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Departments Clarify Required Coverage of At-Home OTC COVID-19 Tests

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The Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments) recently issued [updated FAQ guidance](#) to explain how employer group health plans may comply with the requirement to cover with no cost-sharing or preauthorization at-home over-the-counter (OTC) COVID-19 tests provided with no prescription or health care provider involvement. Initial guidance had created safe harbors for plans to make at-home tests available through a preferred provider network or direct-to-consumer shipping program. Under that guidance, plan sponsors could, under certain conditions, limit the number of OTC at-home tests covered per month to no more than eight tests per individual per month, and limit reimbursement for any such tests purchased outside of an established provider network or direct shipping program to no more than the lesser of \$12 or the cost of the test.

Initial rules, which were effective for tests purchased on or after January 15, have left many questions regarding the delivery of at-home tests and what effect shortages of tests might have on plan sponsors. The new guidance details how plans can continue to comply with the original mandate but with flexibility to deal with testing kit scarcity and other compliance hurdles.

Modified Safe Harbor. The first safe harbor announced in January required plan sponsors to ensure that participants, beneficiaries, and enrollees have adequate access to OTC at-home COVID-19 tests with no upfront out-of-pocket expenses. The new FAQs provide that, effective February 4, 2022, the Departments will consider all the facts and circumstances in judging whether a plan has provided adequate access by requiring at least one direct-to-consumer channel and one in-person channel. Direct-to-consumer channels can include:

- Either online or telephone ordering
- A plan's pharmacy network
- A non-pharmacy retailer (including providing coupons to be used at a retailer)
- An alternative distribution site including independent drive-through or walk-up facilities



The new FAQs clarify that a direct-to-consumer shipping program can be provided through multiple outlets. Also, a plan that engages a specific in-person retailer where individuals can physically get a test will also be deemed to have provided a direct-to-seller option where the retailer also has an online means of delivering tests.

The FAQs provide that adequate in-person access to at-home OTC testing kits also will be determined based on all relevant facts and circumstances which will include:

- Where participants, beneficiaries and enrollees live
- The current utilization of a pharmacy network (if used to make tests available)
- The information provided to individuals regarding the types of kits available and the locations where they can access them

Plans do not have to cover every available at-home OTC test; they can limit tests to manufacturers with whom a plan has a contractual relationship or from whom a plan has been able to obtain tests. Finally, plans also must cover routine shipping costs in the same way they cover such expenses for other items available through mail order. The FAQs confirm that the \$12 safe harbor limit on non-network tests includes shipping and sales tax.

Providing Program Information. Plans must inform participants, beneficiaries, and enrollees which tests are available under the program, and whether there are differences in what is available under a direct shipping program or in-person network. The Departments can request a plan to provide proof of the information they provide participants, beneficiaries and enrollees to determine its adequacy.

Supply Shortages. The FAQs clarify that a plan that has established a direct coverage program that meets the original safe harbor, as modified, will not be deemed non-compliant just because it temporarily cannot ensure adequate access due to testing kit supply shortages. In these cases, a plan can still impose limits on the number and covered amount of OTC at-home tests that individuals buy outside of the plan's established channels.

Restricting Individual Sellers and Re-sellers. The FAQs further note that the Departments expect plans to take reasonable steps to prevent and detect fraud and abuse. Reasonable steps include limiting reimbursement to kits purchased from retailers that would normally be expected to sell OTC COVID-19 tests. Thus, plans could disallow reimbursement for tests purchased from an individual or from an online seller that uses an auction or resale marketplace. Moreover, a plan could require proof of purchase that identifies the product and seller or an original receipt from the seller to prove the test qualifies under Families First Coronavirus Response Act (FFCRA) guidelines. Finally, a plan can require a participant, beneficiary, or enrollee to attest that the test has not been and will not be reimbursed from another source including resale. The FAQs require plans to clearly explain any substantiation requirements or rules restricting buying tests from resellers.

Tests Requiring Medical Provider Involvement. The FAQs also confirm that tests which are not completely self-service with no health care provider involvement are not subject to the mandate and subsequent guidance. Rather, such tests are covered with no safe harbor limits as provided under original FFCRA guidance.

No FSA, HRA or HSA Reimbursement. The FAQs warn that because OTC at-home test kits are medical expenses, the costs cannot be reimbursed by both a plan or insurer and an FSA, HRA, or HSA. The Departments suggest that plans should advise participants, beneficiaries, and enrollees not to use an



FSA debit card or to otherwise seek reimbursement under an FSA, HRA, or HSA for the same costs paid or reimbursed by the plan. Individuals should work with FSA or HRA administrators to correct any improper reimbursements. Similarly, individuals who received HSA reimbursement for covered OTC at-home kits should take steps to include the amounts in gross income or, if possible under IRS guidance, repay the distribution.

Conclusion

The updated FAQs should help employer plan sponsors better understand their obligations to cover at-home OTC COVID-19 testing, but there are still practical implementation questions that could prove challenging. We will continue to monitor developments and provide updates as we receive more details.

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