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New Guidance on Coverage of Over-the-Counter COVID-19 Tests

January 14, 2022

On January 10, 2022, federal regulators issued FAQs explaining what is required of group health plans and insurers with respect to over-the-counter ("OTC") COVID-19 testing. The FAQs are issued under the Families First Coronavirus Response Act ("FFCRA") (as modified by the CARES Act), which requires health plans and insurers to provide cost-free COVID-19 testing while the national emergency is in effect.

This Client Alert explains the FAQ requirements and next steps employers should consider taking to provide coverage for OTC COVID-19 testing.

What OTC COVID-19 tests are covered?

The FFCRA and the CARES Act require group health plans, both insured and self-insured, to cover certain items and services related to testing for COVID-19. Coverage for these items and services must be provided without prior authorization, cost-sharing, or other medical management requirements. The FAQs explain that such coverage requirements apply to specified OTC COVID-19 tests. Effective January 15, 2022, the FAQs require group health plans to cover, at no cost, OTC COVID-19 tests without regard to whether a healthcare provider was involved in procuring the test. Those tests must be covered if:

- The OTC COVID-19 test has been authorized by the U.S. Food and Drug Administration, and
- The test is primarily intended for individualized diagnosis or treatment of COVID-19 (and not for employment purposes).

How is a group health plan required to pay or reimburse OTC COVID-19 tests?

A group health plan may provide direct coverage or reimburse a participant for an OTC COVID-19 test.Under the direct coverage safe harbor, the participant is not required to seek reimbursement post-purchase; instead, the plan processes payments to sellers directly.

The FAQs establish a safe harbor arrangement that, if used, will not result in enforcement action. A health plan that provides coverage for OTC COVID-19 tests through both a pharmacy network and a direct-to-consumer shipping program may limit reimbursement for tests from non-preferred pharmacies/retailers to the actual price of the test or $12.00 (whichever is lower). Plans may elect to provide more generous reimbursement programs.

In designing a safe harbor direct coverage program, a plan must take reasonable steps to ensure that the participant has access to OTC COVID-19 tests through an adequate number of retail locations (both in-person and online locations). The purpose of the safe harbor is to facilitate testing, so it is important for plans to inform participants of the program's availability, as well as the program's participating retailers/locations.

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What can group health plans do to facilitate access to, promote effective use of, and ensure prompt payment for OTC COVID-19 tests?

To facilitate testing and ensure prompt payment, a plan may provide education and information resources to participants. That educational information should:

- Make clear what coverage/reimbursement is available and which OTC COVID-19 tests are covered:
- Provide guidance on how to use OTC COVID-19 tests and the difference between healthcare provider/laboratory tests and OTC COVID-19 tests;
- Include quality information (such as shelf life, rate of false positives, etc.);
- Detail how and where to obtain the no-cost OTC COVID-19 tests directly from the plan or designated sellers; and
- Describe how to submit claims for reimbursement.

The OTC COVID-19 safe harbor does not apply to those tests ordered by a healthcare provider.

Can a group health plan limit the OTC COVID-19 test coverage?

Yes. The safe harbor limit is eight tests per participant every 30 days. This limit applies to each individual participant, beneficiary, or enrollee. For example, an employee, the employee's spouse, and two children would be covered for 32 tests every 30 days. Restrictions outside of the safe harbor will be subject to enforcement actions. This safe harbor limit does not apply to tests administered or procured with the involvement of a healthcare provider.

What happens if a group health plan suspects fraud or abuse?

Plans that suspect fraud and abuse may require a participant to attest that the OTC COVID-19 test was purchased for personal use, not for employment purposes, and will not be resold or reimbursed by another source. The plan may also require reasonable documentation of proof of purchase for an OTC COVID-19 test, such as a UPC code and/or a receipt documenting the test's date of purchase.

Action Items

Health plans should:

- Ensure they are facilitating adequate access to OTC COVID-19 testing through their direct coverage and reimbursement networks. Group health plans should contact their insurers or third-party administrators for information on how they are implementing the reimbursement and coverage requirements.
- Update their health plan documents and summary plan descriptions to reflect changes in coverage for OTC COVID-19 tests.
- Determine whether they would like to take advantage of the safe harbor arrangement. Employers should consider this option to safeguard against unreasonable reimbursement requests for overly expensive OTC COVID-19 tests.
- Consider developing educational materials describing the direct coverage and reimbursement arrangements.

If you have any questions about the requirements for covering OTC COVID-19 tests, updating plan documents, or preparing educational materials, please contact a member of the Kutak Rock Employee Benefits Practice Group.