

Harter Secrest & Emery LLP

ATTORNEYS AND COUNSELORS

EMPLOYEE BENEFITS AND EXECUTIVE COMPENSATION

BIDEN ADMINISTRATION REQUIRES COVERAGE OF OVER-THE-COUNTER COVID-19 TESTS OBTAINED WITHOUT PROVIDER INVOLVEMENT

On January 10, 2022, the Department of Health and Human Services, Department of Labor, and Treasury Department issued joint guidance requiring insurers and group health plans to cover the cost of over-the-counter (“OTC”) diagnostic COVID-19 tests without a cost-sharing or other pre-approval requirement, expanding upon the requirement that plans cover COVID-19 diagnostic tests ordered by a medical provider after clinical assessment of the individual. This requirement is set to take effect January 15, 2022, and is applicable for OTC tests purchased on or after that date. The FAQ style guidance follows a directive issued by the Biden administration on December 2nd in connection with the Families First Coronavirus Response Act (“FFCRA”) and Coronavirus Aid, Relief, and Economic Security (“CARES”) Act, requiring health plans to provide coverage for diagnostic COVID-19 tests and bolstering its efforts to increase Americans’ access to affordable or no-cost at home tests.

[The January 10th FAQ](#) specifies that group health plans and insurers must cover OTC COVID-19 tests without out-of-pocket expense to participants, either through covering the cost at the point of sale, or by reimbursing the individual through the plan’s reimbursement procedure. Beginning January 15th, plans must provide coverage for at least eight OTC tests, per participant, every 30 days (or, at the option of the plan, per calendar month). This means a covered family of four can get at least 32 tests per month.

In order to encourage plans and insurers to “facilitate consumer access and provide for a seamless experience in obtaining free OTC COVID-19 tests,” the guidance allows plans and insurers that establish a qualifying “direct coverage” arrangement for OTC tests to cap the amount they reimburse for OTC tests purchased outside of the direct coverage arrangement (i.e., “out-of-network”) to \$12 per individual test. If multiple tests are packaged together, the reimbursement is up to \$12 per test (e.g., if tests are sold in a pack of two, a participant would be reimbursed up to \$24 per pack purchased). If a plan or insurer does NOT establish a qualifying direct coverage arrangement, the plan cannot place a dollar limit on the amount the plan or insurer will reimburse for a test.

In order to be a qualifying direct coverage arrangement, the plan or insurer must make arrangements to process payments to the pharmacy or retailer directly, or have tests delivered to the individual through a direct-to-individual shipping program. The guidance specifies that a plan or insurer that establishes a qualifying direct coverage arrangement must take “reasonable steps to ensure that participants, beneficiaries, and enrollees have adequate access to OTC COVID-19 tests through an adequate number of retail locations (including both in-person and online locations).” Whether there is adequate access for this purpose is determined on a facts and circumstances basis.

Practice Group Leader
Paul W. Holloway

Health and Welfare
Thomas J. Hurley
John W. Brill

Counsel
Leslie E. DesMarteau
Lisa G. Pelta
Joseph E. Simpson

Associates
Amanda M. Karpovich
Crosby A. Sommers

Benefits Litigation
Jessica N. Clemente
Erika N. D. Stanat

Retirement
Mark R. Wilson

Executive Compensation
Christopher M. Potash

Law Clerk
Hailey S. Trippany

If the arrangement does not satisfy the requirements, the plan or insurer must cover the full cost of the OTC test acquired out-of-network. The guidance puts the risk of delays in availability due to supply chain problems on the plan or insurer, noting that “if there are delays that are significantly longer than the amount of time it takes to receive other items under the plan’s or issuer’s direct-to-consumer shipping program” the plan or insurer wouldn’t satisfy the direct coverage requirement and would be required to reimburse the individual for the full cost of OTC tests purchased by the individual out-of-network. Given the current demand for tests and supply issues, this could make it difficult for plans and insurers to establish a qualifying “direct coverage” arrangement and could result in higher costs due to reimbursement of out-of-network tests priced higher than the \$12 per test cap.

The guidance reiterates that COVID-19 tests administered with a provider’s involvement or prescription continue to be subject to existing reimbursement requirements and are not subject to any limitation on quantity. The guidance also reiterates that plans are not required to cover the costs of tests purchased by participants for employment purposes (e.g., for use in complying with the weekly testing requirement under the pending OSHA emergency temporary standard vaccine-or-test workplace mandate or other employment-based testing requirements). Given the requirements that must be satisfied if a plan or insurer wants to satisfy the direct purchase arrangement provision, it may be difficult for plans or insurers to apply this “exclusion” for employment-related use. However, the guidance does allow plans and insurers to take reasonable steps to prevent fraud and abuse, including taking “reasonable steps to ensure that an OTC COVID-19 test for which a covered individual seeks coverage under the plan or coverage was purchased for the individual’s own personal use (or use by another participant, beneficiary, or enrollee who is covered under the plan or coverage as a member of the individual’s family), provided that such steps do not create significant barriers for participants, beneficiaries, and enrollees to obtain these tests.” The guidance says that a plan or insurer could “require an attestation, such as a signature on a brief attestation document, that the OTC COVID-19 test was purchased by the participant, beneficiary, or enrollee for personal use, not for employment purposes, has not been (and will not be) reimbursed by another source, and is not for resale.” Such an attestation may be challenging to obtain in the context of a direct purchase arrangement. Obviously, in the case of a reimbursement request, the plan or insurance carrier could require that the individual submit an attestation with his or her reimbursement request.

Finally, the guidance says that plans and insurance carriers may provide education and information resources to support consumers seeking OTC COVID-19 testing, provided that the information satisfies certain requirements specified in the guidance, including that it describes how to submit a claim for reimbursement including electronic and paper filing options, the required information needed for such a claim, and a description of the documentation that must be submitted in order for the plan or insurer to be able to process the claim promptly and accurately.

Next Steps

For employers with fully insured health plans, the plan’s insurance carrier will be responsible for complying with these requirements. Self-insured employers should contact their claims administrator to discuss whether the claims administrator plans to establish a qualifying direct purchase arrangement and whether the claims administrator will be able to manage a meaningful attestation process. Once the details of any

direct coverage arrangement are known, the employer should consider whether to communicate applicable coverage details to employees.

If you have any questions regarding this LEGALcurrents, please contact any member of the Employee Benefits & Executive Compensation group at 585.232.6500, 716.853.1316, or visit www.hselaw.com.

Attorney Advertising. Prior results do not guarantee a similar outcome. This publication is provided as a service to clients and friends of Harter Secrest & Emery LLP. It is intended for general information purposes only and should not be considered as legal advice. The contents are neither an exhaustive discussion nor do they purport to cover all developments in the area. The reader should consult with legal counsel to determine how applicable laws relate to specific situations. © 2022 Harter Secrest & Emery LLP

