

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

Alert

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By Lisa Rippey, Audrey Fenske & Tom Dowling

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.

CONTACTS

Thomas R. Dowling

Audrey A. Fenske

Lisa M. Rippey

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