GROOM LAW GROUP

www.groom.com

Update! Departments Issue More Guidance Addressing Coverage of Over-the-Counter COVID-19 Tests

PUBLISHED: February 7, 2022

On December 2, 2021, President Biden announced new actions to combat COVID-19, given the emergence of the new Omicron variant. As part of his nine-point plan, the President included a directive that "the more than 150 million Americans with private insurance . . . will also be able to get at-home [COVID-19] tests reimbursed by their insurance." On January 10, 2022, the Departments of Labor, Health and Human Services, and the Treasury (the "Departments") issued guidance addressing the President's directive by releasing a set of Frequently Asked Questions ("first FAQs") that require coverage for over-the-counter ("OTC") COVID-19 tests during the public health emergency by either direct coverage or reimbursement for the cost of the test from a group health plan or health insurance issuer. Most recently, on February 4, 2022, the Departments issued an additional set of FAQs ("second FAQs ") that modifies and clarifies certain aspects of the first FAQs. Below, we have updated our original alert to reflect the second FAQs.

The requirement that group health plans and health insurance issuers cover the cost of OTC COVID-19 tests builds on the provision in the Families First Coronavirus Response Act ("FFCRA"), as amended by the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, which requires that group health plans and issuers cover in vitro diagnostic COVID-19 tests without cost-sharing if they meet certain criteria. Prior to the issuance of the first FAQs, that provision had been understood generally to require group health plans and issuers to cover COVID-19 diagnostic tests only when ordered by a medical

If you have any questions, please do not hesitate to contact your regular Groom attorney or the authors listed below:

Katie Bjornstad Amin
kamin@groom.com
(202) 861-2604

Jon Breyfogle
jbreyfogle@groom.com
(202) 861-6641

Lisa Campbell
lcampbell@groom.com
(202) 861-6612

Christine Keller
ckeller@groom.com
(202) 861-9371

Tammy Killion
tkillion@groom.com
(202) 861-6328

Seth Perretta
sperretta@groom.com
(202) 861-6335

Christy Tinnes
ctinnes@groom.com
(202) 861-6603

Jessica Winslow
jwinslow@groom.com
(202) 861-0155

This publication is provided for educational and informational purposes only and does not contain legal advice. The information should in no way be taken as an indication of future legal results. Accordingly, you should not act on any information provided without consulting legal counsel. To comply with U.S. Treasury Regulations, we also inform you that, unless expressly stated otherwise, any tax advice contained in this communication is not intended to be used and cannot be used by any taxpayer to avoid penalties under the Internal Revenue Code, and such advice cannot be quoted or referenced to promote or market to another party any transaction or matter addressed in this communication.

© 2021 Groom Law Group, Chartered • 1701 Pennsylvania Ave NW • Washington, DC 20006. All rights reserved.

provider. Under the new requirement for OTC COVID-19 tests, there is no required medical provider involvement.

In prior guidance, the Departments clarified that this mandate does not encompass tests taken for surveillance or return to work purposes, and that clarification remains unchanged by the new FAQs.

Coverage of OTC COVID-19 Tests

Plans and issuers must cover OTC COVID-19 tests as outlined in the first and second FAQs, including OTC tests obtained without an order or individualized clinical assessment by a health care provider (superseding prior guidance that limited coverage to situations in which the at-home test was ordered by a health care provider). The plan or issuer must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements.

GROOM INSIGHT: "Cost-sharing" does not include the contributions or premiums paid by an individual for coverage, which means that plans and issuers may take into account the increased costs due to this OTC COVID-19 test coverage requirement, along with other claims experience, when setting contributions or premiums for future years.

