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New FAQs Clarify Coverage Requirements for COVID-19 Testing and Vaccines

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On February 26, 2021, the Departments of Labor, Health and Human Services (HHS) and Treasury (collectively the "Departments") released *FAQs About Families First Coronavirus Response Act (the "FFCRA") and Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") Implementation Part 44* (the "FAQs").[1] These FAQs provide much-needed clarity regarding the kinds of restrictions that group health plans and health insurance issuers can place on coverage for COVID-19 testing, particularly for asymptomatic individuals who have not been exposed to COVID-19. The FAQs also provide detail regarding the coverage requirements for COVID-19 vaccines. Additionally, the FAQs confirm that an Employee Assistance Program (EAP) may offer benefits for COVID-19 vaccines and still maintain its status as an excepted benefit.

I. COVID-19 Diagnostic Testing

The FFCRA and CARES Act generally require that group health plans ("Plans") must provide benefits for a broad range of items and services related to the detection of SARS-CoV-2 (i.e., the virus that causes COVID-19) or the diagnosis of COVID-19 (collectively, COVID-19 testing or tests) from March 18, 2020 until the end of the applicable emergency period.[2] This Plan coverage must be provided without any cost-sharing requirements, prior authorization or other medical management requirements.

The FAQs clarify the following regarding the coverage of COVID-19 testing:

Medical screening criteria cannot be used to deny (or impose cost-sharing on) a claim for diagnostic testing for an asymptomatic person who has no known or suspected exposure to COVID-19. When an individual seeks and receives a COVID-19 test from a licensed or authorized

health care provider, or when a licensed or authorized health care provider refers an individual for a COVID-19 test, Plans must generally assume that the receipt of the test reflects an "individualized clinical assessment," and the test should be covered without cost-sharing, prior authorization or other medical management. The FAQs note that state and local public health officials retain the authority to direct providers to limit eligibility for testing based on clinical risk or other criteria in order to manage testing supplies and access to testing, but that the responsibility for implementing limits of this kind falls on health care providers, and not on Plans or health insurance issuers.

Plans can distinguish between COVID-19 testing of asymptomatic individuals versus coverage of testing for other purposes not primarily intended for individualized diagnosis or treatment of COVID-19. Plans are not required to provide coverage for COVID-19 testing when the purpose of the test is not for individualized diagnosis or treatment of COVID-19 (e.g., testing for public health surveillance, or employment purposes). Plans may choose to provide coverage for these kinds of tests.

TH COMMENT: Plan sponsors should clearly communicate to participants/beneficiaries the circumstances in which the Plan will cover COVID-19 testing.

Plans must cover COVID-19 testing provided through a state- or locality-administered testing site and point-of-care tests. Plans must cover COVID-19 diagnostic tests received from a licensed or authorized provider, including tests from a state- or locality-administered site, a "drive through" site, and/or a site that does not require appointments. Plans must cover point-of-care COVID-19 tests (meaning a test that delivers rapid results without having to be sent to a lab) in the same way they cover other kinds of COVID-19 tests.

Plans should maintain claims processing and other information technology systems in ways that protect participants, beneficiaries, and enrollees from inappropriate cost-sharing related to the items and services associated with COVID-19 testing.[3] The Departments are also seeking feedback from stakeholders regarding additional steps that Plans should take to ensure there is no inappropriate cost-sharing, while stating that they may take enforcement action where appropriate.

TH COMMENT: When the CARES Act was passed, some Plan vendors were denying coverage for certain costs related to COVID-19 testing. These FAQs should clarify the scope of Plan coverage for COVID-19 testing. Plan sponsors should confirm that the claims administrator is aware of this requirement and has steps in place to comply with it.

II. Rapid Coverage of COVID-19 Vaccines

Under the CARES Act, Plans (except grandfathered group health plans) must cover, without cost sharing requirements, any "qualifying Coronavirus preventive service" which includes:

- 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 Immunizations Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) (regardless of whether immunization is recommended for routine use).

As of the date of the FAQ publication (February 26, 2021), only the Pfizer-BioNTech (for individuals age 16 and up) and Moderna (for individuals age 18 and up) vaccines met the above criteria. On February 28, 2021, the CDC director authorized the use of the Johnson & Johnson vaccine (adopting ACIP's recommendation) for individuals age 18 and up.

The FAQs clarify the following with regard to the coverage of COVID-19 vaccines:

Plans must cover all COVID-19 vaccines that have been recommended by ACIP (and the associated administrative costs) without cost-sharing. Plans are not permitted to exclude coverage of (or impose cost-sharing on) any qualifying coronavirus preventive service. For example, a plan cannot cover just the Pfizer-BioNTech vaccine, but not cover the Moderna or Johnson & Johnson vaccines.

