Broad access to the COVID-19 diagnostic test will enable the Centers for Disease Control and Prevention (CDC) as well as local and State public health departments to accurately track the course of the pandemic in our country, which will in turn lead to more aggressive treatment and the ability to identify when confirmed cases begin to reduce. One key element of the Family First Coronavirus Response Act (H.R. 6201), the Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748), and the Paycheck Protection Program and Health Care Enhancement Act (H.R. 266) was ensuring appropriate coverage, without cost-sharing, for the COVID-19 test. The goal of this primer is to detail the specific coverage and cost-sharing elements within the Federal legislation, identify any gaps in coverage, and detail current State responses.

Who’s Covered
The Family First Coronavirus included provisions to extend coverage, without cost-sharing, for certain COVID-19 tests and related services for those:

- With individual and group health insurance (including ERISA and grandfathered plans) (per section 6001),
- Covered by Medicare fee-for-service (section 6002) and Medicare Advantage (section 6003),
- Covered by Medicaid and the Children’s Health Insurance Program (CHIP)(section 6004),
- With coverage through the Department of Defense (i.e., TRICARE)(Section 6006), the Department of Veterans Affairs (Section 6006), and Federal civilians (i.e., FEHBP) (Section 6006),
- Covered by the Indian Health Service (IHS)(Section 6007), and
- Without insurance by providing a State option to expand Medicaid for those individuals with a 100% FMAP for the COVID-19 services or, if the State does not opt to expand Medicaid, for payment through the National Disaster Medical System (NDMS).

In addition, for many of the Federal programs, the H.R. 6201 adds additional funding for these activities including:

- $82 M for the Department of Defense,
- $60 M for the Department of Veterans Affairs,
- $64 M for the Indian Health Service, and
- $1B for the uninsured through NDMS. H.R. 266 added an additional $1B for the uninsured for a total of $2 B.

What’s Included in the Coverage
H.R. 6201 uniformly provides coverage, without cost sharing, for: (1) COVID-19 testing and (2) for the professional services tied to administering the test (i.e., doctor’s visit, ED visit, or urgent care visit). Further, coverage must be made available without requiring prior authorization from a health insurance plan.

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1 Section 3716 of HR 748 clarified the definition of uninsured by stating: “Such term shall include an individual who is described in subclause (VIII) of section 1902(a)(10)(A)(i) if such individual resides in a State that does not make medical assistance available to individuals described in such subclause. Such term shall also include individuals who are enrolled for benefits under a State program under this title or another Federal health care program (as so defined) but whose benefits under such program do not include coverage at no cost sharing of a COVID-19 vaccine (and the administration of such vaccine) or coverage at no cost sharing of an in vitro diagnostic testing product described in section 1905(a)(3)(B) (and the administration of such product).”
H.R. 6201 initially limited coverage to tests with an Emergency Use Authorization (EUA). On March 16, the Food and Drug Administration (FDA) released a final guidance document which would allow additional tests to be used, beyond those with an EUA. This would include tests approved by States. The guidance also allows a fourteen-day window for use of tests that are in the process of obtaining an EUA. However, in the field, it is unlikely that physicians and other clinicians will know details about the regulatory status of a given test; instead, they must use what is available. The CARES Act addressed this issue in sections 3201 and 3702 by covering all tests under the FDA guidance.

On April 8, Sen. Alexander (R-Tenn.) and Sen. Blunt (R-Mo.) sent a letter to HHS urging coverage of COVID-19 antibody tests. On April 11, the Centers for Medicare and Medicaid Services (CMS) issued FAQs regarding the coverage of COVID-19 testing and clarified two key issues: (1) that antibody tests, while not approved by the FDA for diagnosis, were still covered by the law’s requirements; and (2) the requirement to provide coverage for “related” tests (per Q5).

**Provider Payment Amount**

Under section 3202, the CARES Act further clarified the reimbursement for COVID-related testing from a group health plan (including grandfathered and ERISA plans) or a health insurance issuer would be either (1) the in-network rate or (2) “the cash price for such service as listed by the provider on a public internet website, or such plan or issuer may negotiate a rate with such provider for less than such cash price.”

**What’s Not Included in the Coverage**

Despite these key coverage provisions, there are still a few potential gaps in coverage, including (1) coverage of professional services when the diagnostic is unavailable and (2) subsequent treatment (except for the certain insurers and the uninsured).

**Coverage of Professional Services when Diagnostic is Not Utilized.** Of course, any discussion of COVID-19 diagnostic reimbursement assumes that a diagnostic is utilized. However, there are widespread reports of insufficient diagnostics as well as policies regarding presumptive testing. As patients present, clinicians are assessing patients and recommending self-quarantine in suspected cases, even when there is no diagnosis confirmed by diagnostic testing. On March 20, several members of Congress wrote to key insurers asking them to cover “presumptive” testing, given that the tests are not always available. The letter also urged insurers to cover subsequent treatment. Subsequent to that letter, CVS, Cigna, and Humana opted to provide such coverage, with certain caveats.