Plans and issuers are not required to cover tests at the point of sale ("direct coverage") and may instead require that a covered individual pay out-of-pocket and then submit a claim for reimbursement. However, the Departments strongly encourage plans and issuers to provide direct coverage for OTC COVID-19 tests so that covered individuals do not have to pay for such tests upfront. Plans and issuers that do so, and otherwise meet a specific "safe harbor" enumerated in the first FAQs, may limit the dollar amount that they pay for a given OTC COVID-19 test (subject to specific rules outlined below) compared to the dollar amount that they reimburse to a participant who paid for the test upfront. If the plan or issuer does not provide direct coverage, such plan or issuer may not limit the reimbursement amount for the test, but rather, must reimburse the actual cost.

Limiting Coverage to Preferred Pharmacies or Other Retailers

Plans and issuers cannot limit coverage of OTC COVID-19 tests to only tests that are provided through preferred pharmacies or other retailers. However, the first FAQs provided a "safe harbor" under which, if the plan or issuer arranges for direct coverage of OTC COVID-19 tests through both its pharmacy network and a direct-to-consumer shipping program, plans and issuers can limit reimbursement for OTC COVID-19 tests purchased from non-preferred pharmacies or other retailers to the lower of (1) the actual price or (2) $12 per test. This amount applies per test, so if a package includes more than one test, the reimbursement amount is increased (e.g., for a package of two tests, the reimbursement must be the lower of (1) the actual price or (2) $24).

A direct-to-consumer shipping mechanism is any program that provides direct coverage of OTC COVID-19 tests without requiring the covered individual to obtain the test in-person, including online or telephone ordering. It can be provided through a pharmacy or other retailer, the plan or issuer directly, or any other entity, and plans and issuers do not have to provide exclusive access through one entity so long as they allow a covered individual to have the tests shipped to him/her directly.

- **New!** The second FAQs state that plans and issuers "have significant flexibility in how they provide access to OTC COVID-19 tests" and "must provide direct coverage by ensuring participants, beneficiaries, and enrollees have adequate access to OTC COVID-19 tests with no upfront out-of-pocket expenditures." Whether a plan or issuer provides "direct coverage" still depends on the facts and circumstances and "will generally require that OTC COVID-19 tests are made available through at least one direct-to-consumer shipping mechanism and at least one in-person mechanism."

GROOM INSIGHT: Many plans and issuers were not able to have a direct-to-consumer shipping program up and running with such short notice. A footnote in the second FAQs gives possible limited relief while programs are getting started – the footnote states that the Departments recognize that there may be some limited circumstances in which a direct coverage program could provide adequate access without establishing both a direct-to-consumer shipping program and an in-person mechanism. For example, where a small employer's plan covers only employees who live and work in a localized area, it could be possible that distribution at a nearby location constitutes adequate access without establishing a direct-to-consumer shipping mechanism. It is not clear whether this exception would also apply to large employers and, if so, under what circumstances a large employer's distribution would constitute adequate access without a direct-to-consumer shipping program.

- **New!** The second FAQs clarify that when providing OTC COVID-19 tests through a direct-to-consumer shipping program, plans and issuers must cover reasonable shipping costs related to covered OTC COVID-19 tests in a manner consistent with other items or products provided by the plan or issuer via mail order. However, a plan or issuer that meets the requirements of the safe harbor may continue to limit reimbursement to $12 per test (or the full cost of the test, if lower) for OTC COVID-19 tests purchased outside of the direct coverage program, and the guidance clarifies that the $12 maximum reimbursement limit includes shipping and sales tax costs.

Plans and issuers must take reasonable steps to make certain that participants have adequate access to OTC COVID-19 tests by ensuring that tests are available through an adequate number of in-person and online retail locations. What constitutes "adequate" access was not specifically defined in the first

FAQs other than that the Departments would consider a facts and circumstances test that requires analysis of the locality of participants and current utilization of the plan's or issuer's pharmacy network. Plans and issuers must also ensure that covered individuals are informed how to access OTC COVID-19 tests, including the date of availability of the direct coverage program and the participating retailers or other locations.

