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EMPLOYEE BENEFITS

Agency Guidance Regarding Coverage for At-Home COVID-19 Tests

January 14, 2022

On January 10, 2022, the Departments of Labor, Health and Human Services (HHS) and the Treasury (collectively, the Departments) issued a new set of FAQs addressing group health plan and health insurance issuer coverage for at-home COVID-19 diagnostic tests. FAQ Part 51 further expands upon and updates past guidance issued by the Departments regarding requirements under the Families First Coronavirus Response Act (FFCRA) and Coronavirus Aid, Relief and Economic Security Act (CARES Act).

Key Takeaways for Group Health Plans:

- Group health plans must cover over-the-counter (OTC) COVID-19 tests under section 6001 of the FFCRA, with or without an order or individualized clinical assessment by an attending health care provider.
- Plans and issuers must begin providing coverage for OTC COVID-19 tests available without an order or individual assessment purchased on or after January 15, 2022, and during the public health emergency.
- FAQ Part 51 does not modify the Department's prior guidance with respect to coverage of COVID-19 testing for employment or public health screening purposes.[1]
- Group health plans will need to ensure appropriate systems are in place for processing reimbursements. This may require working directly with TPAs and carriers.

Background

Guidance under FAQ Part 43 issued in June 2020 stated that plans and issuers must cover, without cost-sharing, COVID-19 tests intended for at-home testing when the test is determined to be medically appropriate for the individual by an attending health care provider who has ordered the test.[2]

President Biden announced on December 2, 2021, plans for expanding free at-home testing while stating that during the public health emergency, individuals who purchase OTC at-home COVID-19 diagnostic tests can seek reimbursement from their group health plans or health insurance issuers to cover the costs of the tests.[3] However, the announcement noted that COVID-19 testing for workplace screening would remain consistent with current guidance. In his announcement, President Biden, also directed the Departments to issue guidance by January 15, 2022, to clarify the above requirements, which they have provided under FAQ Part 51.

[1] See FAQs Part 44, Q2 https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-44.pdf
[2] See FAQ Part 43, Q4 https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf
[3] https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actions-to-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/

Below is a summary of FAQ Part 51, highlighting the most pertinent aspects of the new guidance pertaining to at-home COVID-19 diagnostic testing.

At-Home COVID-19 Diagnostic Testing

Q/A 1. Group health plans and issuers must cover OTC COVID-19 tests regardless of whether an order or individualized clinical assessment was issued by a health care provider. Coverage applies to COVID-19 tests that meet the criteria under section 6001(a)(1) of the FFCRA. FAQ Part 51 revises prior guidance that stated coverage of OTC COVID-19 tests was limited to those with health care provider involvement. The Department's updated guidance applies "only with respect to OTC COVID-19 tests that do not require a health care provider's order under applicable FDA authorization, clearance or approval."

The Departments clarify that under the FFCRA, plans and issuers must provide coverage for these OTC COVID-19 tests without imposing any cost-sharing, prior authorization or other medical management requirements. Furthermore, except as provided in Q/A-2 below, coverage must be provided without any out-of-pocket expense to the participant.

Plans and issuers may require a participant, beneficiary or enrollee who purchases an OTC COVID-19 test to submit a claim for reimbursement (pursuant to the plan or issuer's reasonable claims procedures) and are not required to provide coverage by directly reimbursing sellers of OTC COVID-19 tests (referred to in the guidance as "direct coverage"). However, the Departments encourage plans and issuers to reimburse sellers directly rather than requiring individuals to seek reimbursement following upfront payment. **Note:** For plans and issuers that use direct coverage arrangements to provide benefits for OTC COVID-19 tests, it is unclear how the plan or issuer could continue to exclude coverage for testing conducted for employment or screening purposes.

Q/A 2. According to the guidance, plans and issuers that provide direct coverage reimbursement of OTC COVID-19 tests may *not* limit coverage to only tests that are provided through preferred pharmacies or other retailers unless the below safe harbor requirements are satisfied.

