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EMPLOYEE BENEFITS AND EXECUTIVE COMPENSATION

AGENCIES CLARIFY AND SUPPLEMENT GUIDANCE ON HEALTH PLAN COVERAGE OF OTC COVID-19 TESTS

On Friday, February 4, 2022, the Departments of Health and Human Services, Labor, and Treasury (the "Departments") issued additional guidance regarding the requirement for health insurers and group health plans to cover without cost-sharing the cost of approved over-the-counter ("OTC") diagnostic COVID-19 tests. The Departments' initial guidance on the requirement was published on January 10, 2022 and set off a mad rush by employers who maintain self-insured group health plans to work with their medical and/or pharmacy claims administrators to comply with the requirement by the January 15, 2022 effective date (see our LEGALcurrents on the original guidance here [https://www.hselaw.com/news-and-information/legalcurrents/2584-biden-administration-requires-coverage-of-over-the-counter-covid-19-tests-obtained-without-provider-involvement]).

Direct Coverage Safe Harbor Updates

The original guidance included an important "safe harbor" for "direct coverage" arrangements. If a satisfactory direct coverage arrangement is established, an insurer or plan is permitted to limit the amount of its reimbursement for OTC tests acquired outside the direct coverage arrangement to $12 per test. A satisfactory direct coverage arrangement must permit a covered individual to obtain eligible OTC tests without paying any amount out-of-pocket, either at an "adequate number" of retail establishments or through a direct-to-consumer shipping program. The original guidance said that the adequate access determination is to be made on a facts and circumstances basis.

The updated guidance on the direct coverage safe harbor is effective February 4, 2022. It repeats the facts and circumstances standard for determining adequate access, but says that adequate access will generally require that OTC tests be available through at least one direct-to-consumer shipping mechanism and at least one "in-person mechanism."

The updated guidance says that the "in-person mechanism" can be the insurer's or plan's pharmacy network, other non-pharmacy retailers (including through distribution of coupons that allow the individual to receive tests from certain retailers without cost sharing), or alternative in- person OTC test distribution sites, such as a drive through or walk-up distribution site, including a site that operates independently of a pharmacy or other retailer. In addition, the direct-to-consumer option does not have to be a separate vendor from the in-person retail option vendor--if the retail vendor has an online platform that allows individual to order tests for delivery, that online platform can serve as the direct-to-consumer option.

The updated guidance specifies that the direct-to-consumer option must cover reasonable shipping costs for OTC tests, answering a question raised by many employers and their service providers.

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The updated guidance also emphasizes the importance of communication regarding the direct coverage arrangement established by the insurer or plan, including describing any limitation on the brand/manufacturer of the OTC tests that may be applicable under the direct coverage arrangement and noting that one of the factors to be considered in the facts and circumstances determination as to whether a direct coverage arrangement provides adequate access is how the insurer or plan notifies individuals about the direct coverage arrangement. Clear communication of the direct coverage arrangement will be important. The updated guidance notes that the Departments may request information from insurers and plans to ensure that individuals have adequate access.

Supply Shortages

The original guidance became effective shortly after the Biden Administration announced it was purchasing one billion OTC tests to distribute free of charge to American households. Plus, the Omicron variant had already caused OTC tests to be in short supply. Understandably, insurers and employers were concerned that they would have difficulty establishing satisfactory direct coverage arrangements. The updated guidance says that the Departments will not take enforcement action against an insurer or plan that is temporarily unable to provide adequate access to OTC tests through its direct coverage arrangement due to a supply shortage. In such a case, the insurer or plan may continue to limit reimbursement for OTC tests purchased outside of the direct coverage arrangement to $12 per test (or the cost of the test, if lower).

Fraud and Abuse

Many employers expressed concern regarding reimbursing for the purchase of OTC tests from unscrupulous sellers/re-sellers (e.g., purchases from private individuals via in-person or online person-to-person sales, or from a seller using an online auction or resale marketplace). The updated guidance permits insurers and plans to disallow reimbursement from such sources and to limit reimbursement to tests purchased from "established retailers that would typically be expected to sell OTC COVID-19 tests." In addition, the updated guidance notes that a policy could include requiring reasonable documentation of proof of purchase that clearly identifies the product and seller, such as a UPC code or other serial number, original receipt from the seller, or other documentation. The policy may also require the individual to attest that the test has not been (and will not be) reimbursed by another source, including through resale. If an insurer or plan intends to disallow reimbursement for OTC tests purchased from certain resellers, "it should provide information" to individuals regarding the retailers from which purchased tests are generally covered and about the types of resellers for which individuals are not eligible for reimbursement for purchased tests.

The anti-fraud and abuse provision is welcome news, particularly for those plans and insurers that have not established a direct coverage arrangement. Plans and insurers that have a direct coverage arrangement may not be particularly concerned with reimbursing tests purchased from disreputable sellers, since the plan or insurer could limit reimbursements to $12 per test. But recall that if a plan or insurer does not have a direct coverage arrangement, the plan or insurer cannot place a dollar limit on the amount the plan or insurer will pay for a test. Absent this new guidance, such a plan or insurer could theoretically have been responsible for reimbursing excessive amounts for a test purchased from an unscrupulous seller (e.g., a $400 test purchased on a secondary marketplace from a price gouger). To prevent this sort of abuse, the plan or

insurer must specifically limit the plan or insurer's coverage of tests to established retailers; notably, the updated guidance does NOT permit an insurer or plan that does not have a direct coverage arrangement to combat price-gouging by placing a dollar limit on tests. Thus, to avoid having to pay exorbitant amounts for tests, plans and insurers without a direct coverage relationship should consider promptly establishing (and communicating) restrictions on the reimbursement of tests purchased outside of established retail sellers.

Application of OTC Guidance

The updated guidance clarifies that the requirements to cover OTC tests apply only to tests that can be obtained without a prescription and completely used and processed without the involvement of a lab or other health care provider (i.e., self-administered, self-read tests). Tests where the individual collects the specimen and sends it to be processed by a lab are not covered by the January guidance or this updated guidance. Such tests would be covered in accordance with existing guidance under the Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act.

Interaction with Account Based Plans and HSAs

The updated guidance notes some fundamental principles that were not addressed in the original guidance. The cost of an OTC test purchased by an individual is considered a medical expense, and thus would generally be reimbursable under a health flexible spending account (health FSA) or health reimbursement arrangement (HRA) and could also entitle an individual to take a tax-free distribution from a health savings account (HSA). The guidance reiterates that an individual cannot be reimbursed for the same medical expense more than once. Thus, the cost (or portion of the cost) of an OTC test that is paid or reimbursed by an insurer or group health plan cannot be reimbursed by a health FSA or HRA. Similarly, the amount of an OTC test that is paid or reimbursed by an insurer or group health plan would not be considered a qualified medical expense for which an individual could take a tax-free HSA distribution. The updated guidance notes that an insurer or plan "may wish to advise" individuals not to seek reimbursement from a health FSA or HRA for the cost or portion of the cost of an OTC test paid or reimbursed by the insurer or plan, and not to use a health FSA or HRA debit card to purchase an OTC test for which the individual intends to seek reimbursement from the insurer or plan.

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