COMPLIANCE ALERT

Additional Guidance for Health Plan Coverage of OTC COVID-19 Tests

March 1, 2022

Quick Facts

- Agencies clarify requirements for plan coverage of over the counter (OTC) COVID-19 tests.
- Provides plans and insurers with a safe harbor limiting out of network exposure.
- Addresses fraud protection and participant notification.
- The cost (or portion of the cost) of a test paid or reimbursed by a plan or insurer cannot be reimbursed by a health Flexible Spending Account (FSA), Health Savings Account (HSA) or Health Reimbursement Account (HRA).

Background

On January 10, 2022, The Department of Labor (DOL), Secretary of Health and Human Services (HHS), and Department of the Treasury (Treasury) collectively referred to as "the Departments" released **Frequently Asked Questions (FAQ) Part 51**, in response to the Biden Administration's directive to issue guidance requiring group healthcare plans and insurers to provide coverage of OTC in-home COVID-19 diagnostic tests. Beginning January 15, 2022, group healthcare plans, including fully insured and self-funded plans and individual insurance policies, were required to cover the cost of OTC in-home COVID-19 testing without any cost-sharing or prior authorization for the tests. On February 4, 2022, the Departments released additional frequently asked questions (FAQs) through Affordable Care Act (ACA) **FAQ Part 52** meant to clarify many of questions employers and plans have posed after the initial guidance was released.

Summary of OTC COVID-19 Tests Coverage

The guidance is applicable to self-funded and fully insured group healthcare plans, including grandfathered health plans ("plans").

- As of January 15, 2022, plans and issuers must cover the cost of OTC COVID-19 tests, including tests obtained without a healthcare provider's order or authorization.
- Coverage must be provided without cost-sharing (deductibles, copayments and coinsurance) or prior authorization requirements.
- Plans must reimburse participants for the cost of testing per the plan's claims procedures.
- Plans are not required to reimburse sellers of the kits directly but may do so voluntarily. Plans
 must implement a direct reimbursement model (described below) to be able to limit the cost
 paid per test.
- Plans may set a limit of no less than eight (8) tests per 30-day period (or calendar month) per participant for tests that do not involve a provider.

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NOTE: the guidance specifically states that plans and issuers are not required to provide coverage of testing (including an OTC COVID-19 test) that is for employment purposes.

Limiting Reimbursements to \$12 per Test & Safe Harbor for Direct Plan Reimbursements to Sellers

Plans may not restrict reimbursements to OTC COVID-19 tests provided only by certain pharmacies or other retailers, however, if conditions of the safe harbor described below are met, plans may limit reimbursement for tests purchased from non-network pharmacies or other retailers to \$12 per test, or the actual price, whichever is lower.

The new FAQs clarify that to satisfy this safe harbor, the plan must meet both of the following requirements:

- 1. Implement a process of direct payment to the preferred (i.e. in-network) pharmacies or retailers so that the participant is not required to submit a claim for reimbursement; and
- 2. Offer a "direct-to-consumer" shipping program that can be provided through an internet, mail or phone order arrangement and can be offered through a vendor or relationship separate from the health plan itself.

The new FAQs recognize that there may be supply shortages, but as long as the plan offers a directto-consumer program, the plan can still limit reimbursement for out-of-network tests to \$12, even if the program experiences shortages and is temporarily unable to fulfill orders due to supply issues.

The Departments note that this safe harbor applies only with respect to the coverage of OTC COVID-19 tests that are administered without a provider's involvement or a prescription. Plans and issuers must continue to provide coverage for COVID-19 tests that are administered with a provider's involvement or a prescription, as required by section 6001 of the Families First Coronavirus Response Act (FFCRA) and the Departments' guidance, even when relying on this safe harbor.

Protection Against Fraud

Plans may take reasonable steps to reduce the potential for fraud and ensure that the covered test is purchased for the individual's own use including an attestation by the participant that the test is for the participant's (or beneficiary's or enrollee's) own use. The new FAQs also allow plans to limit reimbursement to established pharmacies and retailers and refuse to reimburse tests purchased from individuals, temporary online marketplaces, etc. Participants should be informed of any limitations on the types of sellers from which tests must be purchased.

HRA, HSA and Health FSA Reimbursements

The new FAQs confirm that OTC tests are eligible medical expenses that can be reimbursed using an HRA, HSA, or Health FSA, but point out that a participant cannot receive a reimbursement from any of these arrangements for tests that have been covered with no cost-sharing by the health plan.

Summary

Health plans have been working since the original rules were released in early January to put the systems in place to reimburse tests as required, and many have already implemented direct pay programs so that out-of-network test reimbursements can be limited to \$12.



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