Direct Coverage Program Safe Harbor

The Departments state that no enforcement action related to the coverage of OTC COVID-19 tests will be taken against any plan or issuer that "provides coverage of OTC COVID-19 tests purchased by participants, beneficiaries, and enrollees during the public health emergency by arranging for direct coverage of OTC COVID-19 tests that meet the statutory criteria under section 6001(a)(1) of the FFCRA through both its pharmacy network and a direct-to-consumer shipping program, and otherwise limits reimbursement for OTC COVID-19 tests from nonpreferred pharmacies or other retailers to no less than the actual price, or $12 per test (whichever is lower)." Direct coverage for these purposes means the participant, beneficiary or enrollee is not required to seek reimbursement post-purchase.

Under the safe harbor discussed in FAQ Part 51, plans and issuers:

- "must make the systems and technology changes necessary to process the plan's or issuer's payment to the preferred pharmacy or retailer directly (including the direct-to-consumer shipping program) with no upfront out-of-pocket expenditure by the participant, beneficiary, or enrollee." Regardless of the program design, plans and issuers may not impose any prior authorization or other medical management requirements on participants, beneficiaries or enrollees that obtain applicable OTC COVID-19 tests.[4]

[4] *FAQ Part 51, Q2* https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf

- "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)" when providing OTC COVID-19 tests through a direct coverage program. Whether access is adequate will depend on all relevant facts and circumstances.[5]

The safe harbor applies only to the requirement to provide coverage of OTC COVID-19 tests that are administered *without* a health provider's prescription or involvement and does not negate the requirement that plans and issuers cover COVID-19 tests administered ***with*** a provider's involvement or prescription.

Q/A 3. It is the Department's view that plans and issuers that otherwise provide coverage without cost-sharing for COVID-19 diagnostic tests may set limits on the number or frequency of OTC COVID-19 tests covered without cost-sharing, but only if the safe harbor conditions described below are satisfied.

Limiting Number of COVID-19 Tests - Safe Harbor

During the public health emergency, with respect to OTC COVID-19 tests available without an assessment or provider's involvement and purchased by participants, beneficiaries and enrollees, the Departments state that they will not take enforcement action against a plan or issuer that "during the public health emergency, provides coverage without cost-sharing for (and does not impose prior authorization or other medical management requirements on) such OTC COVID-19 tests if the plan or issuer limits the number of OTC COVID-19 tests covered for each participant, beneficiary, or enrollee to no less than eight tests per 30-day period (or per calendar month)." The limit applies on a per-participant/beneficiary/enrollee basis, and plans and issuers may set more generous limits.[6]

The Departments note that this safe harbor applies only to the coverage of OTC COVID-19 tests that are administered *without* a health provider's prescription or involvement and does not negate the requirement that plans, and issuers cover COVID-19 tests administered *with* a provider's involvement or prescription.

Q/A 4. The Departments state that when providing coverage of OTC COVID-19 tests, plans and issuers that suspect fraud or abuse may take reasonable action to prevent, detect and address such fraud and abuse. The Departments note; however, that fraud and abuse programs that require individuals to "submit multiple documents or involve numerous steps that unduly delay a participant's, beneficiary's or enrollee's access to, or reimbursement for, OTC COVID-19 tests are not reasonable."[7]

Examples of permissible activities according to the guidance include:

- Taking reasonable steps to ensure the OTC COVID-19 test was purchased for the covered individual's own use (or for use by another covered family member) so long as the steps do not create significant barriers for obtaining the tests.
- Requiring reasonable documentation of proof of purchase with a claim for reimbursement for the cost of the OTC COVID-19 test.

Q/A 5. Plans and issuers may provide educational information to participants, beneficiaries and enrollees to help facilitate access to, effective use of, and prompt payment for OTC COVID-19 tests as long as the resources are clear that the plan or issuer provides coverage for, and reimbursement of all OTC COVID-19 tests meeting the criteria under section 6001(a)(1) of the FFCRA (subject to the safe harbors addressed above), and so long as the information is consistent with the test's emergency use authorization (EUA).[8]

Q/A 6. The Departments state that plans and issuers must begin providing coverage without cost-sharing, prior authorization or other medical management requirements for OTC COVID-19 tests available without an order or individualized clinical assessment by a health care provider purchased on or after January 15, 2022, and during the public health emergency.

[5] *FAQ Part 51, Q2*
[6] *FAQ Part 51, Q3*
[7] *FAQ Part 51, Q4*
[8] *Examples included in FAQ Part 51, Q5*

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