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Frequently Asked Questions on Health Plan Coverage under the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act, Part 3

5-Minute Read

The Department of Labor (DOL), Department of Health and Human Services (HHS), and the Department of the Treasury (collectively, the Departments), issued frequently asked questions (FAQs) regarding implementation of the Families First Coronavirus Response Act (the FFCRA), the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), and other health coverage issues related to coronavirus disease 2019 (COVID-19). These FAQs are in addition to the frequently asked questions the Departments previously released regarding health plan coverage under the FFCRA and CARES Act. See our Part 1 and Part 2 Advisors on the prior FAQs.

Below is a summary of the Departments' answers to the most recently released FAQs.

Coverage Under the FFCRA, as Amended by the CARES Act

Under the FFCRA, plans and issuers, including grandfathered health plans, must provide coverage for an in vitro diagnostic test for the detection of SARS-CoV-2 or the diagnosis of COVID-19, and the administration of such a test that meets one of the following four requirements when those items or services are furnished on or after March 18, 2020, through the applicable HHS public emergency period. Plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements. Note, HHS has sent a letter to state governors that the HHS public health emergency will likely remain in place for all of 2021 and that HHS will provide states with 60 days' notice prior to termination of the public health emergency.

1. The test is approved, cleared, or authorized under the Federal Food, Drug, and Cosmetic Act (FFDCA).

   All in vitro diagnostic tests for COVID-19 that have received an emergency use authorization (EUA) under the FFDCA are listed on the EUA webpage of the FDA website.

2. The developer has requested, or intends to request, EUA under the FFDCA, unless and until the EUA request has been denied or the developer of such test does not submit a request within a reasonable time.

   The FDA website provides a list of clinical laboratories and commercial manufacturers that have notified the FDA that they have validated their own COVID-19 test and are offering the test as outlined in FDA guidance. Plans and issuers must cover in vitro diagnostic tests for COVID-19 that are included on this list. A plan or issuer may take reasonable steps to verify that a test offered by a developer meets the statutory criteria. For example, a plan or issuer may request that a laboratory or commercial manufacturer provide documentation, such as a copy of the EUA request or pre-EUA submitted to the FDA, to demonstrate that it has requested or intends to request an EUA. These requests will not be considered to violate the FFCRA prohibition on medical management requirements if they are reasonable and necessary to verify that a COVID-19 test meets the statutory criteria.

3. The test 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.

   States and territories that have notified the FDA that they choose to use this flexibility are listed on the FDA website.

4. Other tests that the Secretary of HHS determines appropriate in guidance.

COVID-19 Diagnostic Testing

The FAQs provide that plans and issuers are prohibited from using medical screen criteria to deny a claim for COVID-19 diagnostic testing for an asymptomatic person who has no known or suspected exposure to COVID-19 when the purpose of the testing is for individualized diagnosis or treatment of COVID-19. While 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 limits on testing falls on health care providers, not on plans and issuers. However, plans and issuers are not required to provide coverage of testing such as for public health surveillance or employment purposes when the testing is not primarily intended for individualized diagnosis or treatment of COVID-19.

Any health care provider acting within the scope of their license or authorization can make an individualized clinical assessment regarding COVID-19 diagnostic testing. Therefore, if any individual seeks and receives a COVID-19 diagnostic test from a licensed or authorized provider, including from a state or locality-administered site, a drive-through site, or site that

does not require appointments, plans and issuers generally must assume the test reflects an individualized clinical assessment (this includes point-of-care tests).

Under the CARES Act, a health plan or issuer covering diagnostic testing for COVID-19 must reimburse the provider of the diagnostic testing at the negotiated rate for the service. If the health plan or issuer does not have a negotiated rate with the provider, the reimbursement rate will be the cash price for the service as listed by the provider on a public internet website, or a lower negotiated rate. If a plan or issuer does not have a negotiated rate with a provider and the provider has not made public the price, the plan or issuer may negotiate the price. If a health plan or issuer identifies providers who are not complying with these requirements, the FAQs encourage them to report violations to COVID19CashPrice@cms.hhs.gov. The FAQs also encourage plans and issuers to respond to such violations by giving covered individuals information about providers who have negotiated rates for COVID-19 testing with the plan or issuer.

