

FAQs Provide Additional Guidance Regarding At-Home COVID-19 Testing Coverage Requirements

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As discussed in our prior blog post [here](#), employer-provided group health plans, and insurers and other issuers, are required to cover the cost of over-the-counter, at-home COVID-19 tests ("**OTC Tests**") authorized by the Food and Drug Administration ("**FDA**"). The DOL, HHS, and the Treasury Department (collectively, the "**Departments**") previously issued guidance establishing a safe harbor that, if satisfied, allows plans and issuers to limit the reimbursement of OTC Tests to \$12 per test (or the actual cost of the OTC Test, if lower). The Departments recently issued additional guidance in the form of FAQs clarifying how plans and issuers may comply with the safe harbor OTC Test coverage requirements.

- The FAQs clarify that whether a plan or issuer satisfies the safe harbor by providing adequate access to OTC Tests through its direct coverage program will depend on the particular facts and circumstances, but will generally require that OTC Tests are made available through (i) at least one direct-to-consumer shipping mechanism, and (ii) at least one in-person mechanism. This coverage may be provided through programs allowing orders to be placed online or by phone, through a pharmacy network or other non-pharmacy retailers, and alternative distribution sites established by, or on behalf of, the plan or issuer. When OTC Tests are provided through a direct-to-consumer shipping mechanism, plans and issuers must cover reasonable shipping costs.
- The FAQs provide relief for plans or issuers that have established a direct coverage program that otherwise satisfies the safe harbor requirements but are temporarily unable to provide adequate access to OTC Tests due to supply shortages. Plans and issuers that otherwise satisfy the safe harbor requirements, but for the supply shortage, are still permitted to limit reimbursement of OTC Tests purchased outside the direct coverage program to \$12 per test (or the actual cost of the test, if lower).
- The FAQs clarify that a plan or issuer may establish policies that limit coverage of OTC Tests purchased from private individuals (either through an in-person sale or an online sale), from sellers that use online auctions, or from resale marketplaces.
- The FAQs clarify that the safe harbor coverage requirements only apply to OTC Tests that (i) are approved, cleared, or authorized for use by the FDA; (ii) can be obtained without a prescription; and (iii) are completely self-administered (*i.e.*, can be self-read without the involvement of a laboratory or other health care provider). However, other applicable laws may still require the coverage of OTC Tests that do not meet these requirements.
- The FAQs clarify that because plans and issuers are required to cover the cost of OTC Tests, the cost (or the portion of the cost) of OTC Tests paid or reimbursed by a plan or issuer cannot be reimbursed by a health flexible spending account or health reimbursement account. In addition, expenses incurred for OTC Tests paid or reimbursed by a plan or issuer are not treated as qualified medical expenses for purposes of health savings account coverage.

Plan administrators should provide information to participants regarding the key terms and conditions of the plan's coverage of OTC Tests.

The FAQs are available [here](#).