**To:** Foster & Foster Health and Welfare Clients

**From:** Nikki Chriesman-Green, Senior Counsel

**Date:** January 11, 2022

**Re:** DOL FAQ 51: COVID-19 At-home Diagnostic Testing

On January 10, 2022, the Department of Labor (DOL), in partnership with the Department of Health and Human Services (“HHS”) and the U.S. Department of the Treasury (collectively “the Departments”), issued guidance in the form of Frequently Asked Questions (FAQs) to assist plan administrators and employers in fulfilling their obligations under the Families First Coronavirus Response Act (FFCRA), the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), and the Affordable Care Act (ACA) as it relates to coverage of COVID-19 diagnostic tests under group health plans during the public emergency period. Specifically, the FAQs address issues relating to the requirement that group health plans cover at-home and over-the-counter (OTC) COVID-19 diagnostic tests without cost-sharing or other requirements.

1. **OTC COVID-19 Diagnostic Tests**

As a reminder, The FFCRA includes a requirement (as amended by the CARES Act), that group health plans of any size (fully insured and self-insured, including grandfathered plans) and health insurers are required to cover COVID-19 diagnostic tests and related services without cost sharing, prior authorization requirements, or other medical management requirements. Excepted benefits and retiree-only plans are exempt from this requirement. This applies to both in-network and out-of-network providers.

These recently issued FAQs clarify that this mandate to cover COVID-19 diagnostic testing includes coverage for at-home and OTC COVID-19 diagnostic tests purchased on or after January 15, 2022. Specifically, the tests that must be covered without such restrictions include (1) tests that have been approved by the U.S. Food and Drug Administration (FDA), (2) tests for which the developer has requested “emergency use authorization” under the Federal Food, Drugs, and Cosmetics Act, and (3) tests authorized and used by a state to diagnose patients. This coverage requirement does not apply to at-home or OTC COVID-19 diagnostic tests purchased to comply with employment or workplace testing.

1. **Costs and other Plan limitations**

The FAQs provide that plans must cover up to a total of eight tests per 30-day period per covered participant without cost-sharing. Plans may provide direct coverage for reimbursement through pharmacies and retailers, or plans may design a program that requires a participant to submit a claim for reimbursement. Under the safe harbor provided in the FAQs, direct coverage occurs when “a participant, beneficiary, or enrollee is not required to seek reimbursement post-purchase; instead, the plan or issuer must make the systems and technology changes necessary to process the plan’s or issuer’s payment to the preferred pharmacy or retailer directly (including the direct-to consumer shipping program) with no upfront out-of-pocket expenditure by the participant, beneficiary, or enrollee.” Additionally, to qualify as “direct coverage”, plans may not apply pre-authorization or other medical management requirements prior to purchasing the at-home or OTC COVID-19 diagnostic test.

The Departments encourage plan administrators and issuers to establish a network of preferred providers (i.e., retail stores, online retailers, and pharmacies) to provide direct coverage to participants covered under the plan. Under a safe harbor created by the Departments, plans that provide direct coverage of at-home and OTC COVID-19 diagnostic tests may not limit coverage to the preferred providers, but they are permitted to limit reimbursement for non-preferred providers to $12 per test or the actual cost of the test (whichever is lower). However, Plans may provide more generous coverage. If a plan is unable to ensure adequate access to OTC COVID-19 diagnostic tests, or if there are significant delays for plan participants to receive tests via a direct-to consumer program, the plan will not be able to rely on the safe harbor for the duration of the delay or interrupted access and will not be permitted to deny coverage, impost cost-sharing requirements, or impose limits on the reimbursement amount for tests purchased by non-preferred providers.

Plans may take reasonable steps to prevent suspected fraud, waste, and abuse. Plans are permitted to confirm that the tests were purchased for a covered person and may require reasonable documentation of proof of purchase for the test.

Please note that this not an exhaustive list of the FAQs. The FAQs also provide clarification on preventive coverage requirements for non-grandfathered plans related to follow-up colonoscopies and contraceptives. Plan sponsors should review the DOL FAQs in their entirety to review their obligations and key requirements under the law.

**NEXT STEPS**

Plans are encouraged to educate their members and provide other forms of support to ensure they understand how to access and use OTC COVID-19 diagnostic tests. Plan sponsors should contact their claims administrators, vendor partners, or PBM (as applicable) to obtain assistance in developing a direct coverage program to ensure the plan is eligible for the safe harbor. Additionally, plans should prepare to amend their plan documents to include coverage for at-home and OTC COVID-19 diagnostic tests, explain how a member can obtain OTC COVID-19 diagnostic tests using the direct coverage method, and outline the process that a member will use to submit a claim for reimbursement.

Foster & Foster will continue to monitor the efforts to implement the Act and will follow up once additional guidance is released.

**RESOURCES**

To review the DOL FAQs and obtain a word version of the attached model notices, visit:

<https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf>