state, tribal, territorial, and local health departments or professional societies, when

[213] See, for example, Tri-Agency FAQ 44, at 1. For information on agency use and judicial review of general statements of policy, see CRS Report R44468, *General Policy Statements: Legal Overview*.

[214] See Tri-Agency FAQ 42.

[215] Ibid., question five.

[216] See Tri-Agency FAQ 44.

[217] Letter from Frank Pallone, Jr., Chairman, Committee on Energy and Commerce, Robert C. "Bobby" Scott, Chairman, Committee on Education and Labor, Richard Neal, Chairman, Committee on Ways and Means, Patty Murray, Ranking Member, Committee on Health, Education, Labor, and Pensions, Ron Wyden, Ranking Member, Committee on Finance, to Alex Azar, Secretary of Health and Human Services, Eugene Scalia, Secretary of Labor, and Steven T. Mnuchin, Secretary of Treasury (July 7, 2020), https://edlabor.house.gov/imo/media/doc/Democratic%20Health%20Leaders%20Demand%20Trump%20Administration%20Immediately%20Revisit%20Guidance%20Limiting%20COVID-19%20Testing%20Coverage.pdf.

[218] Per Tri-Agency FAQ 43, question five, coverage of testing for asymptomatic individuals was only required if the individuals had known or suspected exposure. This was revised by Tri-Agency FAQ 44, question one, which states that the known or suspected exposure is not required for coverage of individuals' testing.

[219] Tri-Agency FAQ 43, question six. This question addresses coverage of multiple tests in general, not just for asymptomatic individuals. Also see question three regarding "attending providers."

determining whether diagnostic testing is appropriate for a particular individual.[220] FAQ 44 further states,

> State and local public health authorities retain the authority to direct providers to limit eligibility for testing based on clinical risk or other criteria to manage testing supplies and access to testing. Responsibility for implementing such state or local limits on testing falls on attending health care providers, not on plans and issuers. Plans and issuers may not use such criteria to deny (or impose cost sharing on) a claim for COVID-19 diagnostic testing.[221]

As discussed in the prior section, FAQ 43 indicates that plans are not required to cover COVID-19 testing for public health surveillance or employment purposes. This guidance was maintained in FAQ 44, where questions one and two explain that although plans are required to cover testing for *individuals* (including for asymptomatic individuals), plans are not similarly required to cover testing for "*groups* of asymptomatic employees or individuals with no known or suspected recent exposure to COVID-19" (emphasis added).

What Coverage and Provider Reimbursement Requirements Apply to Out-of-Network Testing?

While Section 6001 of FFCRA establishes requirements for private health insurance plans to cover COVID-19 testing, administration of the test, and related items and services, it does so without regard to whether a provider is in a health plan's network. See the text box below for background on provider networks and private health insurance coverage.

Section 3202 of the CARES Act establishes a methodology for determining insurer payments to in-network and out-of-network providers for COVID-19 testing, and the Tri-Agency FAQ 42 clarifies that the FFCRA coverage requirements apply both in-network and out-of-network.[222] Per guidance, Section 3202 of the CARES Act does not address the amount that a health plan must reimburse a provider for any other item or service beyond COVID-19 testing.[223]

[220] Ibid.

[221] Tri-Agency FAQ 44, question one.

[222] Tri-Agency FAQ 42, question seven.

[223] Tri-Agency FAQ 43, question eight.

In-Network and Out-of-Network Coverage in Private Health Insurance

In private health insurance, the amount paid for covered items and services is generally contingent upon whether a consumer's health plan has negotiated with a provider to enter into a contract. The contract between the health plan and the provider generally specifies the total amount that a provider may receive for furnishing particular items or services to that health plan's enrollees. A provider that enters into a contract with a health plan is considered to be part of the health plan's network, otherwise referred to as being *in-network*.

A provider that does not enter into a contract with a health plan is considered *out-of-network*, and as such there is no negotiated rate between the provider and the health plan. In situations involving services provided by an out-of-network provider, the amount that a provider will receive from a health plan depends on whether the health plan covers out-of-network services. In situations where health plans *do not cover* out-of-network services, the health plan will not pay any amount to a provider for services provided to an enrollee of the health plan. In situations where plans *do cover* out-of-network services, as there is no negotiated rate between health plans and out-of-network providers, health plans will use their own methodologies for calculating how much they will pay out-of-network providers for services. If an out-of-network provider's total charge for a service exceeds the amount reimbursed by the health plan, the provider may directly bill (i.e., balance bill) a consumer for the amount of the difference, except when prohibited by applicable state law or other contractual agreements.

For more information, see CRS Report R46856, *Surprise Billing in Private Health Insurance: Overview of Federal Consumer Protections and Payment for Out-of-Network Services*.

Under the CARES Act, if a health plan had a negotiated rate with a provider of diagnostic testing prior to the declaration of the COVID-19 public health emergency declared under PHSA Section 319, then the health plan must apply that negotiated rate throughout the period of the COVID-19 public health emergency. If a health plan did not have a negotiated rate with a provider of diagnostic testing prior to the emergency declaration, then the health plan must either reimburse the provider an amount that equals the cash price for the COVID-19 testing, as listed on the provider's public website, or the health plan and provider may negotiate a rate that is less than the cash price. If there is no cash price listed on the provider's website and the two parties cannot negotiate a rate, then the methodology for determining reimbursement depends on whether there is an applicable state law.[224]

During the period of the COVID-19 public health emergency, providers of COVID-19 diagnostic testing must make public the cash price for the COVID-19 test on the provider's public website. Section 3202 of the CARES Act does not include any further requirements for providers regarding the cash price, including any limitation on the amount that a provider may post as the cash price.

DOL, HHS, and the Treasury published an interim final rule (IFR) in the *Federal Register* on November 6, 2020, to implement and clarify the FFCRA and CARES Act requirements related to the coverage of COVID-19 diagnostic testing furnished by out-of-network providers.[225] The IFR clarified that a provider of a COVID-19 diagnostic test is required to post "a plain-language description of each COVID-19 diagnostic test, the corresponding cash price, the billing code(s) for each such test(s), and any additional information as may be necessary for the public to be certain of the cash price for a particular COVID-19 diagnostic test."[226] If a provider of a COVID-19 diagnostic test does not have its own website, then the provider must make public the

[224] Tri-Agency FAQ 43, question 11.

[225] Department of Health and Human Services, Department of Labor, and the Department of the Treasury, "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," 85 *Federal Register* 71142, November 6, 2020.

[226] Ibid., 71153.

information in writing within two business days upon request and on a sign prominently posted at the location where the provider offers a COVID-19 diagnostic test.[227]

The HHS Secretary may impose a civil monetary penalty on a provider of COVID-19 diagnostic testing that is not in compliance with the above requirement to post the cash price and has not completed a corrective action plan to comply with the requirement. The amount of the civil monetary penalty may not exceed $300 per day that the violation is ongoing.

Are Out-of-Network Providers Allowed to Balance Bill Patients for COVID-19 Testing and Other Related Items and Services?

The Tri-Agency FAQ 43 clarifies that the combination of FFRCA requirement to provide coverage for COVID-19 testing without cost-sharing, and the CARES Act methodology for determining reimbursement for COVID-19 testing, means that an out-of-network provider is generally precluded from directly billing a patient for the difference between provider's charge for COVID-19 testing and the amount reimbursed by the health plan (i.e., balance bill).[228] However, a provider is not prevented from balance billing for other items and services unless there is an applicable state law or other prohibition (e.g., pursuant to the terms of the Provider Relief Fund).[229]

May States Require Plans to Cover Additional Types or Purposes of Testing?

States are the primary regulators of private health insurance, and each state may impose coverage requirements on insurers and the plans they sell in that state.

With regard to COVID-19 testing, states may require coverage that exceeds applicable federal requirements, as long as states do not prevent the implementation of any federal requirements.[230] Some states have implemented expanded requirements, although some such state requirements have been time-limited and may no longer be in effect.[231]

State requirements may apply to individual health insurance coverage, fully insured group coverage, or both, but states cannot regulate self-insured group plans. States may impose requirements on STLDI. (See "What Types of Plans Are Subject to the FFCRA and CARES Act Requirements?" for information on plan types.)

A state or local department of health or other administrative agency may announce requirements or guidelines regarding testing certain populations or testing for certain public health purposes.

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[227] Ibid., 71152.

[228] Question nine in the Tri-Agency FAQ 43 points out that out-of-network providers who accept funds from the Provider Relief Fund may not seek to collect from patients out-of-pocket expenses that would be "greater than what the patient would have otherwise been required to pay if the care had been provided by an in network provider." For background on this funding, see CRS Insight IN11438, *The COVID-19 Health Care Provider Relief Fund*.

[229] Ibid.

[230] See, for example, the introduction of the Tri-Agency FAQ 42.

[231] Several organizations have been tracking these announcements by states. See, for example, the National Association of Insurance Commissioners (NAIC), "Life and Health" resource, updated December 10, 2020, at https://content.naic.org/naic_coronavirus_info.htm. To confirm whether a given state has enacted any requirements related to coverage of COVID-19 testing (or related to other topics) that may not be reflected in that tracking document, check with that state's department of insurance: https://content.naic.org/state_web_map.htm.

This does not necessarily mean that insurers in that state are required to cover such testing, although that would be the case if the state department of insurance or other relevant agency also requires such coverage, or if federal requirements are applicable.

Payment for Testing by Federal Programs: Medicare, Medicaid, and CHIP

The Social Security Act (SSA) defines a federal health care program as any plan or program that provides health benefits—whether directly, through insurance, or otherwise—and that is funded directly, in whole, or in part by the U.S. government (with the exception of the Federal Employees Health Benefits Program) or one of four specified state health care programs.[232] Key federal health programs include (1) Medicare, the national health insurance program that pays for covered services furnished to beneficiaries (generally the elderly and disabled); (2) Medicaid, the federal-state program for certain low-income individuals; and (3) the State Children's Health Insurance program (CHIP), which provides coverage for low-income, uninsured children. The questions below discuss how these federal health care programs provide, establish coverage, or pay for testing for their beneficiaries. FFCRA, as amended by the CARES Act, required each of these programs to cover COVID-19 testing for their enrollees without beneficiary cost-sharing, under certain circumstances. For Medicaid, COVID-19 testing is expanded and extended under the ARPA. The specific testing-related requirements associated with each program are discussed below. In general, these federal health care programs provide coverage for testing of beneficiaries when ordered by an enrollee's physician or practitioner.[233]

How Does Medicare Pay for Testing, and Does That Differ by Type or Use of Test?

In general, Medicare covers health care services furnished to diagnose or rule out a possible illness or condition.[234] Medicare pays for clinical laboratory tests that are medically necessary and ordered by a beneficiary's physician or practitioner for such purposes.[235] There is no cost-sharing required under Part B, or for beneficiaries enrolled in Medicare Advantage (MA) plans, as MA plans must cover all benefits under Medicare Parts A and B.[236]

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[232] Social Security Act (SSA) §1128B(f) [42 U.S.C. §1320a–7b]. The four state health care programs are Medicaid (SSA title XIX), Maternal and Child Health Services Block Grant (SSA title V), Block Grants and Programs for Social Services (SSA title XX). The State Children's Health Insurance Program (CHIP) is included among the list of four programs that are considered to be a state health care program. CHIP is added as a state health care program by reference at SSA Section 2107(e)(2) [42 U.S.C. 1397gg].

[233] For adults under the Medicaid program, states are permitted to limit the extent to which a covered benefit is available under the state plan by defining medical necessity criteria, and the amount, duration, and scope of covered services (see SSA Section(s) 1901; 1902(a)(30)(A); and 1903(m)(2)(A)(vii)). For children under Medicaid and CHIP Medicaid expansion programs, medical necessity requirements are established under Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) (see SSA Section 1905(r)(5)). For separate CHIP programs, medical necessity requirements are established under SSA Section 2110(a)(24).

[234] SSA Section 1862(a)(1)(A) specifies that Medicare covered health care services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

[235] Some preventive or screening tests may also be covered, but these are explicitly addressed in SSA Section 1862(a)(1)(B)-(P) (e.g., screening tests for mammography, prostate cancer, and colorectal cancer).

[236] See CRS Report R40425, *Medicare Primer* for information about Medicare.

HHS has assigned testing for coronavirus as an essential health benefit so the test must be covered under Medicare Part B. However, the coronavirus test must be ordered by a doctor or health care provider. Clinical tests to diagnose or aid in the diagnosis of the coronavirus disease, as well as some tests for related respiratory conditions given with the COVID-19 test, are covered.[237] FDA-authorized antibody (serology) tests for those beneficiaries diagnosed with a known current or prior COVID-19 infection or suspected current or past COVID-19 infection are also covered with no cost-sharing.[238] There is no limit on the number of tests, so long as each test satisfies the coverage requirement.

