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Benefits Alert

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Group health plans must cover OTC COVID-19 tests starting January 15! Here is what you need to know

By Damian A. Myers, Yelena Gray, and Annie Zhang

Plan sponsors and administrators must act immediately to comply with the over-the-counter COVID test coverage mandate.

What's the Impact?

- Starting January 15, group health plans must reimburse participants for OTC COVID-19 tests purchased without an order or clinical assessment from a healthcare provider
- The FAQs issued this week address coverage requirements, safe harbors, and reimbursement guidelines

On January 10, 2022, the Departments of Treasury, Labor, and Health and Human Services (the "Departments") issued frequently asked questions Part 51 ("FAQs 51") covering the new mandate that group health plans reimburse participants (generally without cost-sharing) for over-the-counter ("OTC") COVID-19 tests purchased without an order or clinical assessment from a healthcare provider. FAQs 51 explains that group health plans must begin complying with the coverage mandate **no later than January 15**, so plan sponsors and administrators must act immediately.

Following a brief background discussion regarding coverage of COVID-19 testing, we summarize the parameters of the new coverage mandate and highlight some key takeaways/action items for plan sponsors and administrators. Note that FAQs 51 also provide guidance related to coverage of preventive services (colonoscopies and contraceptives), but that guidance is not addressed in this alert.

COVID-19 testing background

In March 2020, two legislative pieces were passed that set forth parameters for first-dollar (i.e., no cost-sharing) coverage of COVID-19 testing—the Families First Coronavirus Response Act ("FFCRA") and the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). Collectively, these laws require group health plans to cover without cost-sharing or application of medical management techniques (e.g., prior authorization) certain items and services primarily related to the individualized testing for, or diagnosis of, COVID-19. Such tests and diagnostic services are required to be covered when medically appropriate, as determined by an individual's healthcare provider. Health plans are **not** required to cover COVID-19 tests administered for employment-related reasons (e.g., when employees are required to produce a negative test to work onsite). Health plans are also **not** required to cover COVID-19 tests that do not satisfy the statutory criteria of FFCRA § 6001(a)(1) (i.e., generally, Food and Drug Administration (FDA) authorization).

In June 2020, the Departments issued FAQs 43, which, among other things, requires first-dollar coverage of an OTC COVID-19 test when such test is ordered by a healthcare provider who determined that the test is medically appropriate for the individual.

On December 2, 2021, the Biden administration directed the Departments to issue guidance requiring first-dollar coverage for OTC COVID-19 tests even when a healthcare provider does not order the test or perform a clinical assessment of medical appropriateness.

Basic OTC COVID-19 test coverage requirements

FAQs 51 provide for the basic coverage requirements for OTC COVID-19 tests purchased or acquired without involvement of a healthcare provider, as well as two safe harbors that allow plan sponsors and administrators to apply limits to the coverage mandate. The basic coverage requirements are as follows:

- Any FDA-authorized OTC COVID-19 test must be covered by a group health plan without application of cost-sharing, prior authorization, or other medical management techniques. This means that the full cost of the test must be covered (subject to the Reimbursement Limit Safe Harbor described below)
- Direct coverage (i.e., where the covered individual has no upfront cost) is strongly encouraged, but not required. In the absence of direct coverage, a plan must allow for reimbursement of claims in accordance with the plan's claims and appeals procedures.
- Coverage cannot be limited to only tests that are provided through preferred pharmacies or direct-to-consumer shipping programs (subject to the Reimbursement Limit Safe Harbor

described below)

- Plans cannot impose quantity/frequency limits on coverage of OTC COVID-19 tests (subject to the Quantity/Frequency Limit Safe Harbor described below)
- Plans are permitted to apply fraud, waste, and abuse procedures to mitigate against potential fraud. The Departments, however, are concerned that burdensome fraud, waste, and abuse procedures could obstruct reasonable access to OTC COVID-19 tests. Therefore, the Departments provide a couple examples of acceptable requirements that plan sponsors and administrators can implement:
  - Attestation from covered individuals that the test (i) was purchased by the individual for personal use and not for employment purposes, (ii) will not be reimbursed by another source, and (iii) is not for resale
  - Submission of proof of purchase to substantiate the claim for reimbursement

The basic coverage requirements described above have broad applicability and offer little in the way of cost control/abuse mitigation for plans. Therefore, many plan sponsors and administrators may want to consider the safe harbors below. Plans that use these safe harbors will not face enforcement action from the Departments provided the plans otherwise comply with the coverage mandate.

Reimbursement limit safe harbor

As noted above, generally, plans must cover the full cost of FDA-authorized OTC COVID-19 tests. To facilitate access to OTC COVID-19 tests and give plan sponsors some ability to control costs of unlimited testing, FAQs 51 authorize plan sponsors and administrators to apply a dollar limit on certain OTC COVID-19 tests purchased by covered individuals provided that certain conditions are met. The Reimbursement Limit Safe Harbor conditions are described below.

