Eye on Washington

Regulatory Update

Additional Guidance on Coverage of Home COVID-19 Tests

As previously **communicated**, on Monday, January 10, 2022, the Biden Administration, in the form of an FAQ, announced a requirement to expand access to free home COVID-19 tests.

That **FAQ** established safe harbors for this requirement that are intended to facilitate consumer access to over-the-counter (OTC) home COVID-19 tests. Group health plans and insurers would be considered to provide direct coverage of OTC COVID testing if:

- They provide coverage of OTC COVID tests purchased by participants, beneficiaries, and enrollees without an order or individualized clinical assessment by a health-care provider during the public health emergency by arranging for direct coverage of OTC COVID tests through both its pharmacy network and a direct-to-consumer shipping program, and otherwise limits reimbursement for OTC COVID tests from out-of-network pharmacies or other retailers to no less than the actual price, or $12 per test (whichever is lower). For purposes of this safe harbor, direct coverage of OTC COVID 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 directly (including via a direct-to-consumer shipping program) with no upfront out-of-pocket expenditure by the participant, beneficiary, or enrollee, and
- They provide coverage without cost sharing for (and does not impose prior authorization or other medical management requirements on) such OTC COVID tests and limits the number of OTC COVID tests covered for each participant, beneficiary, or enrollee to no less than eight tests per 30-day period (or per calendar month).

Additional **guidance** on this safe harbor was published on February 4, 2022, regarding what is considered direct coverage for purposes of the safe harbor as well as other issues:

- **Defining Direct Coverage of OTC COVID Testing.** In order to be considered providing direct coverage of OTC COVID testing, a health plan must provide direct coverage by ensuring that participants and beneficiaries have adequate access to OTC COVID tests with no upfront out-of-pocket expenditure.

  Whether a plan or issuer provides adequate access through its direct coverage program will depend on the facts and circumstances but will generally require that OTC COVID tests are made available through at least one direct-to-consumer shipping mechanism (e.g., mail order) and at least one in-person mechanism (e.g., pharmacy).

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The FAQ clarifies that a direct-to-consumer shipping mechanism is any program that provides direct coverage of OTC COVID tests for participants and beneficiaries without requiring the individual to obtain the test at an in-person location. A direct-to-consumer shipping mechanism can include online or telephone ordering and may be provided through a pharmacy or other retailer, the health plan directly, or any other entity on behalf of the health plan. A direct-to-consumer shipping program does not have to provide exclusive access through one entity, as long as it allows a participant or beneficiary to place an order for OTC COVID tests to be shipped to them directly. For example, if a plan or issuer has opted to provide direct in-person coverage of OTC COVID tests through specified retailers, and those retailers maintain online platforms where individuals can also order tests to be delivered to them, the health plan is considered to have provided a direct-to-consumer shipping mechanism. When providing OTC COVID tests through a direct-to-consumer shipping program, plans and issuers must cover reasonable shipping costs related to covered OTC COVID tests.

When implementing an in-person mechanism, a plan or issuer must ensure that participants and beneficiaries have access to OTC COVID tests through an adequate number of locations (which could include pharmacies and other retailers, or independent distribution sites set up by, or on behalf of, a health plan). Whether there is adequate access should be determined based on all relevant facts and circumstances, such as the locality of participants, beneficiaries, or enrollees under the plan or coverage; current utilization of the health plan's pharmacy network by its participants and beneficiaries, when making such coverage available through a pharmacy network; and how the plan or issuer notifies participants and beneficiaries of the retail locations, distribution sites, or other mechanisms for distributing tests, as well as which tests are available under the direct coverage program.

- **Supply Shortages.** Health plans won't be considered out if compliance if they have met the direct coverage requirements but are temporarily unable to provide OTC COVID testing due to supply shortages.
- **Preventing Fraud and Abuse.** Heath plans are allowed to limit reimbursement only for OTC COVID tests from established retailers and can require a receipt or proof of purchase that clearly identifies the product and seller. Specifically, health plans are not required to cover tests purchased from a private individual via an in-person or online person-to-person sale, or from a seller that uses an online auction or resale marketplace.
- **Type of COVID Tests to be Covered.** The coverage requirement is for OTC COVID tests that are approved, cleared, or authorized for use by the Food and Drug Administration (FDA), can be obtained without a prescription, and completely used and processed without the involvement of a laboratory or other health-care provider. COVID tests that use a self-collected sample but require processing by a laboratory or other health-care provider to return results (such as home-collection PCR tests that can be purchased directly by consumers) are not required to be covered.
- **Coverage of OTC COVID Testing and Health FSAs, HRAs, and HSAs.** OTC COVID testing would generally be considered a reimbursable medical expense for a health FSA or HRA. The FAQ reiterates, however, that an individual cannot be reimbursed more than once for the same medical expense. So, the cost (or the portion of the cost) of OTC COVID tests paid or reimbursed by a plan cannot be reimbursed again by a health FSA or HRA.

  The FAQ states that employers sponsoring health FSAs and HRAs may want to advise individuals not to seek reimbursement from a health FSA or HRA for the cost (or the portion of the cost) of OTC COVID tests paid or reimbursed by their health insurance plan and not to use a health FSA or HRA debit card to purchase OTC COVID tests for which the individual intends

to seek reimbursement from the plan or issuer. If an individual mistakenly receives reimbursement from a health FSA or HRA for OTC COVID test costs covered by a plan, the individual should contact the health FSA or HRA administrator regarding correction procedures.

Similarly, OTC COVID testing would generally be considered a qualified medical expense for an HSA but only to the extent the expense is not covered by insurance. So, expenses for OTC COVID tests paid or reimbursed by a plan are not qualified medical expenses. If an individual mistakenly takes a distribution from an HSA for OTC COVID test costs paid or reimbursed by a plan, the individual must either (1) include the distribution in gross income, or (2) if and as permitted by the HSA custodial institution, repay the distribution to the HSA.

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ADP, Inc.
One ADP Boulevard, Roseland, NJ 07068
adp.com

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