

Agencies Issue Additional Guidance Regarding Over-the-Counter COVID-19 Test Coverage

Alert

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As indicated in our [January 11, 2022 alert](#), the Department of Labor, the Department of Health and Human Services, and the Treasury issued FAQs Part 51 on January 10, 2022, requiring group health plans to cover over-the-counter (OTC) COVID-19 tests without participant cost-sharing, preauthorization, or medical management. In response to stakeholder feedback regarding FAQs 51, the agencies [released FAQs 52 on February 4, 2022](#).

The new guidance provides additional flexibility for complying with the safe harbor that allows plans providing direct coverage of tests obtained from network pharmacies and a direct-to-consumer shipping program to limit reimbursement for tests purchased from non-preferred pharmacies or retailers to \$12 per test (\$12 Safe Harbor), and answers other questions from stakeholders regarding the mandated OTC COVID-19 test coverage.

GUIDANCE RELATED TO THE \$12 SAFE HARBOR

Effective February 4, 2022, the \$12 Safe Harbor has been clarified as follows:

- To comply with the safe harbor's requirement that the direct coverage program provide adequate access (based on facts and circumstances), OTC COVID-19 tests must generally be made available through "at least one direct-to-consumer shipping mechanism and at least one in-person mechanism." The agencies did, however, recognize that there may be some limited circumstances in which a direct program could provide adequate access without providing both a direct-to-customer shipping mechanism and an in-person mechanism.

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- A “direct-to-consumer shipping mechanism” includes programs that provide direct coverage of tests without requiring plan members to procure the OTC COVID-19 test at an in-person location. Examples include online or telephone ordering, and may be provided through a pharmacy or retailer, the plan, or health insurance issuer directly, or any other entity on behalf of the plan.
- Reasonable shipping costs related to the OTC COVID-19 tests must be covered by the plan or issuer. The shipping costs are included in the \$12 reimbursement limit.
- A plan or insurance issuer will not fail to comply with the \$12 Safe Harbor if it is temporarily unable to provide adequate access to OTC COVID-19 tests through its direct coverage program because of a supply shortage.
- The plan or issuer is not required to cover all FDA-approved OTC COVID-19 tests under its direct coverage program to satisfy the adequate access requirement.

ADDITIONAL GUIDANCE

The February 4, 2022 guidance also provided the following clarifications:

- The requirement to provide OTC tests without participant cost-sharing, preauthorization, or medical management, described in FAQs Part 51 and Part 52, does not apply to at-home OTC COVID-19 tests that require a laboratory or other healthcare provider to process the results.
- A plan or insurance issuer may disallow reimbursement for tests purchased from private individuals or online auctions, limit reimbursement to established retailers who typically sell OTC COVID-19 tests, and establish other reasonable policies to prevent fraud and problematic behaviors that could limit access to tests.
- A participant may not double-dip by having the medical plan reimburse the participant for the costs of the OTC COVID-19 tests and being reimbursed from a health savings account (HSA), health flexible spending account (FSA), or health reimbursement account (HRA). If a participant is reimbursed by both the medical plan and an FSA or HRA, the participant should contact the plan administrator regarding correction procedures.

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