The FFCRA eliminated the Medicare Part B beneficiary cost-sharing for provider visits during which a coronavirus diagnostic test is administered or ordered during the emergency period. Beneficiaries are not responsible for any coinsurance payments or deductibles for any specified COVID-19 testing-related service, defined as a medical visit that falls within the evaluation and management service codes for the following categories: office and other outpatient services; hospital observation services; emergency department services; nursing facility services; domiciliary, rest home, or custodial care services; home services; or online digital evaluation and management services.

Surveillance testing, whether it be for the novel coronavirus or other purposes, does not meet the Medicare coverage criteria that the care be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Similarly, COVID-19 testing for "return-to-work" would not be covered under Medicare.

How Does Medicaid Pay for Testing, and Does That Differ by Type or Use of Test?

Medicaid is a joint federal-state program that finances the delivery of primary and acute medical services, as well as long-term services and supports (LTSS), to a diverse low-income population, including eligible children, pregnant women, adults, individuals with disabilities, and people aged 65 and older. States have flexibility to design their own versions of Medicaid within the federal statute's basic framework. This flexibility results in variability across state Medicaid programs regarding factors such as eligibility and covered benefits.

Section 6004 of the FFCRA, as amended by Section 3717 of the CARES Act, requires state Medicaid programs to cover testing and testing-related services[239] without beneficiary cost-sharing under traditional Medicaid[240] beginning on or after March 18, 2020, through the public

[237] CMS, "Coronavirus disease 2019 (COVID-19) tests" at https://www.medicare.gov/coverage/coronavirus-disease-2019-covid-19-tests.

[238] CMS "Coronavirus disease 2019 (COVID-19) antibody test" at https://www.medicare.gov/coverage/coronavirus-disease-2019-covid-19-antibody-test. For information about molecular pathogen tests versus screening antibody serology tests, see CRS In Focus IF11516, *COVID-19 Testing: Key Issues*.

[239] CMS interpreted COVID-19 testing-related services to include items and services for which payment is available under the Medicaid state plan that are directly related to the administration of COVID-19 testing, or for the evaluation of an individual to determine the need for COVID-19 testing (e.g., an X-ray). For more information, see Centers for Medicare and Medicaid Services (CMS), *Families First Coronavirus Response Act (FFCRA)*, P.L. 116-127; *Coronavirus Aid, Relief, and Economic Security (CARES) Act*, P.L. 116-136; *Frequently Asked Questions (FAQ)*, April 13, 2020.

[240] The FFCRA provision is silent about the addition of this benefit under Medicaid alternative benefit plans (ABPs). Most Medicaid beneficiaries receive services via traditional Medicaid. However, states also may furnish Medicaid in the form of ABPs. States that choose to implement the ACA Medicaid expansion are required to provide ABP coverage to the individuals eligible for Medicaid through the expansion (with exceptions for selected special-needs subgroups).

health emergency period, as defined.[241] Section 9811 of the ARPA expands and extends this benefit by adding testing for COVID-19 without beneficiary cost-sharing to the list of Medicaid mandatory services under traditional Medicaid and alternative benefit plan coverage for the period that begins on the date of enactment of ARPA (i.e., March 11, 2021) and ends the last day of the first calendar quarter that begins one year after the last day of the public health emergency period, as defined.

Testing services are defined as in vitro diagnostic products as defined in FDA regulation[242] including the administration of such products, for the detection of SARS-CoV-2 or the diagnosis of COVID-19. According to guidance from the Centers for Medicare & Medicaid Services (CMS), the FDA has advised that serological tests for COVID-19 meet the FDA definition of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19, and thus must be covered under Medicaid for symptomatic and asymptomatic Medicaid enrollees, as long as such tests are driven by medical necessity.[243] To date, the Medicaid specific CMS guidance has not explicitly addressed the question of whether states can use Medicaid as a payer of public health surveillance testing for SARS-CoV-2 (to screen for general workplace health and safety, as in the case of employee "return to work" programs).

How Does CHIP Pay for Testing, and Does That Differ by Type or Use of Test?

CHIP provides health insurance coverage to low-income, uninsured children in families with incomes above applicable Medicaid income standards, and to certain pregnant women. States have the flexibility to design their own versions of CHIP within the federal statute's basic framework. This flexibility results in variability across state CHIP programs regarding factors such as eligibility and covered benefits.

FFCRA, as amended by the CARES Act, also requires CHIP programs to cover COVID-19 testing and testing-related services[244] without beneficiary cost-sharing for CHIP enrollees for the

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Under ABPs, states may furnish a benefit that is defined by reference to an overall coverage benchmark that is based on one of three commercial insurance products (e.g., the commercial health maintenance organization (HMO) with the largest insured commercial, non-Medicaid enrollment in the state) or a fourth, "Secretary-approved" coverage. For more information on Medicaid ABP coverage, see CRS Report R45412, *Medicaid Alternative Benefit Plan Coverage: Frequently Asked Questions*.

[241] FFCRA, as amended by the CARES Act, also added a new optional Medicaid "COVID-19 testing" eligibility group to provide testing and diagnosis of COVID-19 for certain specified uninsured individuals during the COVID-19 public health emergency. For more information on this optional eligibility group and the limited benefit coverage enrollees in this group are entitled to, see the "Under What Circumstances Will Medicaid Pay for Uninsured Testing?" section of this report.

[242] 21 C.F.R. 809.3(a) defines in vitro diagnostic products as "reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." To date, FDA has authorized one emergency use authorization for a serological test that is intended for use by clinical laboratories. See U.S. Food and Drug Administration, Letter to Cellex Inc. Regarding qSARS-CoV-2 IgG/IgM Rapid Test (April 1, 2020), available at https://www.fda.gov/media/136622/download.

[243] CMS, "Families First Coronavirus Response Act (FFCRA), P.L. 116-127; Coronavirus Aid, Relief, and Economic Security (CARES) Act, P.L. 116-136; Frequently Asked Questions (FAQs)," April 13, 2020, https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-faqs.pdf (hereinafter, *CMS Medicaid FAQs*).

[244] CMS interpreted COVID-19 testing-related services for Medicaid to include items and services for which payment is available under the Medicaid state plan that are directly related to the administration of COVID-19 testing, or for the

period beginning March 18, 2020, through the duration of the public health emergency period, as specified. Section 9821 of the ARPA extends this requirement for the period that begins on the date of enactment of ARPA (i.e., March 11, 2021) and ends the last day of the first calendar quarter that begins one year after the last day of the public health emergency period, as defined. CMS guidance clarifies that, as under Medicaid, such testing must include diagnostic and serological tests for symptomatic and asymptomatic CHIP program enrollees when testing is driven by medical necessity.[245] To date, the CHIP specific CMS guidance has not explicitly addressed the question of whether states can use CHIP as a payer of public health surveillance testing for SARS-CoV-2 (to screen for general workplace health and safety, as in the case of "return to school" programs).

Provision of and Payment for COVID-19 Testing by Federal Systems: BOP, IHS, VA, DOD, and FEMA

In general, the federal government pays for care provided by nonfederal providers. In the cases of the Indian Health Service (IHS), the Veterans Health Administration (VHA), and the DOD through the Defense Health System, the federal government may provide care directly to a limited set of beneficiaries enrolled in these programs. Other federal programs, that that do not have as their primary purpose the delivery of health care, may also, in some cases, directly provide services to individuals who reside in their facilities (for example, the Bureau of Prisons (BOP) may provide care to federal inmates). The questions below focus on federal agencies that directly provide health services to a set of individuals and how these systems provide and pay for testing for their service populations. FFCRA included requirements for federal health systems to provide or pay for testing for IHS, the VHA and DOD. The specific requirements for each agency are discussed in the questions below. In addition, federally operated health systems generally do not provide care to non-beneficiaries except under limited circumstances, some of which have arisen as part of the COVID-19 pandemic. The provision of testing services to non-beneficiaries is also discussed in the questions below.

How Does the Bureau of Prisons Provide or Pay for Testing?

The Bureau of Prisons within Department of Justice (DOJ) operates the federal prison system, which includes 122 BOP-operated prisons in 35 states.[246] BOP was established in 1930 to house federal prisoners, professionalize the prison service, and ensure consistent and centralized administration of the federal prison system.[247] BOP must confine any offender convicted and sentenced to a term of imprisonment in a federal court. BOP provides medically necessary treatment to all federal prisoners in a manner consistent with the standards of care for nonprisoners.[248] Most of this treatment is provided through health care clinics that are operated in

evaluation of an individual to determine the need for COVID-19 testing (e.g., an X-ray). When defining testing-related services available under CHIP, the CMS guidance points to Medicaid specific responses in the Q&A. For more information, see CMS Medicaid FAQs.

[245] CMS Medicaid FAQs.

[246] U.S. Department of Justice, Bureau of Prisons, *Our Locations*, https://www.bop.gov/locations/.

[247] U.S. Department of Justice, Bureau of Prisons, *About the Bureau of Prisons*, June 2015, p. 1.

[248] GAO notes, "Multiple U.S. courts over the years have determined that inmates have a constitutional right to adequate medical and mental health care." U.S. Government Accountability Office, *Bureau of Prisons: Better Planning and Evaluation Needed to Understand and Control Rising Inmate Health Care Costs*, GAO-17-379, June 2017, pp. 2,

each BOP facility.[249] When services cannot be provided at a BOP facility, BOP will transport prisoners to a community health care facility or provider (e.g., a hospital).

According to DOJ's Office of the Inspector General (OIG), testing of federal prisoners "evolved between February and August 2020, in response to [Centers for Disease Control and Prevention] recommendations, the availability of tests, and the evolution of outbreaks in BOP facilities."[250] According to OIG, since March 2020, BOP's guidance has expanded to include testing both symptomatic and asymptomatic prisoners.[251] Prison administrators consult with BOP medical officials to prioritize testing if there are limits on the number of tests that can be performed at a specific facility.[252] Most of the COVID-19 tests administered by BOP from February 2020 to August 2020 were viral tests, and BOP used both commercial molecular tests and rapid molecular RNA tests.[253] BOP sent some test samples to commercial laboratories for processing, but BOP also tested some samples onsite at prison facilities by using rapid molecular RNA testing machines BOP received from the Strategic National Stockpile.[254] Because of their sensitivity and specificity, commercial molecular tests were used by BOP in some specific situations, such as when a prisoner was set to be released from quarantine, and rapid molecular tests in others, such as when prisoners appeared to be symptomatic and rapid results were beneficial.[255] BOP tested approximately 150,000 of the nearly 218,500 prisoners in its custody from February 2020 to August 2020.[256]

The cost of providing health care to federal prisoners is covered by appropriations from BOP's Salaries and Expenses account in the annual Commerce, Justice, Science, and Related Agencies (CJS) Appropriations Act. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) also included $100 million for BOP to "prevent, prepare for, and respond to coronavirus, domestically or internationally, including the impact of coronavirus on the work of [DOJ]." The FY2021 CJS Appropriations Act (P.L. 116-260) included a general provision that provided an additional $300 million for BOP to respond to the COVID-19 pandemic that was in addition to the amount provided for BOP's S&E account.

How Does the Indian Health Service Provide or Pay for Testing?

IHS within HHS is the lead federal agency charged with improving the health of American Indians and Alaska Natives. In FY2019, IHS provided health care to approximately 2.6 million eligible American Indians/Alaska Natives.[257] IHS has 12 areas, and the Navajo area represents

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[249] For more information on how health care is provided to federal prisoners, see CRS In Focus IF11629, *Health Care for Federal Prisoners*.

[250] Pandemic Response Accountability Committee, Federal COVID-19 Testing Report: Data Insights from Six Federal Health Care Programs, p. 48 (hereinafter "Federal COVID-19 Testing Report").

[251] Federal COVID-19 Testing Report, p. 48.

[252] Ibid.

[253] Ibid., p. 51.

[254] Ibid., p. 11.

[255] BOP reported that onsite rapid test results were typically available in 15 minutes, but commercial vendor test results were usually returned within two to four days. However, some facilities experienced wait times of 10 to 14 days for results in late July and early August because of a nationwide spike in cases and corresponding increased demand for testing. Federal COVID-19 Testing Report, pp. 51, 53.

[256] BOP acknowledges that the data it submitted for OIG's review of COVID-19 testing in federal prison is not complete and probably underestimates the amount of testing conducted. Federal COVID-19 Testing Report, p. 48.

