FAQS provide additional guidance on group health plan coverage of COVID-19 testing, telehealth, wellness and more under FFCRA and CARES Act

The Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (Departments) have issued additional 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 COVID-19.

Group health plans. The FAQs confirm, as provided in prior in FAQs (Part 42, Q1), that the requirements of FFCRA Sec. 6001, regarding coverage for certain items and services related to COVID-19 diagnostic testing, apply to both insured and self-insured group health plans.

Covered tests. Section 6001(a) of the FFCRA requires plans and issuers to provide coverage for an in vitro diagnostic test (as defined in 21 CFR 809.3) for the detection of SARS-CoV-2 or the diagnosis of COVID-19, and the administration of such a test, that:

A. is approved, cleared, or authorized under sections 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act;
B. the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act unless and until the emergency use authorization request has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;
C. 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; or
D. other tests that the Secretary of HHS determines appropriate in guidance.

The FAQs indicate that at this time, the FDA has not cleared or approved an in vitro diagnostic test for COVID-19 under the other regulatory pathways outlined in A above.

For purposes of B above, also available on the FDA website is a list of clinical laboratories and commercial manufacturers that have notified FDA that they have validated their own COVID-19 test and are offering the test as outlined in FDA guidance.

For purposes of C above, states and territories may authorize laboratories within that state or territory to develop and perform a test for COVID-19, as outlined in FDA guidance. States and territories that have notified FDA that they choose to use this flexibility are listed at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#offeringtests.

For purposes of D above, no other tests have been specified in guidance by the Secretary of HHS at this time.

Attending health care provider. The Departments clarify that a health care provider need not be "directly" responsible for providing care to the patient to be considered an attending provider, as long as the provider makes an individualized clinical assessment to determine whether the test is medically appropriate for the individual in accordance with current accepted standards of medical practice. Therefore, an attending provider for purposes of FFCRA Sec. 6001 is an individual who is licensed (or otherwise authorized) under applicable law, who is acting within the scope of the provider's license (or

authorization), and who is responsible for providing care to the patient. As stated in FAQs Part 42, a plan, issuer, hospital, or managed care organization is not an attending provider.

At-home testing. The FAQs indicate that COVID-19 tests intended for at-home testing (including tests where the individual performs self-collection of a specimen at home) must be covered, when the test is ordered by an attending health care provider who has determined that the test is medically appropriate for the individual based on current accepted standards of medical practice and the test otherwise meets the statutory criteria. Consistent with FFCRA Sec. 6001, this coverage must be provided without imposing any cost-sharing requirements, prior authorization, or other medical management requirements.

Testing for employment purposes. 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 FFCRA Sec. 6001.

Multiple tests. Plans and issuers are required to cover multiple diagnostic tests for COVID-19. The coverage required for items and services is not limited with respect to the number of diagnostic tests for an individual, 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.

Facility fee. If a facility fee is charged for a visit that results in an order for or administration of a COVID-19 diagnostic test, the plan or issuer also must cover the facility fee without imposing cost-sharing requirements to the extent the facility fee relates to the furnishing or administration of a COVID-19 test or to the evaluation of an individual to determine the individual's need for testing. For example, if an individual is treated in the emergency room and the attending provider orders a number of services to determine whether a COVID-19 diagnostic test is appropriate, such as diagnostic test panels for influenza A and B and respiratory syncytial virus, as well as a chest x-ray, and ultimately orders a COVID-19 test, the plan or issuer must cover those related items and services without cost sharing, prior authorization, or other medical management requirements, including any physician fee charged to read the x-ray and any facility fee assessed in relation to those items and services.

Reimbursements. The reimbursement requirements of CARES Act Sec. 3202(a) do not apply to any items and services other than diagnostic testing for COVID-19. CARES Act Sec. 3202(a) describes the amount a plan or issuer must reimburse a provider for COVID-19 testing, but does not address the reimbursement rate for any other items and services.

The FAQs also indicate that the statute generally precludes balance billing for COVID-19 testing. However, it does not preclude balance billing for items and services not subject to CARES Act Sec. 3202(a) although balance billing may be prohibited by applicable state law and other applicable contractual agreements.