- **New!** The second FAQs detail how plans and issuers can provide direct coverage and direct-to-consumer shipping programs. For example, plans and issuers can provide direct coverage of OTC COVID-19 tests through a number of mechanisms including: (1) a direct-to-consumer shipping program that allows for orders to be placed online or by telephone, (2) the plan's or issuer's pharmacy network, (3) other non-pharmacy retailers, and (4) alternative OTC COVID-19 test distribution sites established by (or on behalf of) the plan or issuer. Plans and issuers should inform covered individuals about whether the type of test available to covered individuals varies based on the coverage mechanism utilized.
- **New!** The Departments note that they may request information from plans and issuers, such as the number and location of in-person options, to ensure that covered individuals have adequate access to OTC COVID-19 tests.
- **New!** The second FAQs clarify that adequate access under the safe harbor does not mean a plan or issuer has to make all OTC COVID-19 tests that meet the statutory criteria under the FFCRA and CARES Act available through the direct coverage program. For example, a plan or issuer could cover tests from a limited number of manufacturers (such as those with whom the plan or issuer has a contractual relationship) if that would provide adequate access based on the facts and circumstances.

The option to create a point of sale coverage network (and limit the payment of a test purchased outside of the network to the $12 maximum) only applies with respect to OTC COVID-19 tests that are administered without a provider's involvement or prescription. When a provider is involved, plans and issuers must continue to provide coverage for COVID-19 tests in accordance with prior guidance.

New! Difficulties Related to Supply Shortages

The second FAQs provide that if a plan or issuer is unable to temporarily provide adequate access through a direct coverage program due to supply shortage, but has otherwise established a compliant direct coverage program, such plan or issuer will not be out of compliance with the direct coverage safe harbor. If this happens, the plan or issuer can limit reimbursement of tests purchased outside of the direct coverage program to $12 per test.

GROOM INSIGHT: This has been a significant concern for plans and issuers because OTC COVID-19 tests continue to be in short supply.

Quantity Limits and the Prevention of Fraud and Abuse

Plans and issuers can limit the number of OTC COVID-19 tests provided pursuant to the FAQs, so long as they cover at least 8 tests per 30-day period (or calendar month) for each covered individual. So, for example, a covered family of four would be able to get up to 32 OTC COVID-19 tests covered by their health plan per 30-day period (or calendar month). In applying this quantity limit, plans and issuers may count each test separately, even if multiple tests are sold in one package. This limit applies solely with respect to coverage of OTC COVID-19 tests that are administered without a provider's involvement or prescription.

Additionally, plans and issuers may take reasonable steps to prevent, detect, and address fraud and abuse. For example, plans and issuers can require a brief attestation that the test was purchased for the covered individual's own personal use or that of a covered dependent. Plans and issuers may also require reasonable documentation of proof of purchase of an OTC COVID-19 test, such as the UPC code and/or a receipt from the seller of the test, documenting the date of purchase and the price.

- **New!** The second FAQs note that plans and issuers can establish a policy that limits coverage of OTC COVID-19 tests purchased without the involvement of a provider to tests purchased from established retailers that would typically be expected to sell OTC COVID-19 tests. Specifically, plans and issuers do not have to reimburse OTC COVID-19 tests that a covered individual purchases from a private individual (either in person or online) or a seller that uses an online auction or resale marketplace. If a plan or issuer implements such a restriction, it should provide covered individuals with information regarding the retailers from which it will generally reimburse the cost of OTC COVID-19 tests and those that retailers or individuals that will not be covered under its OTC COVID-19 test reimbursement program. The second FAQs also permit a plan or issuer to limit coverage where the cost is reimbursed from another source, such as through an FSA or HRA (see below) – or if re-sold by the participant. So the plan or issuer could prohibit participants from receiving plan-covered OTC tests and then re-selling them.

GROOM INSIGHT: This is an important clarification, particularly for plans and issuers that do not implement the direct coverage option, because this allows a plan and issuer to limit its reimbursement of OTC COVID-19 tests to established retailers, which should help minimize financial exposure for price gouging or other excessive pricing strategies by resellers.

