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UPDATE: CHANGES TO THE GROUP HEALTH PLAN MANDATE TO COVER OVER-THE-COUNTER COVID-19 TESTS

As described in our Jan. 11, 2022 alert, the Departments of Labor, Health and Human Services, and Treasury (Departments) issued FAQs expanding coverage of at-home COVID-19 diagnostic tests to include over-the-counter (OTC) kits purchased without a prescription effective as of Jan. 15, 2022. Important updates to the safe harbor coverage structure were issued on Feb. 4, 2022. The FAQs provided more guidance for how to meet the safe harbor provision for direct-to-consumer shipping programs and direct coverage through an inperson network. The guidance is effective Feb. 4, 2022.

ACTION ITEMS:

- Plans or issuers should establish at least one direct-to-consumer shipping mechanism and at least one in-person mechanism per the below guidelines in order to meet the safe harbor requirements for direct coverage.
- Plans or issuers may wish to advise individuals not to seek
 reimbursement for OTC COVID-19 tests from a health FSA or HRA for
 the cost already paid or reimbursed by the plan or issuer and not to
 use health FSA, HRA or HSA debit cards or distributions from an
 individual's HSA account to purchase tests they plan to seek
 reimbursement for from the plan or issuer.

Generally, plans and issuers have flexibility in how to provide direct coverage for OTC COVID-19 tests. Whether a plan or issuer provides adequate access through its direct coverage program will depend on the facts and circumstances but may be met by establishing at least one direct-to-consumer shipping mechanism and at least one in-person mechanism. However, under limited circumstances, such as a small employer's plan which covers employees who work and reside in a localized area, distribution at an in-person location without also establishing a direct-to-consumer shipping mechanism could possibly constitute adequate access. Other relevant facts and circumstances include current utilization of the plan's or issuer's pharmacy network if coverage is provided through that network, notification of the direct coverage

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options, which tests are available under the direct coverage program, and the number and location of in-person options.

- A direct-to-consumer shipping mechanism is any program that provides direct coverage of OTC COVID-19 tests for participants, beneficiaries or enrollees without requiring the individual to obtain the test at an in-person location. This may be met by providing for online or telephone ordering through a pharmacy or other retailer, by the plan or issuer directly, by any other entity on behalf of the plan or issuer, or by a combination of the above. If direct in-person coverage is provided through specified retailers which maintain online platforms for ordering tests to be shipped directly to consumers, this will also meet the requirements for providing a direct-to-consumer shipping mechanism. Plans and issuers must cover reasonable shipping costs related to covered OTC COVID-19 tests in a manner consistent with other items or products provided by the plan or issuer via mail order.
- A direct in-person mechanism includes establishing access to OTC COVID-19 tests from an adequate number of in-person locations, including pharmacies, retailers or independent distribution sites such as standalone drive-through or walk-up distribution set up by, or on behalf of, the plan or issuer.

Departments will not consider a plan or issuer otherwise within the safe harbor to be out of compliance due to a temporary supply shortage in their direct coverage program, and the plan or issuer may continue to limit reimbursement to \$12 per test, for at least eight tests per 30-day period or month, which are purchased outside of the direct coverage program. When providing coverage for OTC COVID-19 tests outside of the direct coverage program, the total cost of tests that must be covered is inclusive of shipping and sales tax costs.

Law Clerk Colleen C. Essid contributed to this client advisory.