Rapid Coverage of Preventive Services for Coronavirus

The CARES Act requires non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover, without cost-sharing requirements, any qualifying coronavirus preventive services pursuant to section 2713(a) of the Public Health Services (PHS) Act and its implementing regulations (or any successor regulations). The term “qualifying coronavirus preventive service” means an item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is, with respect to the individual involved:

- An evidence-based item or service that has in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF); or
- An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) (regardless of whether the immunization is recommended for routine use).

Plans and issuers must cover qualifying coronavirus preventive services without cost sharing starting no later than 15 business days after the date that USPSTF or ACIP recommends the qualifying coronavirus preventive service.

As of the date of this writing, two COVID-19 vaccines have received a recommendation from ACIP. Plans and issuers must cover the Pfizer BioNTech COVID-19 vaccine as of January 5, 2021, and the Moderna COVID-19 vaccine as of January 12, 2021. See our Advisor for more information. Alternative COVID-19 vaccines are likely to be approved by the FDA under emergency authority. Group health plans should continue to stay apprised of other approved COVID-19 vaccines.

The FAQs provide that plans and issuers must cover without cost sharing an immunization that is a qualifying coronavirus preventive service and its administration, regardless of how the administration is billed, and regardless of whether a COVID-19 vaccine or any other immunization requires the administration of multiple doses in order to be considered a complete

vaccination. This includes covering without cost sharing the administration of a required preventive immunization in instances where a third party, such as the federal government, pays for the preventive immunization.

The FAQs provide that plans and issuers must provide coverage without cost sharing of COVID-19 immunizations in accordance with the ACIP recommendations regardless of whether an individual falls into the current prioritization phase set forth by the CDC or prioritization set forth by states or localities (as of the time of this writing, the CDC recommends that individuals in phases 1a, 1b, and 1c should be prioritized). An individual's provider's decision to decline to give the vaccine to someone because he or she is not within a current prioritization category is not an adverse benefit determination made by a group health plan or issuer. Therefore, the provider's decision is not subject to the internal claims and appeals and external review requirements under section 2719 of the PHS Act (incorporated into the Employee Retirement Income Security Act (ERISA) by section 715 of ERISA and the Internal Revenue Code (Code) by section 9815 of the Code).

Notice Requirements

Under the PHS Act, if a plan makes a material modification, as defined under ERISA, in any of the terms of the plan or coverage that would affect the content of the Summary of Benefits and Coverage (SBC) that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees not later than 60 days prior to the date on which the modification will become effective. However, the FAQs reiterate that the Departments will not take enforcement action against any plan or issuer that makes a modification to increase benefits, or reduce or eliminate cost-sharing requirements, for the diagnosis or treatment of COVID-19 and telehealth or other remote care services, without providing at least 60 days' advance notice during the public health emergency or national emergency declaration period related to COVID-19. For example, the FAQs specifically note that it would be impossible to comply with the advance notice requirements regarding coverage of qualifying coronavirus preventive services. The plan or issuer still must provide notice of the changes as soon as reasonably practicable.

Excepted Benefits

The FAQs reiterate that an on-site medical clinic that constitutes an excepted benefit in all circumstances under 26 CFR 54.9831-1(c)(2) may offer benefits for diagnosis and testing for COVID-19 without losing its excepted benefits status. Also, an employee assistance program (EAP) that qualifies as a limited excepted benefit may offer benefits for diagnosis and testing for COVID-19 during the public health emergency declaration under the PHS Act for COVID-19 or a national emergency declaration under the National Emergencies Act related to COVID-19. Under final regulations, an EAP qualifies as a limited excepted benefit if it satisfies the following requirements:

1. The EAP does not provide significant benefits in the nature of medical care. For this purpose, the amount, scope, and duration of covered services are taken into account.
2. The benefits under the EAP are not coordinated with benefits under another group health plan:
    a. Participants in the other group health plan must not be required to use and exhaust benefits under the EAP before an individual is eligible for benefits under the other group health plan; and
    b. Participant eligibility for benefits under the EAP must not be dependent on participation in another group health plan.
3. No employee premiums or contributions are required as a condition of participation in the EAP.
4. There is no cost sharing under the EAP.

3/1/2021