New! Coverage of Tests That Require Laboratory or Provider Involvement

The second FAQs note that the guidance under the first FAQs applies to OTC COVID-19 tests that are approved, cleared, or authorized for use by the Food and Drug Administration and that can be obtained without a prescription. The second FAQs specify that this means tests that are completely used and processed without the involvement of a laboratory or other health care provider. If an OTC COVID-19 test is not approved to be self-administered *and* self-read, the guidance in the OTC COVID-19 FAQs does not apply. However, provisions under the FFCRA, CARES Act, and prior guidance may still apply to such test.

Impact on FSAs, HRAs, and HSAs

Under existing federal tax law, in order for an expense to be reimbursable on a tax-free basis from an FSA, HRA, or HSA, it must not be reimbursed under other coverage. So, if a plan or issuer pays for the OTC COVID-19 test for an individual, his/her FSA or HRA should not also reimburse that expense, and an HSA account owner should not seek a distribution from his/her HSA for that expense (or he/she will be subject to taxes and potential penalties).

- **New!** The first FAQs did not address the impact of the guidance on FSAs, HRAs, or HSAs, but second FAQs do. Specifically, the Departments note that the cost of an OTC COVID-19 test is a medical expense that generally could be reimbursed by an FSA or HRA; however, since an individual cannot be reimbursed more than once for the same medical expense, tests reimbursed by a plan or issuer cannot be reimbursed by an FSA or HRA. Similarly, such expenses are not qualified medical expenses for purposes of distributions from an individual's HSA if reimbursed by a plan or issuer. The Departments suggest that plans and issuers advise covered individuals not to seek reimbursement from their FSA or HRA for the cost of OTC COVID-19 tests that are paid for or reimbursed by the plan or issuer. If an individual mistakenly receives reimbursement from an FSA or HRA for a test already covered by the plan's or issuer's reimbursement program, the individual should contact the account administrator regarding correction procedures. If an individual mistakenly takes a distribution from an HSA for a test already covered by the plan's or issuer's reimbursement program, the individual must either (1) include the distribution in gross income, or (2) if and as permitted under existing guidance, repay the distribution to the HSA.

It is clear from IRS Notice 2020-15 that a plan or issuer can pay for an OTC COVID-19 test without impacting an individual's HSA eligibility even if the individual has not satisfied the deductible under the high deductible health plan. Even without that guidance, however, an OTC COVID-19 test would presumably be preventive care under IRS Notice 2004-23 for which the plan could cover before the deductible is satisfied.

Effective Date for OTC COVID-19 Tests

Plans and issuers must provide coverage in accordance with the FAQs for OTC COVID-19 tests purchased on or after January 15, 2022 and during the public health emergency.

- **New!** The guidance under the second FAQs regarding the flexibility in creating direct-to-consumer shipping and direct coverage in-person programs applies prospectively and is effective beginning February 4, 2022.

Coverage of Preventive Services

The first FAQs also address questions regarding coverage of colorectal screenings and contraceptive services as preventive services.

On May 18, 2021, the U.S. Preventive Services Task Force ("USPSTF") released an updated recommendation that all adults aged 45 to 75 years receive regular screenings for colorectal cancer (previously the USPSTF recommended that screenings begin at age 50). Accordingly, such screenings must be covered without cost sharing in accordance with the requirements of the Affordable Care Act. The USPSTF also noted that a follow-up colonoscopy is needed when stool-based tests or direct visualization reveal abnormal results. Consistent with this note, the Departments clarify that plans and issuers must also cover, without cost sharing, a colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization screening test for individuals described in the USPSTF recommendation. Plans and issuers must provide coverage consistent with the updated USPSTF recommendation for plan or policy years beginning on or after May 31, 2022.

The Departments also include a reminder that non-exempt plans and issuers are required to cover, without cost sharing, all FDA-approved, cleared, or granted contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual, regardless of whether such method is specifically identified in the current FDA Birth Control Guide. This comes in response to complaints and public reports of potential violations of existing coverage requirements.