[257] HHS, Indian Health Service (IHS), FY2021, "Justification of Estimates for Appropriations Committees,"

one of the highest COVID-19 death rates nationally.[258] IHS provides care free of charge to its beneficiaries, who are generally members of federally recognized tribes.[259] These services include COVID-19 testing. IHS reports that most of its facilities have testing capacity, and it has been making data on testing at the area level available on its website.[260] To expand testing, IHS received and provided 470 rapid test analyzers to facilities in its system, prioritizing sites near hot spots and those that were not near centralized lab capacity. IHS also received 300,000 rapid Abbott BinaxNOW Ag CARD point-of-care tests, which the agency prioritized for use by IHS/Indian Tribes/Tribal Organizations/Urban Indian Organizations that operate health programs that serve students enrolled in Bureau of Indian Education schools, students at tribal colleges and universities, or residents of elder care facilities.[261]

IHS has received nearly $8 billion in supplemental funding for COVID-19-related testing and care.[262] FFCRA provided an additional $64 million, to remain available until September 30, 2022 (i.e., through FY2021), for specified COVID-19 testing and related health services and administration.[263] The act also requires IHS to pay the cost of providing any COVID-19-related items and services without imposing any cost-sharing requirements for the period of the COVID-19 emergency. This requirement applies to any American Indian[264] receiving services through the IHS,[265] including through Urban Indian Organizations. Generally, IHS facilities operated by the Indian Health Service do not charge cost-sharing; however, facilities that are operated by Indian tribes or by Urban Indian Organizations may do so. The CARES Act provided an additional $1.032 billion to IHS to prevent, prepare for, and respond to the coronavirus. This funding was not explicitly for testing, but it may be used for testing. PPPHCEA also appropriated $750 million the Public Health and Social Services Emergency Fund (PHSSEF) to be allocated by IHS for testing capacity. APRA provided $6.09 billion to IHS for a variety of specified purposes related to COVID-19 testing, treatment, vaccination and other coronavirus-related preparedness and response activities.[266] The Biden Administration announced that $1 billion would be allocated to testing, contact tracing, and other strategies to mitigate the spread of the coronavirus.[267]

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https://www.ihs.gov/sites/budgetformulation/themes/responsive2017/display_objects/documents/FY_2021_Final_CJ-IHS.pdf. IHS provides health care directly through facilities it operates, or through facilities that are operated by Indian Tribes/Tribal Organizations or Urban Indian organizations.

[258] Kenzi Abou-Sabe, Cynthia McFadden and Didi Martinez, "'Hit us at our core': Vulnerable Navajo Nation fears a second COVID-19 wave," August 3, 2020, https://www.nbcnews.com/specials/navajo-nation-fears-second-covid-19-wave/index.html.

[259] For definition of Indian Tribe see Section 4 of the Indian Health Care Improvement Act (25 U.S.C. §1603(14)).

[260] See HHS, IHS, "Coronavirus (COVID-19)," https://www.ihs.gov/coronavirus/.

[261] HHS, IHS "Coronavirus (COVID-19), FAQs—Federal Response in Indian Country," https://www.ihs.gov/coronavirus/faqs-federal-response-in-indian-country/.

[262] For a discussion of funding provided to the Indian Health Service and Indian Tribes to prepare for and respond to the coronavirus, see CRS Insight IN11333, *COVID-19 and the Indian Health Service*.

[263] CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

[264] FFCRA defines *Indian* with a reference to Section 4 of the Indian Health Care Improvement Act (25 U.S.C. §1603(13)).

[265] The phrase "receiving services through the IHS" is not defined, but it has been used in prior federal guidance to refer to non-IHS facilities that have care coordination agreements with IHS facilities to treat American Indians and Alaska Natives. See Letter to State Health Official: Re: Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives (SHO #16-002), February 26, 2016, https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/sho022616.pdf.

[266] See Sec. 11001 of P.L. 117-2.

[267] "Biden Administration Funds $1B for COVID-19 Testing in Indian Country," 360DX, April 16, 2021, ttps://www.360dx.com/research-funding/biden-administration-funds-1b-covid-19-testing-indian-

Does the Department of Veteran Affairs Offer or Pay for Testing?

The Veterans Health Administration (VHA) of the Department of Veterans Affairs (VA) operates one of the nation's largest integrated direct health care delivery systems.[268] The VHA estimated that in FY2020 it would provide care to about 6.33 million unique veteran patients.[269] In the same year, the VHA estimated that it will employ a staff of about 347,000 full-time equivalent employees[270] at approximately 1,456 VA sites of care,[271] with an appropriation of approximately $80.6 billion.[272] The VHA provides a standard medical benefits package to enrolled veterans for services both related to and unrelated to their military service.[273] These services include COVID-19 testing. The VHA has completed more than 3.3 million diagnostic tests for COVID-19.[274] The VA has been making some data regarding testing publicly available on its website.[275]

Diagnostic testing is generally a covered service under the standard medical benefits package.[276] Some veterans are required to pay copayments for care that is not related to a service-connected disability. However, routine lab tests are exempt from copayment requirements.[277] Furthermore, the FFCRA prohibited the VA from charging any copayment or other cost-sharing payments for COVID-19 testing or medical visits during any period of this public health emergency.[278]

The VA has received supplemental funding for COVID-19-related testing and care.[279] The FFCRA provided an additional $30 million to the VHA medical services account, to remain available until September 30, 2022 (i.e., through FY2021) to fund health services and related items pertaining to COVID-19.[280] The CARES Act provides supplemental appropriations for

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country?adobe_mc=MCMID%3D92168907610703755799155602916300127059%7CMCORGID%3D138FFF2554E6E7220A4C98C6%2540AdobeOrg%7CTS%3D1619469140&CSAuthResp=1%3A%3A2425805%3A1911%3A24%3Asuccess%3A217E8B49928F9ABAF593DDCAE9164D34#.YIcjYpBKhME.

[268] The Veterans Health Administration (VHA) operates under a different model from the predominant health care financing and delivery model in the United States, in which there is a payer for health care services (e.g., Medicare or private health insurance plan), a provider (e.g., hospital, physician), and a recipient of care (the patient). The VHA is not a health insurance financing program that provides reimbursement to providers for all or a portion of a patient's health care costs. The VHA is primarily a direct provider of care; it owns the hospitals and employs the clinicians.

[269] Department of Veterans Affairs (VA), *FY2021 Congressional Submission, Medical Programs and Information Technology Programs*, vol. 2 of 4, February 2020, p. VHA-19.

[270] VA, *FY2021 Congressional Submission, Budget in Brief*, February 2020, p. BiB-4.

[271] Ibid., p. BiB-11. (Sites of care used in this calculation are VA hospitals, community living centers, health care centers, community-based outpatient clinics [CBOCs], other outpatient service sites, and dialysis centers.)

[272] VA, *FY2021 Congressional Submission, Supplemental Information & Appendices*, vol. 1 of 4, February 2020, p. Supplemental Information-1.

[273] For more information on the VHA health system in general, including who can enroll and the services that provided, see CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*.

[274] VHA Daily COVID-19 Update, April 21, 2021.

[275] See VHA, VA, "Novel Coronavirus Disease (COVID-19)," https://www.publichealth.va.gov/n-coronavirus/.

[276] 38 C.F.R. §17.38.

[277] 38 C.F.R. §17.108(e)(14).

[278] Generally, diagnostic testing is a covered service under VA's standard medical benefits package, which is available to all veterans enrolled in the VA health care system (38 C.F.R. §17.38). Some veterans are required to pay copayments for care that is not related to a service-connected disability. However, routine lab tests are exempt from copayments. (38 C.F.R. §17.108(e)(14)). Prior to enactment of FFCRA, it was unclear whether VA was including COVID-19 testing under this exemption.

[279] For a discussion of funding provided to VA to prepare for and respond to the public health emergency, see CRS Report R46340, *Federal Response to COVID-19: Department of Veterans Affairs*.

[280] VHA's annual appropriations consist of five accounts: medical services, medical community care, medical support

FY2020 for certain VA accounts totaling $19.6 billion, designated as emergency spending. The VHA medical services account received $14.4 billion of that total, which is partially intended for testing.[281] Furthermore, ARPA Section 8002 added a supplemental appropriation for FY2021 to remain available until September 30, 2023 (i.e., through FY2022) of $14.5 billion to be used for medical care and health needs, which can include testing.

Can the IHS and the VA Provide Testing for Individuals Who Are Not Otherwise Eligible for Services?

Generally, health services at facilities operated by the IHS are limited to IHS beneficiaries who are generally members of Indian tribes. Facilities operated by Indian tribes, tribal organizations, or Urban Indian Organizations may serve non-IHS beneficiaries, but they may not use IHS funds to do so. The Indian Health Care Improvement Act (IHCIA, P.L. 94-437), which provides general authority for much of IHS's activities, permits IHS facilities to serve non-beneficiaries under limited circumstances, as specified in Section 813 (25 U.S.C. §1680). These circumstances include preventing the spread of a communicable disease or to address a health hazard. IHS provided guidance to tribal facilities stating that tribes may choose to provide care to non-beneficiaries to reduce COVID-19 spread, including, but not limited to, members of Indian households who are not otherwise eligible for IHS services. In this guidance, IHS noted that the decision to provide services to non-beneficiaries would be made at the local level.[282] IHCIA generally requires that services provided to non-beneficiaries be reimbursed. As such, individuals who have another source of coverage would be tested at an IHS-facility billed to the relevant payer. HRSA has stated in its Frequently Asked Questions about the uninsured fund that COVID-19 testing that IHS facilities provide to non-IHS beneficiaries may be reimbursed by the uninsured fund if the individual tested does not have another source of payment.[283]

Similarly, VA health services provided through the VHA are generally limited to veteran enrollees who are subject to specified eligibility and enrollment criteria.[284] The VHA's primary function is to "provide a complete medical and hospital service for the medical care and treatment of veterans" (38 U.S.C. §7301). However, the VA may provide hospital care and medical services through a number of legal authorities to other individuals during periods of war, national disasters, emergencies, or humanitarian crisis.

The Veterans Administration and Department of Defense Health Resources Sharing and Emergency Operations Act (P.L. 97-174) was enacted to serve as the primary health care backup to the military health care system during and immediately following an outbreak of war or a national emergency.[285] Since then, Congress has provided additional authorities to the VA to "use

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and compliance, medical facilities, and medical and prosthetic research accounts. The first four accounts cover the provision of health care and related services.

[281] Based on Senate Appropriations Committee, Coronavirus Supplemental Appropriations Summary, available at https://www.appropriations.senate.gov/download/coronavirus-emergency-supplemental-appropriations-summary.

[282] HHS, IHS, "IHS COVID-19 Interim Guidance for Care Services to Non-Beneficiaries," March 20, 2020, https://www.ihs.gov/sites/coronavirus/themes/responsive2017/display_objects/documents/IHS_COVID-19_InterimGuidanceCareServices_Non-Beneficiaries.pdf.

[283] HHS, HRSA, "Frequently Asked Questions," https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions?field_faq_category_tid=All&combine=indian.

[284] For a detailed discussion of eligibility for VA health care and qualification for enrollment, see CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*.

[285] 38 U.S.C. §811A.

its vast infrastructure and resources, geographic reach, deployable assets, and health care expertise, to make significant contributions to the Federal emergency response effort in times of emergencies and disasters."[286]

The VHA may care for nonveterans and veterans not enrolled in the VA health care system.[287] The VA also has authority to provide certain health services such as medical counter measures[288] to VA employees.[289] The authority to care for nonveterans applies in situations where the President has declared a major disaster or emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), or where the HHS Secretary has declared a disaster or emergency activating the National Disaster Medical System established pursuant to Section 2811(b) of the Public Health Service Act (42 U.S.C. §300hh-11(b)). The President's March 13, 2020, declaration of a national emergency under Section 501(b) of the Stafford Act allows the VA to use this authority.

Does the Department of Defense Offer or Pay for Testing?

Under Chapter 55 of Title 10, *U.S. Code*, the DOD administers statutory health entitlements to approximately 9.6 million beneficiaries (i.e., servicemembers, military retirees, and family members).[290] Collectively, these entitlements are organized under a program called TRICARE that is administered by the Military Health System (MHS). The MHS offers health care services in military hospitals and clinics—known as military treatment facilities (MTFs)—and through civilian health care providers participating in TRICARE.[291] With the exception of active duty servicemembers, MHS beneficiaries may have a choice of TRICARE plan options depending on their status and geographic location. Each plan option has different beneficiary cost-sharing features, including annual enrollment fees, deductibles, copayments, and an annual catastrophic cap.[292]

COVID-19 diagnostic and serologic testing is a TRICARE-covered benefit when deemed medically necessary by a health care provider.[293] Beneficiaries may receive COVID-19 testing at

[286] VA, *Department of Veterans Affairs FY 2018—2024 Strategic Plan*, Refreshed May 31, 2019, May 31, 2019, p. 35.

