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New OTC COVID-19 Testing Coverage Guidance Published

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The Departments of Labor ("DOL"), Health and Human Services ("HHS"), and the Treasury (collectively, "the Departments") released additional guidance to assist group health plans in implementing the over-the-counter ("OTC") COVID-19 testing coverage requirements previously discussed in FAQs Part 51. FAQs Part 52 were published on February 4, 2022, in response to stakeholder questions.

Briefly, the FAQs provide the following guidance:

- Group health plans have flexibility in establishing their direct coverage program.
- A plan will not be out of compliance with the direct coverage safe harbor because there is a temporary testing shortage, provided that the plan offers a direct coverage option.
- To prevent fraud and abuse, plans may limit reimbursements to established retailers and disallow the reimbursement of tests purchased from a private individual, online auction, or resale marketplace.
- The relief does not apply to COVID-19 OTC tests that are self-administered but require processing by a laboratory.
- If funds from a tax-advantaged account, such as an HSA or health FSA, are used to purchase an OTC test, these tests are not eligible for reimbursement from the health plan.

Additional Information

Q. *Is there flexibility in how group health plans establish their direct coverage program to satisfy the requirements of the safe harbor in FAQs Part 51, Q2?*

Yes, the guidance clarifies that group health plans will have significant flexibility in the design of their direct coverage program if the program provides adequate coverage through both a direct-to-consumer shipping mechanism and an in-person mechanism. Direct coverage for OTC COVID-19 tests means that a participant is not required to submit a claim to seek reimbursement from the plan for the purchase of the test. Instead, the plan makes systems and technology changes necessary to process the plan's payment to the preferred pharmacy or retailer directly (including direct-to-consumer shipping programs) with no upfront out-of-pocket expenditure.

Regarding the direct-to-consumer shipping mechanism, this requirement can be met by:

- Any program which provides direct coverage of OTC COVID-19 test for enrollees in the health plan without the individual being required to purchase the test at an in-person location;
- Utilizing a pharmacy or other retailer's online or telephone ordering system; and
- Paying all reasonable shipping costs and sales taxes in a manner consistent with how the plan covers other items supplied through mail order (for example, pharmacy benefits).

Adequate access to an in-person mechanism will depend on an examination of all relevant facts and circumstances. The guidance has clarified that such facts include:

- The locality of enrollees under the plan;
- Current utilization of the plan's pharmacy network by enrollees (when utilizing the pharmacy network as part of the direct coverage option);
- How enrollees are notified of network retail locations; and
- Which tests are covered by the plan under the direct coverage option.

Plans are not required to provide coverage for all manufacturers of COVID-19 testing but may instead limit coverage to specific manufacturers that the plan has a contractual relationship with or from whom the plan is able to secure tests directly.

Q. *Will a temporary testing supply shortage cause a plan to be out of compliance with the safe harbor in FAQs Part 51, Q2?*

No, a plan will not be considered out of compliance due to a temporary testing supply shortage which impacts its ability to offer adequate coverage as long as the plan otherwise meets the requirements for the safe harbor.

Q. Is a plan permitted to address suspected fraud or abuse?

Yes. FAQs Part 51, Q4 specifically allowed for plans to address suspected fraud and abuse and this new guidance provides welcome suggestions on how this can be accomplished.

Plans are permitted to take reasonable steps to prevent and detect fraud and abuse by limiting reimbursements to tests purchased from established retailers and denying reimbursements for tests purchased from a private individual, online auction, or resale marketplace.

Plans may require documentation of the product and seller's identity, such as:

- UPC codes;
- Serial numbers; or
- Original receipt.

If implementing such a limitation, the plan should communicate necessary information to the plan's enrollees regarding retailers covered by the plan, as well as those tests or retailers which will be denied a reimbursement.

Q. *Are COVID-19 tests which are self-administered, but require the sample to be sent to a laboratory for processing required to be covered by a plan pursuant to this guidance?*

No. A test must be both self-administered and self-read (without the involvement of a healthcare provider) for a health plan to be required to cover it, pursuant to the requirements in FAQs Part 51. Importantly, a COVID-19 test which is not self-administered and/or not self-read but is prescribed by a physician and otherwise meets the requirements under the Families First Coronavirus Response Act ("FFCRA") must be covered by the plan according to the FFCRA's terms.

Q. *How are health plan reimbursements affected by the usage of HSAs, health FSAs, and HRAs to initially purchase the tests?*

While COVID-19 OTC tests are considered a qualified medical expense under the Internal Revenue Code, tests purchased from tax-advantaged accounts, such as HSAs, health FSAs, and HRAs, are not eligible for reimbursement by a health plan. IRS rules prevent an individual from being reimbursed more than once for the same medical expense (often referred to as "double dipping").

Health plans may wish to notify enrollees not to utilize such tax-advantaged funds to purchase OTC COVID-19 test for which they will later seek reimbursement from the health plan.

Employer Action

Employers should:

- Discuss with carriers, TPAs, and PBMs how this new guidance affects any direct coverage options which have already been established.
- Communicate any limitations on OTC test points of sale.
- Consider notifying enrollees to avoid utilizing an HSA, health FSA, or HRA to purchase OTC COVID-19 tests that they wish the plan to later reimburse.

* It is possible to utilize an HSA, health FSA, or HRA to reimburse the costs of an OTC test to the extent that the test has not been or will not be reimbursed by the health plan. For example, the health plan offers a direct coverage option and a participant goes "out-of-network" to purchase a test. If the test costs $32 and the plan provides reimbursement for $12, the participant may seek reimbursement for the otherwise unreimbursed $20 through a tax-favored account.