Also, regarding reimbursement rates, the FAQs explain that the requirement to reimburse the provider an amount that equals the cash price of a COVID-19 test is contingent upon the provider making public the cash price for the test, as required by CARES Act Sec. 3202(b). If the provider has not complied with this requirement, and the plan or issuer does not have a negotiated rate with the provider, the plan or

issuer may seek to negotiate a rate with the provider for the test. However, the CARES Act is silent with respect to the amount to be reimbursed for COVID-19 testing in circumstances where the provider has not made public the cash price for a test and the plan or issuer and the provider cannot agree upon a rate that the provider will accept as payment in full for the test. CARES Act Sec. 3202(b) grants the Secretary of HHS authority to impose civil monetary penalties on any provider of a diagnostic test for COVID-19 that does not comply with the requirement to publicly post the cash price for the COVID-19 diagnostic test on the provider's website and has not completed a corrective action plan, in an amount not to exceed $300 per day that the violation is ongoing.

Revoking plan amendments. In FAQs Part 42, Q9 and Q14, the Departments announced temporary enforcement relief that generally applies with respect to changes made to increase benefits, or reduce or eliminate cost-sharing requirements, for the diagnosis and/or treatment of COVID-19 and telehealth or other remote care services during the public health emergency or national emergency declaration period related to COVID-19. If a plan or issuer reverses these changes once the COVID-19 public health emergency or national emergency declaration is no longer in effect, the Departments will consider a plan or issuer to have satisfied its obligation to provide advance notice of a material modification under PHSA Sec. 2715(d)(4) and its implementing regulations with respect to a participant, beneficiary, or enrollee if the plan or issuer had previously notified the participant, beneficiary, or enrollee of the general duration of the additional benefits coverage or reduced cost sharing (such as, that the increased coverage applies only during the COVID-19 public health emergency) or notifies the participant, beneficiary, or enrollee of the general duration of the additional benefits coverage or reduced cost sharing within a reasonable timeframe in advance of the reversal of the changes.

Telehealth and remote care services. A large employer may offer coverage only for telehealth and other remote care services to employees who are not eligible for any other group health plan offered by the employer. In light of the critical need to minimize the risk of exposure to and community spread of SARS-CoV-2, for the duration of any plan year beginning before the end of the public health emergency related to COVID-19, the Departments are providing relief for a group health plan (and health insurance coverage offered in connection with a group health plan) that solely provides benefits for telehealth or other remote care services from the group market reforms with certain exceptions. This relief is limited to telehealth and other remote care service arrangements that are sponsored by a large employer and that are offered only to employees (or their dependents) who are not eligible for coverage under any other group health plan offered by that employer.

Under this temporary relief, the Departments will continue to apply otherwise applicable federal non-discrimination standards. The specified market reforms that these arrangements must continue to satisfy are the following provisions of the PHSA (and corresponding provisions of ERISA and the Code):

- Section 2704 (relating to prohibition of pre-existing condition exclusions or other discrimination based on health status);
- Section 2705 (relating to prohibition of discrimination against individual participants and beneficiaries based on health status);
- Section 2712 (relating to prohibition of rescissions); and
- Section 2726 (relating to parity in mental health or substance use disorder benefits).

Mental health benefits. The FAQs also provide that when performing the "substantially all" and "predominant" tests for financial requirements and quantitative treatment limitations under the

MHPAEA regulations, plans and issuers may disregard benefits for items and services required to be covered without cost sharing under the FFCRA.

Wellness programs. Plans and issuers are permitted to waive a standard (including a reasonable alternative standard) for obtaining a reward under a health-contingent wellness program. However, to the extent the plan or issuer waives a wellness program standard as a result of the COVID-19 public health emergency, the waiver must be offered to all similarly situated individuals, as described in the implementing regulations.

SOURCE: FAQs About Families First Coronavirus Response Act and Coronavirus, Aid, Relief, and Economic Security Act Implementation, Part 43, June 23, 2020; https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf