

**NEWS ALERT****EMPLOYEE BENEFITS****Plans and Issuers Must Cover the Cost of OTC COVID-19 Tests (If You Can Find Them) by Saturday, January 15, 2022**

By Melanie N. Aska and Erek M. Sharp | January 13, 2022

On December 2, 2021, President Biden announced that the Departments of Labor, Health and Human Services (HHS) and the Treasury (the “Departments”) would issue guidance by January 15, 2022 to clarify that individuals who purchase over-the-counter COVID-19 diagnostic tests (“OTC COVID-19 tests”) during the present public health emergency will be able to seek reimbursement from their group health plans or health insurance issuers.

On January 10, 2022, a mere five days before the January 15, 2022 effective date, the Departments jointly issued that guidance, in the form of Frequently Asked Questions (referred to here as “FAQs Part 51”, and available [here](#)). The Departments issued FAQs Part 51 to clarify that individuals who purchase OTC COVID-19 tests on or after January 15, 2022 and during the present public health emergency will be able to seek reimbursement from their group health plan or health insurance issuer. FAQs Part 51 updates existing guidance to generally require coverage of OTC COVID-19 tests, with or without an order or individualized clinical assessment by an attending health care provider, as described below.

**Background on Required Coverage of COVID-19 Diagnostic Testing**

The FFCRA’s Coverage Mandate. The Families First Coronavirus Response Act (“FFCRA”, enacted on March 18, 2020), generally requires group health plans and health insurance issuers offering group or individual health insurance coverage, including grandfathered health plans, to provide benefits for certain items and services related to testing for the detection of SARS-CoV-2 (the virus that causes COVID-19) or the diagnosis of COVID-19, when those items or services are furnished on or after March 18, 2020 and during the present public health emergency period. Under the FFCRA, 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.

The CARES Act Broadened the FFCRA’s Coverage Mandate. The Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”, enacted on March 27, 2020) amended the FFCRA to include a broader range of diagnostic items that plans and issuers must cover without any cost-sharing requirements, prior authorization or other medical management requirements.

The Departments’ Authority to Issue Implementing Guidance. The FFCRA and the CARES Act authorize the Departments to issue guidance implementing those statutes’ coverage mandates and to address other health coverage issues related to COVID-19. The Departments previously issued four sets of implementing FAQs, making the Departments’ FAQs Part 51, issued on January 10, 2022, their fifth set of FAQs on COVID-19-related issues.

FAQs Part 43. One of the Departments' previous sets of FAQs, FAQs Part 43, issued on June 23, 2020, stated that plans and issuers are required to cover COVID-19 tests intended for at-home testing, 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 applicable statutory criteria. In issuing FAQs Part 43, the Departments noted that, as of the date that guidance was issued, the Food and Drug Administration ("FDA") had not yet authorized any COVID-19 diagnostic tests to be completely used and processed at home. However, since the Departments issued FAQs Part 43, the FDA has authorized additional diagnostic tests for COVID-19, including tests that can be self-administered and self-read at home or elsewhere without the involvement of a health care provider, sometimes referred to as "self-tests" or "at-home tests". These tests are now available, either by prescription or over-the-counter ("OTC") (without either a prescription or individualized clinical assessment by a health care provider), through pharmacies, retail stores and online retailers.

FAQs Part 51. In light of the FDA's authorization of at-home COVID-19 tests available OTC, to remove financial barriers and expand access to COVID-19 testing, and to ensure consistency with applicable requirements under the FFCRA and the CARES Act, the Departments issued FAQs Part 51 to clarify that individuals who purchase OTC COVID-19 tests on or after January 15, 2022 and during the present public health emergency will be able to seek reimbursement from their plan or issuer. FAQs Part 51 updates the Departments' previous guidance to generally require coverage of OTC COVID-19 tests, with or without an order or individualized clinical assessment by an attending health care provider, as described below.

- **Plans and Issuers Must Cover OTC COVID-19 Tests Available Without a Doctor's Order**

FAQs Part 51 requires that, no later than January 15, 2022, group health plans and health insurance issuers must cover OTC COVID-19 tests that meet applicable FFCRA and CARES Act requirements, including tests obtained without the involvement of a health care provider, and that participants, beneficiaries or enrollees must not bear any out-of-pocket expenses for the cost of the tests (unless the plan or issuer meets certain enforcement safe harbor conditions, described below). Coverage of OTC COVID-19 tests must be provided without imposing any cost-sharing arrangements, prior authorization or other medical management requirements.

The FFCRA and the CARES Act do not require a plan or issuer to provide coverage of OTC COVID-19 tests by reimbursing sellers of the tests directly (referred to as "direct coverage"); a plan or issuer may instead require a participant, beneficiary or enrollee who purchases an OTC COVID-19 test to submit a claim for reimbursement to the plan or issuer. However, in FAQs Part 51, the Departments strongly encourage plans and issuers to provide direct coverage for OTC COVID-19 tests to participants, beneficiaries and enrollees by reimbursing sellers directly without requiring such individuals to provide upfront payment and then seek reimbursement.

FAQs Part 51 modifies the Departments' previous guidance (in FAQs Part 43) such that the requirement to cover OTC COVID-19 tests is no longer limited only to situations in which the individual has an order or individualized clinical assessment from a health care provider. FAQs Part 51 requires coverage, without an order or individualized clinical assessment from a health care provider, only with respect to OTC COVID-19 tests that do not require a health care provider's order under the applicable FDA's authorization, clearance or approval. FAQs Part 51 does not modify the Departments' previous guidance (specifically, FAQs Part 44, issued on February 26, 2021) which addressed coverage not primarily intended for diagnosis or treatment of COVID-19, including guidance that states that plans and issuers are not required to provide coverage of testing (including an OTC COVID-19 test) that is for *employment purposes*.