**Subsequent Treatment.** In addition to the diagnostic, patients may incur significant out-of-pocket costs for treatment of any disease – including COVID-19. Thus far, the insurance industry has catalogued the response, which does include some coverage for subsequent care and treatment. Further, States have opted to move forward with specific insurer requirements. Additional State efforts to address potential gaps in coverage are being followed by the Commonwealth Fund, with a map here.

**Coverage of the Uninsured**

As outlined in HR 6201, coverage for the uninsured follows two potential routes – (1) either a State opts to temporarily expand its Medicaid program to allow for limited coverage for the uninsured under a section 1135 waiver for the COVID-19 test and professional services related to that test; or (2) for States that do not provide such expansion, reimbursement from the National Disaster Medical System (NDMS).

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2 Note: This expansion is separate and distinct from the Medicaid expansion related to the Affordable Care Act (ACA).
**Section 1135 waivers.** To determine whether a particular State has opted to expand Medicaid to cover the uninsured for COVID-19 testing, please visit the CMS website. Separately, the Kaiser Family Foundation is tracking which States opt to expand testing coverage to the uninsured.

**NDMS.** According to the statute, for States who do not opt to expand Medicaid, then those services would be reimbursed through the NDMS. HHS seems to have opted to provide such reimbursement through the CARES Act Provider Relief Fund (more below).

**Subsequent Treatment.** On April 3, during the Task Force press conference, Secretary Azar noted that a portion of the $100B provided to the Public Health and Social Services Fund (PHSSEF) for health care providers in the CARES Act would be allocated to cover the cost of the treatment for the uninsured. Such funding would be through the same mechanism as COVID-19 testing. As a condition of receiving the funds, providers would have to agree not to balance bill, and the reimbursement rates would be set at Medicare rates.

On April 7, CMS Administrator Seema Verma noted that $30B of the $100B fund through the PHSSEF for health care providers, **$30 billion will be available, based on Medicare revenue**, and such funds will NOT be on a first come, first serve basis and would not need to be repaid. To receive the funds, providers will need to register with CMS. Money can be direct deposited. She acknowledged that certain providers (e.g., pediatricians, OB/Gyns, etc.) do not serve a large portion of the Medicare population. As such, CMS will address those issues in the second wave of funding from the fund. During that announcement, there was no discussion regarding the uninsured. On **April 10**, the first wave of funds were made available. During that announcement, HHS clarified that there would be a subsequent determination regarding coverage of the uninsured.

On April 7, the Kaiser Family Foundation (KFF) released a report that estimated that “total payments to hospitals for treating uninsured patients under the Trump administration policy would range from $13.9 billion to $41.8 billion. At the top end of the range, payments on behalf of the uninsured would consume more than 40% of the $100 billion fund Congress created to help hospitals and others respond to the COVID-19 epidemic.”

On April 22, HHS provided key information regarding coverage of the uninsured through the CARES Act Provider Relief Fund. It seems as if the intent is to bypass the NDMS and provide reimbursement through this separate mechanism. Every health care provider, who has provided treatment for uninsured COVID-19 patients in the U.S. on or after February 4, 2020, can request claims reimbursement through the program and will be reimbursed at Medicare rates, subject to available funding.

To receive the funds, providers must enroll in the program (starting on April 27), confirm patient eligibility and benefits, submit patient information, submit claims (starting on May 6), and receive payment via direct deposit (starting mid-May). Providers must also agree to program terms and conditions and may be subject to post-reimbursement audit review. All claims will be subject to the same timely filing requirements required by Medicare, and all claims must be complete and final.

Reimbursement will be made for qualifying testing for COVID-19 and treatment services with a primary COVID-19 diagnosis, including:

- Specimen collection, diagnostic and antibody testing.
- Testing-related visits including in the following settings: office, urgent care or emergency room or via telehealth.
- Treatment: office visit (including via telehealth), emergency room, inpatient, outpatient/observation, skilled nursing facility, long-term acute care (LTAC), acute inpatient rehab, home health, DME (e.g., oxygen, ventilator), emergency ground ambulance transportation, non-emergent patient transfers via
ground ambulance, and FDA approved drugs as they become available for COVID-19 treatment and administered as part of an inpatient stay.

- When an FDA-approved vaccine becomes available, it will also be covered.

Services not covered by traditional Medicare will also not be covered under this program. In addition, the following services are excluded:

- Air and water ambulance.
- Any treatment without a COVID-19 primary diagnosis, except for pregnancy when the COVID-19 code may be listed as secondary.
- Hospice services.
- Outpatient prescription drugs covered under Medicare Part D.

For more HHS information, visit here.

**Other Federal Efforts**

With regard to Medicare and Medicaid, the Centers for Medicare and Medicaid Services (CMS) has issued information related to coverage of COVID-19 testing, which was further updated on April 21 for Medicare Advantage and Part D plans as well as individual and small group plans. In addition, CMS has also stated that COVID-19 testing is an Essential Health Benefit (EHB), and the IRS has issued guidance regarding High Deductible Health Plans to allow for the elimination of cost-sharing for COVID-19 testing.