[287] 38 U.S.C. §1785 and 38 C.F.R. §17.86 establish VA authority to provide hospital care and medical services to nonveterans responding to, involved in, or otherwise affected by a disaster or emergency. These individuals may include active duty servicemembers, as well as National Guard and Reserve component members activated by state or federal authority. This authority also allows the VA to treat veterans not enrolled in the VA health care system. Unless another federal agency reimburses the VA, individuals could be charged for this care. "[I]ndividuals who receive hospital care or medical services under this section [38 C.F.R. §17.86] are responsible for the cost of the hospital care or medical services when charges are mandated by Federal law (including applicable appropriation acts) or when the cost of care or services is not reimbursed by other-than-VA Federal departments or agencies." 38 C.F.R. §17.86.

[288] Medical counter measures are "are life-saving medicines and medical supplies regulated by the U.S. Food and Drug Administration (FDA) that can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear (CBRN) threats, emerging infectious diseases, or a natural disaster" (https://www.cdc.gov/cpr/readiness/mcm.html); see CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

[289] 5 U.S.C. §7901; also see Appendix A of Department of Veterans Affairs, Veterans Health Administration, *All-Hazards Emergency Cache Program*, VHA Directive 1047, Washington, DC, April 21, 2020, pp. A-1-A-2.

[290] Defense Health Agency, "Patients by Beneficiary Category," accessed March 19, 2021, https://www.health.mil/I-Am-A/Media/Media-Center/Patient-Population-Statistics/Patients-by-Beneficiary-Category.

[291] For more on the Military Health System, see CRS In Focus IF10530, *Defense Primer: Military Health System*.

[292] For more on TRICARE cost-sharing features, see Defense Health Agency, TRICARE Fact Sheet, *TRICARE Costs and Fees 2021*, December 2020, https://tricare.mil/-/media/Files/TRICARE/Publications/Misc/Costs_Sheet_2021.pdf.

[293] DOD generally follows CDC guidance on COVID-19 screening, testing, diagnosis, and treatment. For more on DOD-specific clinical guidance, see DOD, "DoD COVID-19 Practice Management Guide," March 4, 2021,

certain MTFs or through TRICARE-authorized civilian heath care providers or laboratories. DOD has 158 clinical laboratories (stand-alone or embedded at MTFs) worldwide with COVID-19 diagnostic capabilities and can support up to 300,000 tests per week.[294]

There are no out-of-pocket costs for MHS beneficiaries obtaining medically necessary COVID-19 tests. Pursuant to FFCRA Section 6006(a), DOD is required to waive all TRICARE cost-sharing requirements related to COVID-19 testing, administration of the test, and related items and services provided during an associated health care office, urgent care, or emergency department visit for the duration of the declared public health emergency.[295]

In addition to COVID-19 diagnostic and serologic testing, DOD conducts asymptomatic screening and ongoing surveillance testing of certain active duty servicemembers to mitigate potential impacts to national security or ongoing military operations. Servicemembers subjected to mandatory surveillance testing include those assigned to strategic and nuclear deterrence positions, initial recruitment or accession training, and forward-deployed forces.[296]

Does FEMA Pay for COVID-19 Testing?

FEMA may provide financial assistance for certain costs incurred for COVID-19 testing. The presidential declarations of emergency and major disaster for COVID-19 under the Stafford Act specifically authorized Public Assistance (PA) for Emergency Protective Measures.[297] Under

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https://www.health.mil/Reference-Center/Technical-Documents/2021/03/04/DoD-COVID-19-Practice-Management-Guide-Version-7.

[294] Military Health System Communications Office, "DOD continues to increase COVID-19 test capacity," *Health.mil News*, December 7, 2020, https://www.health.mil/News/Articles/2020/12/07/DOD-continues-to-increase-COVID-19-test-capacity.

[295] For more on DOD-specific requirements and appropriations included in the FFCRA, see CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*; and Defense Health Agency, *Decision Memorandum on TRICARE Implementation of the "Families First Coronavirus Response Act*, April 7, 2020, https://www.health.mil/Reference-Center/Publications/2020/04/07/TRICARE-Implementation-of-the-Families-First-Coronavirus-Response-Act.

[296] See Jim Garamone, "DOD Starts Tiered COVID-19 Testing Process to Ensure Safety," *DOD News*, April 22, 2020, https://www.defense.gov/Explore/News/Article/Article/2160008/dod-starts-tiered-covid-19-testing-process-to-ensure-safety/; DOD, "Force Health Protection Guidance (Supplement 9) – Department of Defense Guidance for Deployment and Redeployment of Individuals and Units during the Novel Coronavirus Disease 2019 Pandemic," May 26, 2020, https://media.defense.gov/2020/May/26/2002305748/-1/-1/1/FORCE-HEALTH-PROTECTION-GUIDANCE-SUPPLEMENT-9.PDF; and DOD Memorandum, "Force Health Protection (Supplement 15) – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Testing Services," January 1, 2021, https://www.whs.mil/Portals/75/Coronavirus/FHP%20Guidance%20(Supplement%2015)%20DoD%20Guidance%20for%20Coronavirus%20Disease%202019%20Laboratory%20Testing%20Services.pdf?ver=QqAUZYPv1pNNnJ4Tod00lQ%3d%3d. Forward-deployed forces, also called "forward presence," refers to the positioning of military personnel and capabilities within or near a theater of operation in order to "demonstrate national resolve, strengthen alliances, dissuade potential adversaries, and enhance the ability to respond quickly to contingencies." Forward-deployed forces are typically positioned in overseas locations. For more on forward presence, see DOD, DOD Dictionary of Military and Associated Terms, updated January 2021, p. 88, https://www.jcs.mil/Portals/36/Documents/Doctrine/pubs/dictionary.pdf.

[297] The President issued an emergency declaration, and subsequently issued major disaster declarations for all 50 states, five territories, the District of Columbia, and three tribes, authorizing Public Assistance (PA) for COVID-19 response efforts. FEMA, "COVID-19 Disaster Declarations," https://www.fema.gov/coronavirus/disaster-declarations (Stafford Act Declarations as of April 9, 2021). Public Assistance (PA) provides grant assistance to state, tribal, territorial, and local governments, as well as eligible private nonprofit organizations, for the costs of urgent response and long-term recovery work following an emergency or major disaster declared under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act; P.L. 93-288, as amended; 42 U.S.C. §§5121 et seq.). For more information, see CRS Report R46749, *FEMA's Public Assistance Program: A Primer and Considerations for Congress*, by Erica A.

these declarations, FEMA may reimburse costs incurred by state, local, territorial, and tribal governments, as well as eligible nonprofits, including nonprofit health care providers, (collectively referred to as "PAApplicants") while executing eligible emergency response work in response to the COVID-19 pandemic. Under these declarations, PAApplicants may receive reimbursement for certain emergency medical care costs directly related to the COVID-19 pandemic, including "triage and medically necessary tests and diagnosis related to COVID-19 cases as well as screening testing needed to safely open and operate eligible public facilities, including schools."[298] Related eligible costs include, but are not limited to

- the costs of temporary and expanded medical facilities;
- overtime for budgeted medical staff treating COVID-19 patients;
- regular time and overtime for temporary and contracted staff for testing and treatment of COVID-19 patients;
- training for individuals to administer tests;
- the purchase and delivery of specialized medical equipment, PPE, and durable and consumable medical supplies;
- laboratory testing materials and test kits, including antigen tests;
- contracting for testing by a third party; and
- technology to register and track testing results.[299]

FEMA is to reimburse PAApplicants for 100% of eligible costs incurred from January 2020 to December 31, 2021, while performing eligible work, including medically necessary tests, pursuant to the COVID-19 Stafford Act declarations.[300] For example, U.S. Senators from Illinois reported that FEMA had provided funds to the state for costs incurred from January 20, 2020, through August 31, 2020, for COVID-19 test collection, among other expenses.[301]

FEMA may reimburse at least 75% of eligible costs after December 31, 2021; the agency intends to provide 30 days' notice before assistance may lapse.[302]

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[298] FEMA, "Coronavirus (COVID-19) Pandemic: Medical Care Eligible for Public Assistance (Interim) (Version 2)," FEMA Policy #104-21-0004, p. 4 (hereinafter FEMA, "COVID-19: Eligible Medical Care"), https://www.fema.gov/sites/default/files/documents/fema_public-assistance-covid-19-medical-care-v2-with-equity-job-aid_policy_3-15-2021.pdf; FEMA, "FEMA Funding for COVID-19 Testing," August 28, 2021, https://www.fema.gov/fact-sheet/fema-funding-covid-19-testing.

[299] Eligibility for the costs of PPE and medical supplies are subject to disposition requirements. For a nonexclusive list of eligible medical care costs and requirements, see FEMA, "FEMA Funding for COVID-19 Testing," August 28, 2021, https://www.fema.gov/fact-sheet/fema-funding-covid-19-testing.

[300] FEMA, "FEMA, "COVID-19: Eligible Medical Care," p. 4, https://www.fema.gov/sites/default/files/documents/fema_public-assistance-covid-19-medical-care-v2-with-equity-job-aid_policy_3-15-2021.pdf; FEMA, "Statement on 100% Cost Share," February 7, 2021, https://www.fema.gov/press-release/20210203/fema-statement-100-cost-share; and FEMA, "FEMA Funding for COVID-19 Testing," August 28, 2021, https://www.fema.gov/fact-sheet/fema-funding-covid-19-testing.

[301] Sen. Tammy Duckworth, "Duckworth, Durbin Announce More Than $71 Million in FEMA Reimbursement Funding for Illinois COVID-19 Response," March 25, 2021, https://www.duckworth.senate.gov/news/press-releases/duckworth-durbin-announce-more-than-71-mil-in-fema-reimbursement-for-il-covid-response. See also News 7 KWWL.com, "FEMA Awards Iowa with $78 million for COVID-19 Response," May 7, 2020, https://kwwl.com/2020/05/07/fema-awards-iowa-with-78-million-for-covid-19-response/. The TestIowa website is available at https://www.testiowa.com/en.

[302] FEMA, "COVID-19: Eligible Medical Care," p. 13.

There is no predetermined limit on the amount of funding available through the PA program.[303] However, FEMA will not reimburse costs covered by another source, which may include private or publicly funded insurance, funding provided through the CARES Act (P.L. 116-136), the COVID-19 Uninsured Program for uninsured patients, or programs overseen by HHS, among others.[304] In addition, to be eligible for reimbursement, FEMA must confirm that costs are reasonable.[305] FEMA has advised it will use Medicare rates as the basis to determine cost reasonability for eligible medical care.[306]

PA is funded through the Disaster Relief Fund (DRF), the primary source of funding for the federal government's domestic general disaster relief programs.[307] DRF appropriations are not generally allocated for specific emergencies, disasters, or forms of assistance, and may generally be obligated for disasters past and present. FEMA reported that it obligated approximately $5.8 billion from the DRF for PA for the COVID-19 pandemic response in FY2020; the agency estimates that it will obligate approximately $35 billion in spending from the DRF for PA for COVID-19 response costs in FY2021.[308] FEMA reported that projected obligations in 2021 for PA for the COVID-19 pandemic reflect, among other costs, the increased federal cost share from 75% to 100% in through December 31, 2021, as well as costs for vaccine distribution, National Guard activities, and reopening and safe operation of eligible facilities.[309]

Payment for Testing for Individuals with No Source of Coverage

As mentioned above, some community-based testing and testing at some types of facilities may be available to individuals who do not have a source of payment. The federal government has created an uninsured fund that may reimburse facilities for testing provided to uninsured individuals. In addition, Congress has enacted legislation that has expanded Medicaid eligibility under limited circumstances so that Medicaid funds may be available for testing for some uninsured individuals who are otherwise ineligible for Medicaid.

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[303] Stafford Act assistance is subject to the availability of funds in the Disaster Relief Fund.

[304] FEMA, "COVID-19: Eligible Medical Care," pp. 12-13; Stafford Act Section 312 (42 U.S.C. §5155) (Section 312 addresses duplication of benefits). The HHS Uninsured Program fund is discussed in the "How Can Facilities That Provide Testing for Uninsured Individuals Be Reimbursed?" section of this report.