- **Enforcement Safe Harbor for Plans and Issuers that Limit Reimbursement for OTC COVID-19 Tests at Non-Preferred Pharmacies or Retailers**

FAQs Part 51 provides that if a plan or issuer provides direct coverage of OTC COVID-19 tests, the plan or issuer may not limit coverage to only tests that are provided through preferred pharmacies or other retailers.

However, FAQs Part 51 provides an enforcement safe harbor which permits a plan or issuer to limit reimbursement for OTC COVID-19 tests, provided that the conditions of the safe harbor are met.

Under the enforcement safe harbor, the Departments will not take enforcement action against any plan or issuer that provides coverage of OTC COVID-19 tests purchased by participants, beneficiaries and enrollees on or after January 15, 2022 and during the present public health emergency by arranging for direct coverage of OTC COVID-19 tests through both its pharmacy network and a direct-to-consumer shipping program, but otherwise limits reimbursement for OTC COVID-19 tests from non-preferred pharmacies or other retailers to no less than the actual price or \$12 per test (whichever is lower). (In FAQs Part 51, the Departments recognize that some OTC COVID-19 tests are sold in packages containing more than one test. If a plan or issuer limits reimbursement for OTC COVID-19 tests from non-preferred sellers, pharmacies or retailers to \$12 per test, as allowed under the enforcement safe harbor, the plan or issuer must calculate reimbursement based on the number of tests in a package.) Plans and issuers may elect to provide more generous reimbursement up to the actual price of the test. In addition, under the enforcement safe harbor, the direct-to-consumer shipping program may be provided through one or more in-network providers or another entity designated by the plan or issuer.

For purposes of this enforcement safe harbor, “direct coverage” of OTC COVID-19 tests means that 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 (including the direct-to-consumer shipping program) with no upfront out-of-pocket expenditure by the individual. Under this safe harbor, and consistent with the general guidance under FAQs Part 51, plans or issuers may not impose any prior authorization or other medical management requirements on participants, beneficiaries or enrollees who obtain OTC COVID-19 tests via a direct coverage program or otherwise. In providing OTC COVID-19 tests through its direct coverage program, a plan or issuer must take reasonable steps to ensure that such individuals have adequate access to OTC COVID-19 tests, through an adequate number of retail locations (including both in-person and online locations).

- **Additional Enforcement Safe Harbor for Plans or Issuers that Limit the Number or Frequency of OTC COVID-19 Tests**

FAQs Part 51 provides another enforcement safe harbor that allows a plan or issuer which otherwise provides coverage without cost sharing for COVID-19 diagnostic tests to set limits on the number or frequency of OTC COVID-19 tests covered without cost sharing, provided the conditions of the safe harbor are met.

Under this enforcement safe harbor, with respect to OTC COVID-19 tests purchased by participants, beneficiaries and enrollees on or after January 15, 2022 and during the present public health emergency that are available without an individualized clinical assessment or a health care provider’s involvement, the Departments will not take enforcement action against any plan or issuer that provides coverage without cost sharing for (and does not impose prior authorization or other medical management requirements on) such OTC COVID-19 tests, if the plan or issuer limits the number of OTC COVID-19 tests covered for each participant, beneficiary or enrollee to no less than 8 tests per 30-day period (or per calendar month). The Departments recognize that some OTC COVID-19 tests are sold in packages containing more than one test. In applying the quantity limit of 8, plans and issuers may count each test separately, even if multiple tests are sold in one package.

In addition, under this enforcement safe harbor, a plan or issuer would be required to set the limit for at least 8 individual tests per 30-day period (or per calendar month) per participant, beneficiary or enrollee, but must not limit such individuals to a smaller number of tests over a shorter period (for example, limiting individuals to 4 tests per 15-day period), although plans and issuers may set more generous limits.

- **Addressing Fraud and Abuse**

Like previous guidance issued by the Departments, FAQs Part 51 provides that, although the FFCRA and the CARES Act prohibit medical management of coverage of COVID-19 diagnostic testing, plans and issuers may act to prevent, detect and address fraud and abuse. Examples of permissible activities include the following:

- A plan or issuer may take reasonable steps to ensure that an OTC COVID-19 test for which a covered individual seeks coverage from the plan or issuer was purchased for the individual's own personal use (or use by another participant, beneficiary or enrollee who is covered as a member of the individual's family), provided that such steps do not create significant barriers for such individuals to obtain these tests. For example, a plan or issuer could require an attestation, such as a signature on a brief attestation document, that the OTC COVID-19 test was purchased by the participant, beneficiary or enrollee for personal use, not for employment purposes, has not been (and will not be) reimbursed by another source, and is not for resale. By contrast, FAQs Part 51 states that, in the Departments' view, fraud and abuse programs that require an individual to submit multiple documents or involve numerous steps that unduly delay the individual's access to, or reimbursement for, OTC COVID-19 tests are not reasonable.
- A plan or issuer may require reasonable documentation of proof of purchase with a claim for reimbursement for the cost of an OTC COVID-19 test. Examples of such documentation could include the UPC code for the OTC COVID-19 test to verify that the item is one for which coverage is required under the FFCRA and the CARES Act, and/or a receipt from the seller of the test, documenting the date of purchase and the price of the OTC COVID-19 test.

- **Effective Date**

Plans and issuers must provide coverage, without cost-sharing, prior authorization or other medical management requirements, of OTC COVID-19 tests available without an order or individualized clinical assessment by a health care provider purchased on or after Saturday, January 15, 2022 and during the present public health emergency. Coverage may, but is not required to, be provided for OTC COVID-19 tests purchased without a provider order or individualized clinical assessment before January 15, 2022.

*If you have any questions, please contact:*

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