Federal Agencies Issue Additional Guidance on Group Health Plan Coverage of Over-the-Counter COVID Tests

Related Professionals

Wendy M. Swary

Elizabeth Howard

Related Services

Employee Benefits and Executive Compensation

Labor and Employment

CLIENT ALERT | 2.7.2022

On February 4, 2022, the U.S. Departments of Labor, the Treasury, and Health and Human Services (Tri-Agencies) issued additional Frequently Asked Questions (FAQs) regarding group health plan coverage of over-the-counter COVID-19 tests (OTC Tests). As background, in January, the Tri-Agencies issued guidance that group health plans are required to cover certain OTC Tests without a prescription or individualized clinical assessment from a medical provider and without cost-sharing, prior authorization, or other medical management requirements. This requirement went into effect on January 15, 2022. You can read our overview of that January guidance here.

The newly issued FAQs clarify and expand on that initial guidance and, overall, provide good news to plan sponsors. The main elements of the new guidance are as follows:

Clarification and Expansion of Direct Coverage Safe Harbor

The January guidance included a safe harbor for plans that provide direct coverage of OTC Tests, both through their pharmacy networks and a direct-to-consumer shipping program. If a plan utilizes a direct coverage program, then it can limit coverage of OTC Tests bought outside that program to a maximum of $12 per test.

Changes to Direct Coverage Safe Harbor. The safe harbor is intended to provide adequate access to OTC Tests without any upfront out-of-pocket expenditure to the individual, and the FAQs recognize the need to provide flexibility to plan sponsors in the design and implementation of direct coverage programs. Whether a plan provides adequate access to OTC Tests through its direct coverage program will be based on the specific facts and circumstances. The FAQs indicate that a compliant direct coverage program generally will ensure OTC Tests are available through *at least* one direct-to-consumer shipping mechanism (such as online or telephone ordering) and *at least* one in-person mechanism (such as through retail pharmacies). The FAQs provide a number of examples of how plans can provide adequate coverage to satisfy the

safe harbor, greatly expanding on the Tri-Agencies' prior guidance. The FAQs also clarify that plans must cover the reasonable shipping costs of the direct-to-consumer shipping option.

Communicating the Direct Coverage Safe Harbor. Plan sponsors that want to use the direct coverage safe harbor must communicate to participants the key information needed to access OTC Tests, such as (1) which tests are available under the direct coverage program, and (2) how participants can access OTC Tests both through the direct-to-consumer shipping option and in person.

Impact of Test Shortage on Direct Coverage Safe Harbor

The FAQs clarify that the Tri-Agencies will not take enforcement action against a plan sponsor that is temporarily unable to provide OTC Tests through its direct coverage program due to a test supply shortage. Thus, plans can continue to limit reimbursement of OTC Tests purchased outside of the direct coverage program to a maximum of $12 per test even if tests are temporarily unavailable through the direct coverage program.

Clarification of Ability to Limit Fraud or Abuse

The FAQs provide plan sponsors with more examples of how they can limit fraud and abuse when covering OTC Tests. For example, a plan may establish a policy that limits coverage of OTC Tests to tests purchased from established retailers that would typically be expected to sell OTC Tests. This means plans do not have to reimburse OTC Tests purchased from a private individual or via online auctions or resale marketplaces. If a plan sponsor establishes this type of policy, the policy must be communicated to participants.

Home Collection PCR Tests

The FAQs clarify that the requirement to cover OTC Tests without an individualized clinical assessment does not apply to tests that use a self-collected sample but require processing by a lab or other health care provider to return results, such as home-collection PCR tests. Note: this does not mean that these tests do not have to be covered at all. If ordered by a health care provider, this type of test is likely required to be covered by the Families First Coronavirus Response Act.

Reimbursement from FSA, HRA or HSA

The FAQs state that because plans are required to cover OTC Tests at no cost to the participant, the participant should not also be reimbursed from a health flexible spending arrangement (FSA) or health reimbursement arrangement (HRA) for that expense. Additionally, the OTC Test would not be considered a "qualifying medical expense" for purposes of a health savings account (HSA). To avoid potential complications, plan sponsors may want to communicate to participants that they should not request reimbursement from their FSA, HRA, or HSA for OTC Tests and should not use an account debit card to purchase OTC Tests.

Contact your Vorys lawyer if you have questions.