Plans must begin providing coverage for qualifying COVID-19 va ccines no later than 15 business days after the date the CDC director adopts ACIP's recommendation regarding the vaccine.

- The requirement to cover the Pfizer-BioNTech vaccine became effective on January 5, 2021 (the CDC director adopted ACIP's recommendation on December 12, 2020).
- The requirement to cover the Moderna vaccine became effective on January 12, 2021 (the CDC adopted ACIP's recommendation on December 20, 2020).
- The requirement to cover the Johnson & Johnson vaccine will become effective on March 19, 2021 (the CDC Director adopted ACIP's recommendation on February 28, 2021).

Plans may not deny coverage for a COVID-19 vaccine because a participant, beneficiary or enrollee is not in a category recommended for early vaccination.[4] Plans may communicate with participants/beneficiaries/enrollees about which individuals will be vaccinated first when vaccine supply is limited. However, Plans may not communicate that *coverage* is limited only to individuals who are recommended for early vaccination. Additionally, decisions by an individual provider (including a provider integrated with a Plan) to decline to give the vaccine to someone because she or he is not within a prioritization category is not an adverse benefit determination made by a Plan, and therefore it is *not* subject to ERISA's internal claims and appeals procedure and external review.

Summary of Benefits and Coverage (SBC) Notice Requirement Relief. Normally, a Plan is required to provide notice of any material modification in any of the terms of the Plan that would affect the contents of the SBC not later than 60 days *prior* to the date on which the modification will become effective. Consistent with prior guidance[5], this FAQ states that the Departments will not take enforcement action when a Plan covers a COVID-19 vaccine prior to satisfying the SBC notice of modification requirements. Plans must provide any required notice of the changes as soon as reasonably practicable.

III. EAPs May Offer COVID-19 Vaccines and Remain Excepted Benefits

The market reform rules of the Patient Protection and Affordable Care Act generally do not apply to certain types of benefits, known as "excepted benefits." Excepted benefits include (among

other categories not applicable here): on-site medical clinics, and "limited excepted benefits." EAPs are considered limited excepted benefits if they meet the following requirements:

(A) The EAP does not provide significant benefits in the nature of medical care;

(B) The benefits under the EAP are not coordinated with benefits under another group health plan;

(C) No employee premiums or contributions are required as a condition of participation in the EAP; and

(D) There is no cost-sharing under the EAP.

Previously, the Departments had stated that an employer may offer benefits for diagnosis and testing for COVID-19 under an EAP that constitutes an excepted benefit, as long as the Public Health Emergency declaration or National Emergency declaration remain in effect.[6]

These FAQs clarify the following:

- ***An employer may offer benefits for COVID-19 vaccines (and their administration) under an EAP that constitutes an excepted benefit.*** An EAP will not be considered to provide benefits that are "significant in the nature of medical care" solely because it offers benefits for COVID-19 vaccines and their administration, including when offered in combination with COVID-19 testing. The EAP must still comply with the applicable requirements, including no cost-sharing.
- ***An employer may offer benefits for a COVID-19 vaccine (and their administration) at an on-site medical clinic.*** Coverage of on-site medical clinics is an excepted benefit in all circumstances.

If you have any questions regarding this article, please contact its authors.

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[1] The FAQs contain the following disclaimer, "[t]he contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law."

[2] This emergency period refers to the public health emergency that was declared by the Secretary of HHS in January 2020, and which was renewed most recently on January 7, 2021. HHS has stated publicly that it has determined that the public health emergency will likely remain in place for the entirety of 2021.

[3] FFCRA requires plans to provide coverage for items and services furnished to an individual during health care provider office visits (including in-person visits and telehealth visits), urgent

care center visits, and emergency room visits that result in an order for, or administration of, an in vitro diagnostic product, but only to the extent that the items and services relate to the furnishing or administration of the product or to the evaluation of the individual for purposes of determining the need of the individual for that product.

[4] Although the CDC and ACIP have made recommendations regarding the categories of individuals to prioritize for vaccination during the initial phases of the COVID-19 vaccination program (e.g., based on age, health conditions, and whether the individual is an essential worker), ACIP does not currently recommend against vaccinating individuals in other prioritization categories. ACIP recommends vaccination of all individuals in the specified age groups (as explained above).

[5] In the previously released *FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42* (released on April 11, 2020), the Departments relaxed the SBC notice of modification requirements for plans that added benefits, or reduced or eliminated cost-sharing, for COVID-19 testing and telehealth.

[6] *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42*, Q-11.