[305] 2 C.F.R. §200.404; FEMA, *Public Assistance Program and Policy Guide (PAPPG),* v. 3.1, April 2018, pp. 21-23, https://www.fema.gov/sites/default/files/documents/fema_pappg-v3.1-archived_policy_5-4-2018.pdf; and FEMA, "Public Assistance: Reasonable Cost Evaluation," Job Aid, October 13, 2018, https://www.fema.gov/sites/default/files/2020-07/fema_pa_reasonable-cost-evaluation-job-aid.pdf.

[306] FEMA will use standard Medicare rates that do not include the 20% increase in COVID-19 Medicare Diagnosis-Related Group (DRG) rates implemented by the CARES Act. FEMA, "COVID-19: Eligible Medical Care," p. 10.

[307] For more information, see CRS Report R45484, *The Disaster Relief Fund: Overview and Issues*, by William L. Painter.

[308] FEMA, "Disaster Relief Fund: Monthly Report as of March 31, 2021," April 8, 2021, Fiscal Year 2021 Report to Congress, p. 13, https://www.fema.gov/sites/default/files/documents/fema_april-2021-disaster-relief-fund-report.pdf.

[309] See explanation in FEMA, "Disaster Relief Fund: Monthly Report as of February 28, 2021," March 11, 2021, Fiscal Year 2021 Report to Congress, p. 23, https://www.fema.gov/sites/default/files/documents/fema_mar-2021-disaster-relief-fund-report.pdf; and FEMA, "Disaster Relief Fund: Monthly Report as of March 31, 2021," April 8, 2021, Fiscal Year 2021 Report to Congress, p. 25, https://www.fema.gov/sites/default/files/documents/fema_april-2021-disaster-relief-fund-report.pdf.

How Can Facilities That Provide Testing for Uninsured Individuals Be Reimbursed?

Various laws enacted in response to the COVID-19 pandemic provide reimbursement to providers who offer testing to uninsured individuals. FFCRA provides $1 billion for testing of individuals who are uninsured as defined in FFCRA.[310] PPPHCEA supplements that appropriation with an additional $1 billion for uninsured testing.[311] The CARES Act appropriated $100 billion for provider relief, termed the Provider Relief Fund (PRF), which was established "to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus."[312] The fund was supplemented twice—PPPHCEA provided an additional $75 billion for the PRF, and the Consolidated Appropriations Act, 2021 (P.L. 116-260) provided an additional $3 billion for the fund.[313] An unspecified portion of this fund is being used to test, treat, and vaccinate the uninsured.[314] Collectively the specifically appropriated funds for testing and the PRF funds allocated are being termed the "Uninsured Fund," which is being administered by HRSA.[315] GAO analyzed COVID-19 related spending and found that $10 billion was being allocated for testing and treatment of the uninsured, but that unallocated PRF funds may supplement that allocation if necessary.[316] HHS tracks the amount reimbursed for uninsured testing and treatment and reports that more than $5.5 billion has been reimbursed; this exceeds the amount that had been specifically appropriated.[317] On May 25, 2021, the Biden Administration announced that it was allocating $4.8 billion of ARPA funds for uninsured testing.[318]

Entities that seek reimbursement for testing and related services from the Uninsured Fund must comply with certain terms and conditions.[319] For example, entities must register with the fund, provide required information about the services provided and the patient the services were provided to, agree to accept the Medicare rate as full payment, and may not seek cost-sharing from individuals. For patients who were tested prior to the funds' establishment, and for whom a facility may have already sought reimbursement, the facility must agree to return the already collected cost-sharing to individuals.[320] Facilities are not required to seek reimbursement from

[310] For more information, see CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*, and HHS, HRSA, "COVID-19 Claims Reimbursements to Health Care Providers and Facilities for the Testing and Treatment of the Uninsured," https://coviduninsuredclaim.linkhealth.com/.

[311] CRS Report R46325, *Fourth COVID-19 Relief Package (P.L. 116-139): In Brief*

[312] P.L. 116-136.

[313] For information on the HHS Provider Relief Fund, see CRS Insight IN11438, *The COVID-19 Health Care Provider Relief Fund*.

[314] CRS Report R46353, *COVID-19: Overview of FY2020 LHHS Supplemental Appropriations*.

[315] CRS Insight IN11526, *COVID-19 and the Uninsured: Federal Funding Options to Pay Providers for Testing and Treatment*

[316] U.S. Government Accountability Office, *COVID-19: Sustained Federal Action Is Crucial as Pandemic Enters Its Second Year*, 21-387, March 2021, p, 60, https://www.gao.gov/assets/gao-21-387.pdf.

[317] HHS, "HHS COVID-19 Funding: Treatment & Testing of the Uninsured," https://taggs.hhs.gov/Coronavirus/Uninsured.

[318] Department of Health and Human Services, "HHS to Dedicate $4.8 Billion from the American Rescue Plan to COVID19 Testing for the Uninsured," press release, May 25, 2021, https://www.hhs.gov/about/news/2021/05/25/hhs-to-dedicate-billions-from-the-american-rescue-plan-for-the-uninsured.html.

[319] HHS, HRSA, "FFCRA Relief Fund Payment Terms and Conditions," https://www.hhs.gov/sites/default/files/terms-and-conditions-ffcra-relief-fund.pdf.

[320] HHS, HRSA, "COVID-19 Claims Reimbursements to Health Care Providers and Facilities for the Testing and

this fund, and they may provide care to individuals who are uninsured and seek payment from the patient who received testing or treatment directly. If a facility does submit for reimbursement to the Uninsured Fund, the fund would verify that the individual meets the FFCRA definition of uninsured for purposes of uninsured testing. HRSA notes that individuals who have limited Medicaid enrollment do not qualify for the uninsured testing fund, but would qualify for uninsured treatment.[321]

Under What Circumstances Will Medicaid Pay for Uninsured Testing?

Section 6004 of the FFCRA, as amended by the CARES Act, added, at state option, a new Medicaid eligibility group (referred to as the "COVID-19 testing" eligibility group) to provide testing and diagnosis of COVID-19, including testing-related services, testing-related visits and the administration of the testing,[322] without beneficiary cost-sharing (as required under Medicaid) for certain specified uninsured individuals, beginning no earlier than March 18, 2020, through the end of the COVID-19 public health emergency period, as specified. FFCRA provides a 100% federal medical assistance percentage (FMAP or federal matching rate) for medical assistance and administrative costs associated with Medicaid enrollees under this group, during such period.

FFCRA, as amended by the CARES Act, defines "uninsured individuals" as

- individuals who are not enrolled in another health care program funded by the federal government, including CHIP, Basic Health Program (BHP), Medicare, TRICARE and the VA, and federal employee health plans;
- individuals who are not enrolled in a group health plan or health insurance coverage offered by a health insurance issuer (as defined in PHSA Section 2791), including a qualified health plan through an exchange, employer-sponsored health insurance, retiree health plans and Consolidated Omnibus Budget Reconciliation Act (COBRA) continuation coverage;[323]
- individuals who are not eligible to receive coverage under one of Medicaid's existing mandatory eligibility groups (e.g., poverty-related children);
- individuals who would be eligible for Medicaid via the Affordable Care Act (ACA, P.L. 111-148) Medicaid expansion pathway in states that have not adopted this eligibility pathway (i.e., non-ACA Medicaid expansion states); and
- certain specified Medicaid enrollees who, by virtue of their Medicaid eligibility pathway, are entitled to limited Medicaid benefits, including

Treatment of the Uninsured," https://coviduninsuredclaim.linkhealth.com/.

[321] HRSA, "Frequently Asked Questions for the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured Program," at https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions.

[322] As with the new Medicaid mandatory coverage of in vitro diagnostic testing added under FFCRA, as amended by the CARES Act, diagnostic and serological testing may be covered for symptomatic and asymptomatic Medicaid enrollees determined eligible via the "COVID-19 testing" pathway, as long as such tests are driven by medical necessity. To date, the Medicaid specific CMS guidance has not explicitly addressed the question of whether states can use Medicaid as a payer of public health surveillance testing for SARS-CoV-2 (to screen for general health and safety).

[323] CMS Medicaid FAQs. For questions about these types of private health insurance plans, congressional clients may contact Vanessa C. Forsberg.

- low-income tuberculosis-infected individuals who are entitled to services related to the tuberculosis infection,
- individuals eligible only for family planning services and supplies,
- individuals eligible through the medically needy pathway[324] whose coverage does not meet minimum essential health coverage,[325] and
- certain low-income pregnant woman who are entitled to limited pregnancy-related services.

While there is no income or resource test associated with the "COVID-19 testing" eligibility pathway, applicants must be otherwise eligible for Medicaid (e.g., they must meet federal and state requirements regarding residency, immigration status, and documentation of U.S. citizenship). Like all other Medicaid eligibility pathways, applicants for the optional "COVID-19 testing" pathway are required to provide a Social Security number.[326]

COVID-19 testing without beneficiary cost-sharing for the "COVID-19 testing" eligibility group is extended under Section 9811 of the ARPA for the period that begins on the date of enactment of ARPA (i.e., March 11, 2021) and ends the last day of the first calendar quarter that begins one year after the last day of the public health emergency period, as defined. However, regular FMAP rates will apply for such services with the sunset of the COVID-19 public health emergency period.

Can the Uninsured Fund Reimburse Testing Provided to the Optional Medicaid COVID-19 Testing Group?

Medicaid enrollees eligible through the optional "COVID-19 testing" group are not eligible for coverage of COVID-19 testing and testing-related services through the HRSA-administered COVID-19 Claims Reimbursement Program. In instances where an HRSA-administered COVID-19 Claims Reimbursement Program pays a claim for COVID-19 testing or testing-related services to a provider, but later determines that such services were delivered to a Medicaid enrollee (regardless of that person's Medicaid eligibility pathway), HRSA is required to recover payment(s) made to the provider and to advise the provider to bill Medicaid as the primary payer.[327]

[324] Medically needy individuals (e.g., children, pregnant women, aged, blind, or disabled) are those who are otherwise eligible for Medicaid but who have incomes too high to qualify and spend down their income on medical care. For this medically needy subgroup, states may offer a more restrictive benefit package than is available to other enrollees.

[325] For more information on the CMS criteria used to evaluate whether a given state's medically needy coverage meets the minimum essential health coverage standard, see CMS, Dear State Health Official, Dear State Medicaid Director, SHO# 14-002, Re: Minimum Essential Coverage, November 7, 2014, https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SHO-14-002.pdf. For more general information on minimum essential coverage under Medicaid, see https://www.medicaid.gov/medicaid/eligibility/minimum-essential-coverage/index.html.

[326] 42 C.F.R. §435.910.

[327] Centers for Medicare & Medicaid Services, *NEW FAQs- Released June 30, 2020*, COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies, June 30, 2020, https://www.medicaid.gov/state-resource-center/downloads/covid-19-new-faqs.pdf.

How Can Individuals Who Are Unauthorized Immigrants Obtain Testing?

Unauthorized (sometimes referred to as *undocumented*) immigrants are eligible to obtain testing anywhere that COVID-19 testing is offered; for example, doctors' offices, public health sites, hospitals' emergency departments, and community health centers.

Over half (55%) of the nonelderly[328] unauthorized population in the United States has health insurance.[329] Nonelderly unauthorized immigrants who are uninsured can receive free or reduced-cost testing at some of the aforementioned locations. Health care providers can seek reimbursement through the HRSA-administered COVID-19 Claims Reimbursement Program. HRSA has stated that "health care providers are not required to confirm immigration status prior to submitting claims for reimbursement."[330]

Under What Circumstances Will Medicaid Pay for Testing for Unauthorized Immigrants?

With a few exceptions, state Medicaid programs are prohibited from covering unauthorized immigrants.[331] Under one such exception, emergency Medicaid, unauthorized immigrants who are otherwise eligible for Medicaid except for their immigration status may receive "medical assistance under Title XIX of the Social Security Act … for care and emergency services that are necessary for the treatment of an emergency medical condition (as defined in Section 1903(v)(3) of such Act) of the alien involved and are not related to an organ transplant procedure."[332]

In response to the COVID-19 public health emergency, some states have extended coverage for certain specified COVID-19-related health care expenses (e.g., testing) to otherwise eligible unauthorized immigrants under emergency Medicaid.[333] The duration and scope of COVID-19-related emergency Medicaid coverage vary depending on the state.[334]

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[328] Individuals under the age of 65.

[329] Samantha Artiga and Maria Diaz, "Healthcare Coverage and Care of Undocumented Immigrants," Kaiser Family Foundation, July 15, 2019, at https://www.kff.org/disparities-policy/issue-brief/health-coverage-and-care-of-undocumented-immigrants/.