- Plans must provide for direct coverage of FDA-authorized OTC COVID-19 tests through both its preferred pharmacy network and a direct-to-consumer shipping program (e.g., a mail order pharmacy or other distributor of OTC COVID-19 tests)
  - A plan's pharmacy benefit manager will presumably manage OTC COVID-19 test claims purchased at pharmacies participating in the benefit manager's preferred network
  - The direct-to-consumer shipped program can be through one or more in-network provider(s), mail order pharmacies, or another entity designated by the plan
- Plans must make reasonable efforts to ensure covered individuals have reasonable access to OTC COVID-19 tests through an adequate number of retail locations, both in-person and online. Reasonable access is determined based on the facts and circumstances, taking into account the location of covered individuals, pharmacy network utilization, and participant communication efforts. For example, ensuring reasonable access generally requires plans to inform covered individuals of the OTC COVID-19 test coverage program (i.e., how to access the tests, what the preferred pharmacy network is, how to use the direct-to-consumer program, etc.)

The Reimbursement Limit Safe Harbor **does not** apply to OTC COVID-19 tests that are ordered by a healthcare provider based on a determination of medical appropriateness.

If a plan provides for direct coverage through its pharmacy network and a direct-to-consumer shipping program, the plan can limit the reimbursement from non-preferred pharmacies and other retailers to $12 per test. Note that many OTC COVID-19 testing kits contain two tests, so for those kits, the reimbursement limit is $24 (i.e., $12 per test). If a plan is not able to satisfy the requirements of the Reimbursement Limit Safe Harbor, the plan must cover all OTC COVID-19 tests without any limit on the reimbursement.

Quantity/frequency limit safe harbor

To address concerns regarding potential abuse of the OTC COVID-19 test mandate and to ensure that individuals who need tests have access to them, FAQs 51 provide for a Quantity/Frequency Limit Safe Harbor. Key components of this safe harbor are described below.

- A plan may limit the number of FDA-authorized OTC COVID-19 tests a covered individual receives at first-dollar coverage to 8 tests per 30-day period (or per calendar month). When applying the quantity limit, tests contained in a multi-test kit are counted separately
- The quantity limit is determined on a covered individual basis. For example, if an employee covers a spouse and three dependents, each of them can receive 8 tests at first-dollar coverage per 30-day period (or per calendar month)
- Because some situations may warrant frequent testing within a short period of time (i.e., exposure to COVID-19), plans may not apply shorter limit parameters. For example, a plan cannot limit tests to 4 per 15-day period

The Quantity/Frequency Limit Safe Harbor **does not** apply to OTC COVID-19 tests that are ordered by a healthcare provider based on a determination of medical appropriateness.

Participant Support

In FAQs 51, the Departments encourage robust communications to ensure that covered individuals are adequately informed about the OTC COVID-19 test coverage parameters. For example, plan sponsors and administrators should consider informing covered individuals of the following:

- The general requirements of the OTC COVID-19 testing coverage mandate, including post-purchase reimbursement procedures, access to direct coverage through the preferred pharmacy network and direct-to-consumer shipping program, and reimbursement and quantity/frequency limits
- Description of the various types of COVID-19 tests, when different types of COVID-19 tests are appropriate, and how to access and use the testing alternatives
- Information on test quality, such as expiration dates, list of FDA-authorized tests, and reliability of test results

Key takeaways and action items

Without a doubt, the new OTC COVID-19 test coverage mandate increases overall group health plan spend and makes administration more difficult. Nevertheless, plans must be ready to comply by January 15. With that in mind, plan sponsors and administrators should note the following:

- FAQs 51 do not change the existing rule that employers and group health plans are not required to cover the cost of COVID-tests used for medical surveillance or employment-related purposes. Employers can require that employees pay for the full cost of tests that are conducted to screen for general workplace health and safety
- Sponsors of fully insured plans should reach-out to insurance carriers to (i) determine whether they will be able to provide direct coverage and a direct-to-consumer option, and (ii) whether the insurance carrier will distribute communications regarding the coverage mandate
- Sponsors/administrator of self-insured plans should contact third-party medical plan administrators and pharmacy benefit managers to allocate responsibility for compliance. Most likely, the third-party vendors will provide assistance subject to an additional administrative fee, so the scope of services and the fee should be addressed in amendments to service agreements. If, however, pharmacy benefit managers are using their own retail or mail order pharmacies, plan sponsors should ask for favorable pricing or waiver of any additional administrative fees
- If third-party vendors are unable to provide a direct-to-consumer shipping option, plan sponsors and administrators may need to contract with a separate distributor of tests (assuming a desire to utilize the Reimbursement Limit Safe Harbor)
- Plans should work closely with third-party vendors to prepare participant communications explaining the policies and procedures related to the coverage mandate

Note that the OTC COVID-19 testing coverage mandate will remain in place for the duration of the public health emergency, as determined by the Secretary of the Department of Health and Human Services. The public health emergency has been in place since January 27, 2020 and will likely continue for the foreseeable future.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

Damian A. Myers
202.585.8485
dmyers@nixonpeabody.com

Yelena F. Gray
312.977.4158
yfgray@nixonpeabody.com

Annie Zhang
202.585.8606
azhang@nixonpeabody.com