Background
On Saturday, April 11, 2020 CMS, together with the Departments of Labor and the Treasury, issued guidance to ensure that Americans with private health insurance have coverage of COVID-19 diagnostic testing and certain other related services, including antibody testing, at no cost.

The Families First Coronavirus Response Act (FFCRA) was enacted on March 18, 2020. According to the FAQ released on April 11:

"Section 6001 of the FFCRA generally requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits for certain items and services related to diagnostic testing for the detection of SARS-CoV-2 or the diagnosis of COVID-19 (referred to collectively in this document as COVID-19) when those items or services are furnished on or after March 18, 2020, and during the applicable emergency period. Under the FFCRA, plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance) or prior authorization or other medical management requirements."

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted on March 27, 2020 and amended Section 6001 of the FFCRA:

"Section 3201 of the CARES Act amended section 6001 of the FFCRA to include a broader range of diagnostic items and services that plans and issuers must cover without any cost-sharing requirements or prior authorization or other medical management requirements.

Additionally, section 3202 of the CARES Act generally requires plans and issuers providing coverage for these items and services to reimburse any provider of COVID-19 diagnostic testing an amount that equals the negotiated rate or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on a public website. (The plan or issuer may negotiate a rate with the provider that is lower than the cash price)."

The Acts apply to:

- Group health plans and health insurance issuers offering group or individual health insurance coverage including:
  - Grandfathered health plans as defined in section 1251(e) of the Patient Protection and Affordable Care Act.
  - Insured and self-insured group health plans.
  - Private employment-based group health plans (ERISA plans).
  - Non-federal governmental plans (such as plans sponsored by states and local governments).
  - Church plans.

- Individual health insurance coverage includes
  - Coverage offered in the individual market through or outside of an Exchange.
  - Student health insurance coverage (as defined in 45 CFR 147.145).

Section 6001 does not apply to:

- Short-term, limited-duration insurance (as defined in 26 CFR 54.9801-2, 29 CFR 2590.701-2, and 45 CFR 144.103).

- Plan or coverage in relation to its provision of excepted benefits (as defined in 26 CFR 54.9831-1(c), 29 CFR 2590.732(c), and 45 CFR 146.145(b) and 148.220).

- Group health plans that do not cover at least two employees who are current employees (such as plans in which only retirees participate).

The Acts require plans and issuers to provide coverage for the following items and services provided on or after March 18, 2020:

- In vitro diagnostic test for the detection of SARS-CoV-2 or the diagnosis of COVID-19 including administration of such a test that:
  - Is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act.
- The developer has requested, or intends to request, emergency use authorization, unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe.

- Is developed in and authorized by a State that has notified the Secretary of HHS of its intention to review tests intended to diagnose COVID-19.

- Includes other tests that the Secretary of HHS determines appropriate such as Serological tests for COVID-19 that are used to detect antibodies against the SARS-CoV-2 virus, and are intended for use in the diagnosis of the disease or condition of having current or past infection with SARS-CoV-2, the virus which causes COVID-19.

- Items and services furnished to an individual during health care provider visits that result in an order for or administration of an in vitro diagnostic product described above but only to the extent:
  - Service was rendered during one of the following:
    - Office visits (which includes in-person visits and telehealth visits).
    - Urgent care center visits.
    - Emergency room visits.
    - COVID-19 drive-through screening and testing sites where licensed healthcare providers are administering COVID-19 diagnostic testing.

- Evaluation of the individual for purposes of determining the need of the individual for such product. If the individual's attending provider determines that other tests (e.g., influenza tests, blood tests, etc.) should be performed 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.

Guidance
- Review guidelines with registration and collection staff to ensure the exemption to cost sharing is applied to all applicable groups.
- Refund out-of-pocket collections after March 18, 2020 related to these services.
- Follow specific commercial insurance instruction for use of Modifier CS, Cost Sharing Waived, or other guidance regarding claim submission.

Sources