[330] HRSA, "Frequently Asked Questions for the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured Program," at https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions.

[331] These exceptions are (1) emergency Medicaid; (2) State Children's Health Insurance Coverage (CHIP) coverage for fetuses as permitted through federal regulation (often referred to as the CHIP unborn child pathway); and (3) the CHIPRA option that allows states to provide Medicaid coverage to certain lawfully residing children and/or pregnant women within the five-year waiting period when certain conditions are met. For more information, see CRS In Focus IF11912, *Noncitizen Eligibility for Medicaid and CHIP*.

[332] See Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA; P.L. 104-193), §401(a)(1)(A).

[333] For more information about states that are covering COVID-19 testing and treatment under emergency Medicaid, see Jane Shubel, *States are Leveraging Medicaid to Respond to COVID-19*, Center on Budget and Policy Priorities, June 18, 2020, https://www.cbpp.org/sites/default/files/atoms/files/5-7-20health.pdf#page=7.

[334] For more information, see CRS Report R46339, *Unauthorized Immigrants' Eligibility for COVID-19 Relief Benefits: In Brief*.

Also, on May 20, 2020, CMS approved two temporary Emergency Medicaid State Plan Amendments (SPAs) in the Commonwealth of Northern Mariana Islands (CNMI). The first permits CNMI to adopt the FFCRA "COVID-19 testing" eligibility pathway to extend COVID-19 testing without cost-sharing to uninsured individuals (as defined in FFCRA and as amended by CARES), among other changes.[335] The second allows CMNI to extend full Medicaid coverage to applicants whose attested gross income does not exceed 180% of the SSI federal benefit rate, and allows specified entities to make eligibility determinations regardless of an applicant's immigration status.[336] This is done by using the presumptive eligibility Medicaid enrollment facilitation tool to relax requirements regarding citizenship documentation. This SPA temporarily extends full Medicaid (or eligibility for the COVID-19 testing group, as the case may be) to unauthorized immigrants outside of emergency Medicaid and is in place from April 1, 2020, through the end of the public health emergency, including any extensions.

Emergency Supplemental Funding for Testing

During the COVID-19 pandemic, given the role of testing as both a clinical care function and as a part of disease control and response efforts, different types of tests have been provided in a number of different settings. This includes the direct provision of diagnostic tests in traditional health care settings, the provision of testing in community-based and other less traditional settings for both screening and diagnostic purposes, and the provision of public health testing outside of the clinical context. Further, testing has been expanded at scale to meet both clinical and public health needs. As described above, the testing supply chain has been under stress, as has the capacity of clinical laboratories, health care providers, and public health agencies to carry out necessary testing. To help address these issues, Congress and the President have appropriated emergency supplemental FY2020 and FY2021 funding to be used to support developing testing infrastructure and capacity and for the clinical provision of tests. The two questions below discuss examples of these types of funding sources separately; however, this distinction is not always clear-cut, as some funding mechanisms could be used for testing capacity and infrastructure and to pay for testing of individuals.

What Funds Have Been Appropriated for Testing Capacity and Infrastructure?

Recently enacted appropriations in COVID-19 relief laws have included many appropriations that can be used to support COVID-19 testing capacity and infrastructure. Testing capacity and infrastructure are defined here as activities and functions intended to help provide COVID-19 testing at scale to help control the spread of the virus. Such activities and functions can include increasing laboratory capacity (facilities, equipment, and workforce); procuring testing supplies and improving supply chains; establishing and supporting community-based testing sites; and supporting public health testing programs. (The following does not focus specifically on appropriations that support test-related research and development, manufacturing or regulation,

[335] The Commonwealth of the Northern Mariana Islands (CNMI) emergency Medicaid state plan amendment is available at https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CNMI/MP-20-0001.pdf.

[336] The Commonwealth of the Northern Mariana Islands (CNMI) emergency Medicaid state plan amendment is available at https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CNMI/MP-20-0001-B.pdf.

though these activities also have implications for testing capacity and some of the below listed appropriations may also be used for those purposes.)

While many accounts across the federal government can support activities related to testing capacity and infrastructure, the following major appropriations (greater than $20 billion dollars each) were specifically directed in the COVID-19 relief laws to, in large part, aid in expanding testing capacity and infrastructure (all of which were either appropriated or have been budgeted to the HHS Public Health and Social Services Emergency Fund account):[337]

Paycheck Protection Program and Health Care Enhancement Act (PPPHCEA; P.L. 116-139**, Division B, Title I)** provided $25 billion total and directed HHS to reserve or transfer some of these funds for specific purposes. For example, not less than $11 billion was for states, localities, territories, tribes, tribal organizations (SLTT), urban Indian health organizations, and health service providers to tribes. Of this total for SLTT grantees, not less than $2 billion was to be allocated according to the formula that applied to the Public Health Emergency Preparedness (PHEP) cooperative agreement in 2019,[338] and $4.25 billion was to be allocated according to a formula that is based on the relative number of COVID-19 cases. In addition, $750 million of the total for SLTT was to be allocated in coordination with the IHS Director to tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes. In addition, the law specified that certain amounts of these funds were to be transferred to other HHS agencies, including not less than $1 billion to CDC for "surveillance, epidemiology, laboratory capacity expansion, contact tracing, public health data surveillance and analytics infrastructure modernization, disseminating information about testing, and workforce support necessary to expand and improve COVID–19 testing."[339] The remaining funds were authorized to be used for notably broad activities to boost testing infrastructure, production, capacity, and administration, including for the purchase of testing supplies; for "construction, alteration, renovation, or equipping of non-federally owned facilities for the production of diagnostic, serologic, or other COVID–19 tests"[340] and "for grants for the rent, lease, purchase, acquisition, construction, alteration, renovation, or equipping of non-federally owned facilities to improve preparedness and response capability at the state and local level for diagnostic, serologic, or other COVID–19 tests."[341]

Consolidated Appropriations Act, 2021 (P.L. 116-260; Division M) provided a total of $22.4 billion. The law directed that funds shall be for SLTT entities, and that funding may be awarded as grants or cooperative agreements. Of the total, $790 million was designated as a transfer to IHS, and a separate amount of not less than $2.5 billion was directed for "strategies for improving testing capabilities and other purposes … in high-risk and underserved populations, including racial and ethnic minority populations and rural communities as well as identifying best practices

[337] The PHSSEF account receives annual appropriations for the routine operations of several HHS offices, including the Office of the HHS Assistant Secretary for Preparedness and Response (ASPR), the lead office for health emergency preparedness and response strategy. This account is also used for one-time or short-term funding, such as emergency supplemental appropriations. Of the appropriations listed, PPPHCEA and Consolidated Appropriations Act provided the appropriations directly to the PHSSEF account, while funds from ARPA (an authorizing measure) were budgeted into the PHSSEF account according to HHS budget documents. See HHS, *Fiscal Year 2022: Budget in Brief,* https://www.hhs.gov/sites/default/files/fy-2022-budget-in-brief.pdf, p. 22.

[338] The Public Health Emergency Preparedness (PHEP) cooperative agreement is a grant program that provides annual funding to 62 state, territorial, and local grantees. It is authorized by Public Health Service Act, §319C-1 [42 U.S.C. §247d–3a].

[339] 134 Stat. 624.

[340] 134 Stat. 625.

[341] Ibid.

for states and public health officials to use for contact tracing in high-risk and underserved populations, including racial and ethnic minority populations and rural communities."[342] The funding, except for the transfer to IHS, was directed to be awarded according to the formula that applied to the PHEP cooperative agreement in FY2020.

American Rescue Plan Act of 2021 (ARPA, P.L. 117-2**, Title II, Section 2401)** provided a total of $47.8 billion to the HHS Secretary, to remain available until expended, to carry out activities to detect, diagnose, trace, and monitor SARS–CoV–2 (the virus that causes COVID-19) and COVID-19 infections, and related strategies to mitigate the spread of COVID-19. The law directed funds to carry out the following pandemic response activities: (1) implement a national testing, contact tracing, surveillance, and mitigation strategy; (2) provide grant or cooperative agreement funding and technical guidance to SLTT public health departments for this effort; (3) support the development, manufacture, procurement, and distribution of supplies necessary for administering tests (e.g., PPE), and the acquisition, construction, renovation, or alteration of nonfederal sites used for the production of COVID-19 tests and related supplies; (4) invest in improving laboratory and contact tracing capacity, including through academic and research labs, community testing sites and organizations, and mobile testing services, as well as investments with respect to quarantine and isolation of contacts; (5) support public health data sharing through information technology, data modernization, and reporting; (6) provide grants to SLTT to improve the public health workforce; and (7) cover administrative and program support costs. The provision did not specify how much of the total appropriation is to be awarded as SLTT grants or cooperative agreements, and generally gives discretion to the HHS Secretary to determine SLTT award amounts.

Aside from the above major appropriations, several other HHS accounts received funding in COVID-19 relief acts that could be allocated towards testing capacity and infrastructure-related purposes—for example, CDC supports SLTT public health laboratories and testing programs; CDC received several broad appropriations for pandemic response that could be allocated toward related activities. ASPR also plays a role in procurement and distribution of testing supplies; other appropriations to the PHSSEF account could also be used for related purposes by ASPR.[343] Additional funding of $10 billion for Defense Production Act actions specific to medical supplies (including those related to testing) was made available in ARPA (Title III, Section 3101), and these funds have been budgeted to HHS.[344]

GAO reported that, as of May 31, 2021, HHS had allocated $61.4 billion for testing capacity and infrastructure-specific activities[345] from all COVID-19 relief laws and obligated $21.2 billion of that amount. This testing-specific total is in addition to other spending categories that have supported testing programs, such as the SLTT public health grant category, which totaled $40.1

[342] U.S. Congress, House Committee on Rules, *Rules Committee Print 116-68 Text of the House Amendment to the Senate Amendment to H.R. 133*, committee print, 116th Cong., 2nd sess., December 21, 2021, p. 4561.

[343] For an overview of supplemental appropriations in COVID-19 relief acts, see the following CRS reports: CRS Report R46711, *U.S. Public Health Service: COVID-19 Supplemental Appropriations in the 116th Congress*, and CRS Report R46834, *American Rescue Plan Act of 2021 (P.L. 117-2): Public Health, Medical Supply Chain, Health Services, and Related Provisions*.

[344] The HHS FY2022 budget shows the American Rescue Plan Act (ARPA) DPA appropriations as a new HHS account. See HHS, *Fiscal Year 2022: Budget in Brief*, https://www.hhs.gov/sites/default/files/fy-2022-budget-in-brief.pdf, p. 22.

[345] The GAO "testing" category includes "procurement and distribution of testing supplies, community-based testing programs, testing in high-risk and underserved populations and Indian Health Services' programs, implementing a national strategy, CDC testing-related activities such as technical assistance, and other activities."

billion in allocations and $25.1 in obligations (total includes grants for all public health purposes, encompassing testing as well as others such as vaccination programs).[346]

Outside of HHS, several federal agencies and departments have also supported activities related to testing capacity and infrastructure. For example, many states and other jurisdictions have used the Department of Treasury's Coronavirus Relief Fund (CRF) funding from the CARES Act to support testing-related activities.[347] Additional CRF funds made available in ARPA can also support SLTT testing activities.[348] As discussed above, FEMA has supported several activities related to testing capacity and infrastructure, including the procurement and distribution of related supplies, as well as supporting community-based testing sites through funding in the Disaster Relief Fund (DRF).[349] In addition, funding made available to the statutory DOD account for DPA-related purposes in the CARES Act (P.L. 116-136) was used in small part to support testing supply related activities.[350]

What Funds Have Been Appropriated for the Clinical Provision of Tests?

Congress has appropriated funding in each of the response measures for testing specific populations. Some of this funding is for testing populations where the federal government directly provides services (e.g., to veterans through the VHA), to test specific populations that might otherwise lack access to testing (e.g., the uninsured), or to facilities to provide testing to underserved populations (e.g., rural health clinic testing). Below are a few examples of these types of appropriations:

Funds for Federal Health Program Testing: FFCRA included appropriations of $82 million to DOD for testing for Defense Health Program beneficiaries, $64 million to IHS for testing the agency's beneficiaries, and $60 million total to the VA for testing VA beneficiaries.[351] Subsequent response measures have also included appropriations to these agencies to test their service populations.

Funds to Testing Specific Populations: FFCRA appropriated $1 billion for uninsured testing. Subsequently, PPPHCEA included $1 billion for this purpose. The Biden Administration has also

[346] GAO, *COVID-19: Continued Attention Needed to Enhanced Federal Preparedness, Response, Service Delivery and Program Integrity*, GAO-21-551, July 2021, pp. 104-105, https://www.gao.gov/assets/gao-21-551.

