Federal Agencies Issue Guidance Requiring Coverage of Over-the-Counter COVID-19 Tests

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On January 10, 2022, the Departments of Labor, the Treasury and Health and Human Services (the Tri-Agencies) released new guidance that requires group health plans to cover certain authorized over-the-counter COVID-19 tests (OTC Tests) purchased on and after January 15, 2022 without cost sharing, prior authorization, or other medical management requirements. This requirement applies to both fully insured and self-insured group health plans, including grandfathered group health plans.

As background, the Families First Coronavirus Response Act currently requires group health plans and health insurance issuers to cover certain diagnostic COVID-19 tests without cost sharing. However, under previous Tri-Agency guidance, group health plans were only required to cover OTC Tests without cost sharing when those tests were ordered by a health care provider as medically necessary. This new guidance overrules that prior guidance. A group health plan is now required to cover OTC Tests without cost sharing, regardless of whether those tests are ordered by a health care provider or determined to be medically necessary.

The main elements of this new guidance are as follows:

- ***How to provide coverage*:** Group health plans can provide this coverage in one of two ways. First, the plan can make tests available free to participants by directly paying providers for the OTC Tests (referred to as "direct coverage program"). Under a direct coverage program, the plan will provide tests through its pharmacy network or other retailers (including a direct-to-consumer shipping program) without any out-of-pocket cost to the participant. Alternatively, the plan can reimburse participants for their out-of-pocket costs by having the participant submit a claim for reimbursement.
- ***Direct coverage safe harbor*:** While the guidance does not require a direct coverage program, if a plan establishes one, the plan can limit the reimbursement of any tests purchased outside of that program to a maximum of $12. In order to rely on this safe harbor, the plan must take reasonable steps to ensure participants have adequate

access to tests under the direct coverage program by providing an adequate number of retail locations to obtain the tests (both in-person and online). If a plan does not establish a direct coverage program, the plan may not limit the amount of reimbursement.

- ***Quantity*:** Plans are required to cover at least eight OTC Tests per 30 day period (or per calendar month) for every individual enrolled in the plan (including the employee and any enrolled family members or dependents).
- ***Scope of coverage*:** Plans are required to reimburse OTC Tests used for "diagnostic" purposes only. Plans are not required to cover OTC Tests purchased for non-diagnostic purposes, including for screening or employment purposes (such as employer-mandated testing). Plans are allowed to put procedures in place to prevent and detect fraud and abuse as long as the procedures do not create "significant barriers" for participants to obtain the tests. For example, a plan may require an employee attestation that the OTC Test was purchased for personal use, not employment purposes, and that the test will not be reimbursed by another source or resold. Additionally, a plan may request proof of purchase, such as a receipt and/or UPC code.
- ***Coverage period:*** The coverage requirement applies with respect to OTC Tests purchased on or after January 15, 2022, and during the public health emergency. It is expected that the public health emergency will continue to be extended into the foreseeable future.

Next steps for plan sponsors:

Fully-insured plans

- We anticipate that insurers will put processes in place to comply with this new requirement. Contact your group health plan insurer to determine how they are ensuring compliance and how they intend to communicate this benefit change to participants.

Self-insured plans

- We anticipate that pharmacy benefit managers and/or medical third party administrators are putting processes in place to comply with this new requirement. Contact your pharmacy benefit manager and medical third party administrator to determine how they are ensuring compliance and to coordinate which vendor(s) will be responsible for this compliance.
- Once you coordinate with the vendor, you will need to communicate with plan participants. The communication should explain any direct coverage program, as well as how to submit a claim for reimbursement. We also recommend that you communicate the main points of the coverage, such as quantity limit and the diagnostic requirement.
- Plans can choose to cover more than 8 OTC Tests per 30 day period (or calendar month). Additionally, plans can choose to cover tests purchased before January 15, 2022. You will need to decide whether you are going to make either of these options available to participants.
- Until a plan establishes a direct coverage program, the plan must reimburse participants' actual cost to purchase the OTC Tests. Given the variability in the price of OTC Tests (including those sold on secondary markets), employers may see a significant increase in costs to the plan.

If you have questions about this new guidance, please contact your Vorys attorney.

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VORYS COVID-19 TASK FORCE

Vorys attorneys and professionals are counseling our clients in the myriad issues related to the coronavirus (COVID-19) outbreak. We have also established a comprehensive Coronavirus Task Force, which includes attorneys with deep experience in the niche disciplines that we have been and expect to continue receiving questions regarding coronavirus. Learn more and see the latest updates from the task force at vorys.com/coronavirus.