[347] GAO, *COVID-19: Sustained Federal Action is Crucial as Pandemic Enters Its Second Year*, GAO-21-387, March 31, 2021, pp. 94-95.

[348] For eligible uses of Coronavirus Relief Fund (CRF) funding from ARPA see relevant guidance and other documents at U.S. Department of Treasury, "Coronavirus State and Local Fiscal Recovery Funds," https://home.treasury.gov/policy-issues/coronavirus/assistance-for-state-local-and-tribal-governments/state-and-local-fiscal-recovery-funds.

[349] FEMA's COVID-19 Healthcare Resource Roadmap lists public health capacity activities related to testing as an eligible use of funding from its Public Assistance program. See FEMA, "COVID-19 Healthcare Resource Roadmap (Version 2.0)," July 28, 2021, https://www.fema.gov/sites/default/files/documents/fema_covid-19-healthcare-resource-roadmap-version2.0_07-08-2021.pdf. For general information about the Disaster Relief Fund, see CRS Report R45484, *The Disaster Relief Fund: Overview and Issues*.

[350] One public announcement of a testing-related allocation of the DPA funding was on April 29, with $75 million for nasal swab production. See CRS Insight IN11387, *COVID-19: Defense Production Act (DPA) Developments and Issues for Congress*.

[351] This includes $30 million for testing at the VA and $30 million for testing through the Veterans Health Administration's Community Care program.

allocated $4.8 billion for uninsured testing drawn from the $47.8 billion appropriated in ARPA for testing.

Funds for Testing at Specific Types of Facilities: Supplemental appropriations have been provided for testing at specific types of nonfederal facilities. For example, $600 million of the amount appropriated to the PHSSEF in PPPHCEA was transferred to HRSA to support testing at health centers. PPPHCEA also appropriated $225 million for testing at rural health clinics, which are small outpatient facilities in rural areas.[352]

This discussion of specific funding appropriated for testing and testing related purposes does not include the mandatory spending budgetary effects of clinical testing-related provisions carried in COVID-19 response legislation. For example, FFCRA and the CARES Act included several provisions to expand coverage of testing paid by federal health programs, such as Medicare and Medicaid, as well as private insurance. (These are covered in this report and in other CRS reports.)[353]

Public Health Reporting of COVID-19 Test Data

What Types of Testing Data Are Collected?

CDC collects many types of data related to testing, some provided by states or other jurisdictions and some provided directly by laboratories to CDC.[354] These data are used to monitor public health trends, understand the virus, and better understand disease trends and affected populations. Existing testing-related surveillance (i.e., data collection) systems include the following:

- **Case-based surveillance.** Positive COVID-19 test results are reported by laboratories to jurisdictions that then link and collect detailed information on each case, including demographic and health information. Jurisdictions use a case reporting system to report to CDC.[355] Case reporting occurs through CDC's National Notifiable Diseases Surveillance System.[356]
- **Virologic surveillance.** CDC collects data on all COVID-19 diagnostic laboratory test results through its COVID Electronic Laboratory Reporting system, which collects data shared by over 1,000 laboratories with state and other jurisdictions' health departments with CDC. These data do not include nonlaboratory or point-of-care test sites, and therefore reflect the majority, but not all, of COVID-19 testing in the United States. Test result data allow for tracking infection rates over time, by location, and identifying groups of individuals at higher risk for infection.[357]

[352] HHS, HRSA, "HHS Providers $225 Million for COVID-19 Testing in Rural Communities," https://www.hhs.gov/about/news/2020/05/20/hhs-provides-225-million-for-covid19-testing-in-rural-communities.html.

[353] See also CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)*, and CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

[354] CDC, *CDC Activities and Initiatives Supporting the President's Plan for Opening Up America Again*, May 2020, https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf.

[355] CDC, "Coronavirus Disease 2019: Reporting a Confirmed Case," updated May 5, 2020, https://www.cdc.gov/coronavirus/2019-ncov/php/reporting-pui.html.

[356] CRS correspondence with CDC, May 6, 2020.

[357] HHS Protect Data Hub, "National Testing," last updated May 30, 2021, https://protect-public.hhs.gov/pages/national-testing.

- **Genomic Surveillance.** CDC uses multiple strategies to conduct genomic surveillance and identify and monitor variants, including the National SARA-CoV-2 Strain Surveillance system, partnerships with commercial diagnostic laboratories, collaboration with universities, and supporting local health jurisdictions' detection and sequencing efforts.[358]

Traditionally, most public health data reporting requirements have been based in state law. States or other jurisdictions can mandate that laboratories or health care providers report data related to certain diseases to jurisdictions' public health departments. States then voluntarily share de-identified data with CDC as a part of national surveillance.[359] The CARES Act added new authorities for the HHS Secretary related to COVID-19 testing data. Specifically, Section 18115 of the CARES Act requires that every clinical laboratory that performs or analyzes a test intended to detect or diagnose a possible case of COVID-19 report the test results to the HHS Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary's Public Health Emergency declaration (PHSA §319) with respect to COVID-19 or any extension of such declaration. The provision allows the Secretary to decide which laboratories must submit reports pursuant to that section and does not require the data be made publicly available. In addition, funding has been made available through several COVID-19 relief acts, which can be used to facilitate data sharing between the public health and health care sectors.

CDC can also form partnerships with specific jurisdictions, other federal agencies, and academic and nonprofit research institutions for public health data, an approach taken with some of CDC's genomic surveillance activities.[360]

What Are the Federal Testing Data Requirements, and Do They Vary by Type or Purpose of the Test?

On January 8, 2021, HHS updated June 2020 guidance to implement Section 18115 of the CARES Act. As a part of the guidance, the Secretary requires that all laboratories report data with a minimum set of required elements to state, local, tribal or territorial public health departments using existing reporting channels.[361] The minimum required data elements that must be reported for each test include, among other things, test result, patient characteristics (e.g., age, race, ethnicity, and sex), and geographic location (e.g., zip code and county). The guidance also provides that public health departments should collect information about a patient's address and

[358] CDC, "Genomic Surveillance for SARS-CoV-2 Variants," Updated April 2, 2021, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance.html.

[359] Lawrence O. Gostin and Lindsay F. Wiley, "Chapter Nine: Surveillance and Public Health Research: Privacy, Security, and Confidentiality of Personal Health Information," in *Public Health Law: Duty, Power, and Restraint*, 3rd ed. (University of California Press), pp. 303-344.

[360] CDC, "Coronavirus Disease 2019: SARS-CoV-2 Sequencing (SPHERES)," updated July 7, 2020, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/spheres.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fspheres.html.

[361] HHS "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115" guidance refers only to reporting requirements to state and local public health departments; however, complementary CDC guidance notes that "[t]hese data must be reported daily, within 24 hours of test completion, to the appropriate state, tribal, local, or territorial public health department based on the individual's residence." See CDC, How to Report COVID-19 Laboratory Data, updated January 26, 2021, at https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html#:~:text=Laboratories%20are%20not%20required%20to,with%20state%20law%20or%20policies).

phone number (which would allow for case investigation and contact tracing), but should not share this information with CDC.[362]

The guidance gives laboratories several options for submitting the data.[363] Health jurisdictions governments then share data with CDC on a daily basis.[364] Laboratories may submit through an automated platform that shares data automatically with jurisdictional authorities as well as with CDC.[365] According to CDC, 100% of state and territorial jurisdictions (including all 50 states, Washington DC, and five territorial jurisdictions) have converted to COVID-19 electronic laboratory reporting, representing 100% of the total laboratory testing volume in the country, as of April 21, 2021.[366]

CDC has clarified that all COVID-19 testing sites performing tests for diagnostic or screening purposes—including molecular, antigen, and antibody testing—are to report positive and negative test results to the respective health department within 24 hours of test completion per the HHS guidance.[367] Tests that are conducted for screening or diagnostic purposes should have results reported to the individual who was tested and the respective public health department; however, results of tests that are conducted for public health surveillance purposes should not be reported to the individual who was tested, and can be reported in aggregate to the respective health jurisdiction upon request, strictly for public health surveillance purposes.[368]

Some test types, in particular, have faced reporting challenges—especially antigen tests, which have been referred to as "rapid tests" and which are more often carried out at the point of care rather than in a centralized laboratory. In the months following the introduction of antigen tests in summer 2020, states and other jurisdictions varied in terms of whether they grouped molecular and antigen testing together in testing data, reported results for different test types separately, or reported antigen test results at all. Given differences in use of antigen tests compared with molecular tests, testing indicators that combine the two would lead to different overall testing positivity rates than testing metrics that rely solely on molecular tests.[369] GAO also reported in January 2021 that overall antigen test reporting by states and other jurisdictions was incomplete; therefore, HHS was not publicly reporting antigen test data and did not have plans to do so. Though requirements are in place to report antigen test results mentioned above, many institutions that conduct such tests for screening purposes—such as nursing homes, schools, pharmacies, correctional facilities—do not have procedures or capabilities in place to report test results to their respective health departments. HHS has thus far addressed the issue for nursing

[362] HHS, "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115," January 8, 2021, https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.

[363] Ibid. Specifically, laboratories may use existing reporting systems, as required by state or local law or policy, or may report through a state or regional health information exchange systems.

[364] Ibid.

[365] Association of Public Health Laboratories (APHL), "APHL AIMS Platform," https://www.aphl.org/programs/informatics/pages/aims_platform.aspx.

[366] CDC, "COVID-19 Electronic Laboratory Reporting Implementation by State," Updated April 20, 2021, https://www.cdc.gov/coronavirus/2019-ncov/lab/electronic-reporting-map.html; does not account for Tribal or local jurisdictions outside of the District of Columbia.

[367] CDC, "How to Report COVID-19 Laboratory Data," updated January 26, 2021, http://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.htlml.

[368] CDC, "Testing Strategies for SARS-CoV-2," updated March 11, 2021, https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/sars-cov2-testing-strategies.html#anchor_1615061534186.

[369] The COVID Tracking Project, "The State of State Antigen Test Reporting," October 19, 2020, https://covidtracking.com/analysis-updates/antigen-testing-reporting.

home data by facilitating data submission through a specific CDC data module used for nursing home data.[370] As of June 2021, HHS had not released similar guidance for other settings.

Looking ahead, newly introduced at-home diagnostic tests may present unique reporting challenges. These at-home tests are generally available over the counter or by provider prescription, and some at-home tests can be completed by the patient at home without the need to send specimens to a laboratory. CDC recommends that individuals report their results to their health care provider, who is required to subsequently send results to their patient's respective health jurisdiction; alternatively, some at-home tests come with instructions on how to report results directly to the patient's health jurisdiction via an online or mobile application.[371] FDA's guidance to manufacturers has recommended that at-home test design facilitate reporting results to health authorities, and some EUAs for at-home tests have required manufacturers to develop tools to facilitate reporting as a condition of the EUA (e.g., an online or mobile application).[372] Still, because these at-home tests require individuals, not institutions with legal obligations, to report results, there may be concerns that results will be underreported.

How Is Demographic Data on Individuals Who Have Been Tested Reported, and What Issues Have Arisen?

States and other jurisdictions are usually responsible for deciding what information to collect and share with CDC.[373] State and other jurisdictional law can constrain the data elements that can be shared with the federal government.[374] In the early stages of the pandemic, many jurisdictions were not collecting and/or reporting patient demographic information in case and testing data, such as on patients' race and ethnicity.[375] These reporting gaps owe to many factors. Throughout the COVID-19 pandemic, many jurisdictions have faced issues with incomplete data from laboratories. In many reported cases, testing data reported from laboratories were missing key patient information needed to contact the patient and conduct contact tracing. After a positive test result, public health departments follow up with patients and providers to obtain full details about the case—a difficult and time-consuming task, especially when jurisdictions experience a surge in cases. In addition, many public health departments rely on records shared by health care entities,

[370] U.S. Government Accountability Office, COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention, January 28, 2021, https://files.gao.gov/reports/GAO-21-265/index.html#appendix7.

[371] CDC, "Self-Testing," updated April 25, 2021, https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Ftesting%2Fat-home-testing.html.

[372] FDA, "Coronavirus (COVID-19) Update: FDA Posts New Template for At-Home and Over-the-Counter Diagnostic Tests for Use in Non-Lab Settings, Such as Homes, Offices or Schools," press release, July 29, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-posts-new-template-home-and-over-counter-diagnostic-tests-use-non, and Kelly Lewis Brezoczky, *Lucira COVID-19 All-In-One Test Kit*, FDA, November 17, 2020, https://www.fda.gov/media/143810/download.

[373] Lawrence O. Gostin and Lindsay F. Wiley, "Chapter Nine: Surveillance and Public Health Research: Privacy, Security, and Confidentiality of Personal Health Information," in *Public Health Law: Duty, Power, and Restraint*, 3rd ed. (University of California Press), pp. 303-344.

[374] Partnership for Public Health Law, "Legal Issues Related to Sharing of Clinical Health Data with Public Health Agencies," April 2016, https://www.astho.org/Public-Policy/Public-Health-Law/Legal-Issues-Related-to-Sharing-Clinical-Health-Data-with-Public-Health-Agencies/.

[375] Kelly Servick, "'Huge Hole' in Testing Data Blurs Racial, Ethnic Disparities," *Science*, July 17, 2020, https://science.sciencemag.org/content/369/6501/237.

such as laboratories. Laboratories, in particular, do not typically collect demographic data related to race/ethnicity. Patients may also be unwilling to share such information with providers.[376]

As described above, guidance issued pursuant to the provision in the CARES Act changed federal reporting requirements for jurisdictions, adding a requirement to report race/ethnicity with all test results in June 2020. According to data from April 30, 2021, 50 states report COVID-19 cases and deaths by race/ethnicity, and 7 states and DC report testing data (positive and negative results) by race only.[377] As of June 3, 2021, 62% of total cases reported to CDC included data on race/ethnicity.[378]

Though data collection has somewhat increased, such missing data issues have hindered the public health response and experts' ability to maintain situational awareness. CDC and the federal government are seeking to address data issues through several efforts, including its Data Modernization Initiative and various taskforces for public health data strategies and policy development.[379]

[376] Darius Tahir, "Virus Hunters Rely on Faxes, Paper Records as More States Reopen," *Politico*, May 10, 2020; and Council of State and Territorial Epidemiologists, *Driving Public Health in the Fast Lane: The Urgent Need for a 21st Century Data Superhighway*, September 2019, https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/Driving_PH_Display.pdf.

[377] Johns Hopkins University (JHU) Coronavirus Resource Center, "Racial Data Transparency: States that have Released COVID-19 Data by Race," last viewed April 30, 2021, https://coronavirus.jhu.edu/data/racial-data-transparency.

[378] CRS Report R46588, *Tracking COVID-19: U.S. Public Health Surveillance and Data*.

[379] Health IT.gov, "Public Health Data Systems Task Force 2021," last updated April 30, 2021, https://www.healthit.gov/hitac/committees/public-health-data-systems-task-force-2021.

Appendix A. Acronyms Used in This Report

Acronym	Definition
AACC	American Association for Clinical Chemistry
ABP	Alternative Benefit Plans
ACA	Patient Protection and Affordable Care Act
AIMS	APHL Informatics Messaging Services
APHL	Association of Public Health Laboratories
AMP	Association for Molecular Pathology
ARPA	American Rescue Plan Act
ASCM	Association for Supply Chain Management
ASM	American Society for Microbiology
ASPR	Assistant Secretary for Preparedness and Response
BHP	Basic Health Program
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CBTS	Community-Based Testing Sites
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
CNMI	Commonwealth of Northern Mariana Islands
COBRA	Consolidated Omnibus Budget Reconciliation Act
CRF	Coronavirus Relief Fund
DCIPHER	Data Collation and Integration for Public Health Event Response
DOD	Department of Defense
DOL	Department of Labor
DPA	Defense Production Act
DRF	Disaster Relief Fund
EMTALA	Emergency Medical Treatment and Active Labor Act
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
EUA	Emergency Use Authorization
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FEHB	Federal Employees Health Benefits Program
FEMA	Federal Emergency Management Agency
FFCRA	Families First Coronavirus Response Act
FMAP	Federal Medical Assistance Percentage

Acronym	Definition
FQHC	Federally Qualified Health Center
HHS	Department of Health and Human Services
HMO	Health Maintenance Organization
HRSA	Health Resources and Services Administration
IDRRRF	Infectious Disease Rapid Response Reserve Fund
IHCIA	Indian Health Care Improvement Act
IHS	Indian Health Service
IVD	In Vitro Diagnostics
LDT	Laboratory-Developed Test
LTCF	Long-Term Care Facility
LTSS	Long-Term Services and Support
MA	Medicare Advantage
MHS	Military Health Services
MOU	Memorandum of Understanding
MTF	Military Treatment Facility
NAIC	National Association of Insurance Commissioners
NCI	National Cancer Institute (of the National Institutes of Health)
NF	Nursing Facility
NGA	National Governors Association
NIH	National Institutes of Health
NNDS	National Notifiable Diseases Surveillance System
OIG	Office of Inspector General (HHS)
OS	Office of the Secretary (HHS)
OTC	Over-the-Counter
PA	Public Assistance (FEMA)
PAPPG	Public Assistance Program and Policy Guide (FEMA)
PCR	Polymerase Chain Reaction
PHSA	Public Health Service Act
PHEP	Public Health Emergency Preparedness
PHSSEF	Public Health and Social Services Emergency Fund
POC	Point-of-Care
PPE	Personal Protection Equipment
PPPHCEA	Paycheck Protection Program and Health Care Enhancement Act
PRF	Provider Relief Fund
PRWORA	Personal Responsibility and Work Opportunity Reconciliation Act of 1996
RHC	Rural Health Clinic
RNA	Ribonucleic acid

Acronym	Definition
SLTT	State, local, territorial, and tribal
SNF	Skilled Nursing Facility
SNS	Strategic National Stockpile
SPA	State Plan Amendment
SPHERES	Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance
SSA	Social Security Act
STLDI	Short-term, limited duration insurance
TTSI	Testing, Tracing, and Supported Isolation
USC	United States Code
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VTM	Viral Transport Media

Appendix B. Policy Experts Table

Topic	Contact
Types of COVID-19 Testing and Their Uses	Amanda K. Sarata
Test Accuracy	Amanda K. Sarata
Testing Infrastructure, Capacity and Strategies	Amanda K. Sarata Hassan Z. Sheikh
Testing Supply Chain	Amanda K. Sarata Erica A. Lee
Priority for Testing Individuals	Kavya Sekar Hassan Z. Sheikh
Role of Federal Emergency Management Agency in Testing: Infrastructure, Delivery and Payment	Erica A. Lee
Role of Public Health Departments in Testing	Kavya Sekar Hassan Z. Sheikh Taylor R. Wyatt Sarah Lister
Testing for Uninsured Individuals	Elayne J. Heisler
Testing Disparities	Taylor R. Wyatt
Bureau of Prison Health Care	Nathan James
Defense Health Care	Bryce H. P. Mendez Alan Ott
Veterans Health Care	Sidath Viranga Panangala Jared S. Sussman
Indian Health Service	Elayne J. Heisler Taylor R. Wyatt
Medicaid and the State Children's Health Insurance Program (CHIP)	Evelyne P. Baumrucker
Medicare	Jim Hahn
Private Health Insurance	Vanessa C. Forsberg
Private Health Insurance (Out of Network)	Noah D. Isserman
Private Health Insurance (Legal Issues)	Jennifer A. Staman
Funding for Testing	Kavya Sekar Taylor R. Wyatt
Unauthorized Immigrants' Access to Testing	Abigail F. Kolker
Use of Uninsured Fund for Testing	Elayne J. Heisler
Medicaid Funding for Testing Uninsured Individuals	Evelyne P. Baumrucker
Testing Data Reporting	Kavya Sekar Taylor R. Wyatt Sarah Lister
Resources on Testing	Kate M. Costin

Appendix C. Additional Resources

Below are frequently cited resources related to COVID-19 testing in the United States. This appendix includes selected federal, academic, and stakeholder resources available at the time of this report's publication. Federal agencies continue to update guidance to reflect the current situation. Please note, this is not a comprehensive list of resources.

Data Repositories

Preliminary data reported by U.S. laboratories including commercial reference, public health, and hospital; totals may include antibody data from some states.

Centers for Disease Control and Prevention (CDC)

- CDC COVID Data Tracker: United States Laboratory Testing, Testing and Seroprevalence, updated regularly, https://www.cdc.gov/covid-data-tracker/#testing
- Previous U.S. Viral Testing Data August 27, 2020, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/previous-testing-in-us.html

Coronavirus Resource Center, John Hopkins University & Medicine

For a complete list of data contributors, visit https://github.com/CSSEGISandData/COVID-19/blob/master/README.md

- COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University, updated regularly, https://coronavirus.jhu.edu/map.html
- Johns Hopkins COVID-19 Testing Insights Initiative, updated regularly, https://coronavirus.jhu.edu/testing
- Testing Trends Tool, updated regularly, https://coronavirus.jhu.edu/testing/tracker/overview
- All State Comparison of Testing Efforts, updated regularly, https://coronavirus.jhu.edu/testing/states-comparison
- Daily State-by-State Testing Trends, updated regularly, https://coronavirus.jhu.edu/testing/individual-states
- Which U.S. States Meet WHO Recommended Testing Criteria?, updated regularly, https://coronavirus.jhu.edu/testing/testing-positivity
- International Comparison of Positivity Rates and Tests Per Capita, updated regularly, https://coronavirus.jhu.edu/testing/international-comparison
- Racial Data Transparency: States that have released breakdowns of COVID-19 data by race, updated regularly, https://coronavirus.jhu.edu/data/racial-data-transparency

Department of Health and Human Services (HHS) Guidance

Department of Health and Human Services (HHS)

- COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115, https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf
- COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting, https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf%3C

Centers for Disease Control and Prevention (CDC)

- CDC COVID-19 Search Guidance Documents, Testing, https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Adesc&Topic=Disease%20Information%20%3E%20Testing
  - Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19, https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
  - Testing Guidelines for Nursing Homes, https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
  - Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2, https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.html
  - Interim Considerations for Institutions of Higher Education Administrators for SARS-CoV-2 Testing, https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html
  - Interim Guidelines for COVID-19 Antibody Testing, https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

Centers for Medicare & Medicaid Services (CMS)

- Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency, https://www.cms.gov/files/document/qso-20-21-clia.pdf-0
- Frequently Asked Questions: SARS-CoV-2 Surveillance Testing, https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf
- Medicare Administrative Contractor (MAC) COVID-19 Test Pricing, https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf
- COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies, https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf
- Current emergencies, Coronavirus Disease 2019, updated regularly, https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

- Coronavirus Disease 2019 (COVID-19) Guidance, Updated as new Center for Consumer Information and Insurance Oversight guidance documents are published, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#COVID-19

Food and Drug Administration (FDA)

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), May 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised
- FAQs on Testing for SARS-CoV-2, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2

HHS, Department of Labor, and the Treasury

- FAQS about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42, April 11, 2020, https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf
- FAQS about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43, June 23, 2020, https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf
- Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 *Federal Register* 71142, November 6, 2020
- FAQS ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 44, February 26, 2021, https://www.cms.gov/files/document/faqs-part-44.pdf

Federal COVID-19 Guidance (Non-HHS)

U.S. Equal Employment Opportunity Commission (EEOC)

- What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

White House

Biden Administration

- National Strategy for the COVID-19 Response and Pandemic Preparedness, January 2021, https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf

Trump Administration

- Testing Blueprint: Opening Up America Again, April 2020, https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/04/Testing-Blueprint.pdf
- Testing Overview: Opening Up America Again, April 2020, https://www.trumpwhitehouse.gov/wp-content/uploads/2020/04/Testing-Overview-Final.pdf
- Guidance on Interpreting COVID-19 Test Results, May 6, 2020, https://www.trumpwhitehouse.gov/wp-content/uploads/2020/05/Testing-Guidance.pdf
- Addendum to the Testing Blueprint, June 2020, https://www.trumpwhitehouse.gov/wp-content/uploads/2020/06/Addendum-to-the-testing-blueprint-FINAL.pdf

Test Strategies

Centers for Disease Control and Prevention (CDC)

- SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces, https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html
- Testing Strategy for Coronavirus (COVID-19) in High-Density Critical Infrastructure Workplaces after a COVID-19 Case is Identified, https://www.cdc.gov/coronavirus/2019-ncov/community/worker-safety-support/hd-testing.html
- COVID-19 Serology Surveillance Strategy, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html

Department of Health and Human Services (HHS)

- Report to Congress: COVID-19 Strategic Testing Plan, May 24, 2020, https://www.democrats.senate.gov/imo/media/doc/COVID%20National%20Diagnostics%20Strategy%2005%2024%202020%20v%20FINAL.pdf

National Academy of Medicine (NAM)

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