ACA COMPLIANCE BULLETIN

Agencies Issue FAQs on Coverage of COVID-19 Diagnostic Testing

On Feb. 4, 2022, the Departments of Labor (DOL), Health and Human Services (HHS) and the Treasury (Departments) jointly issued FAQs (FAQs Part 52) regarding coverage of over-the-counter (OTC) COVID-19 tests.

These FAQs modify and clarify the guidance in FAQs Part 51, which specified that plans and issuers must cover OTC COVID-19 tests available without an order or individualized clinical assessment by a health care provider.

The new FAQs include the following guidance:

- Plans and issuers have flexibility in how they establish a direct-to-consumer shipping program and direct coverage through an in-person network in order to qualify for the safe harbor.
- The Departments will not take enforcement action against a plan or issuer that is temporarily unable to provide adequate access to OTC COVID-19 tests through its direct coverage program due to a supply shortage.
- Plans and issuers are permitted to take reasonable steps to prevent, detect and address fraud and abuse.
- The OTC test coverage requirements do not apply to tests that use a self-collected sample but require processing by a laboratory or other health care provider to return results.

The FAQs also address how a plan's or issuer's coverage of OTC COVID-19 tests impacts health flexible spending arrangements (FSAs) and similar account-based plans.

This Compliance Bulletin includes the full text of the Departments' FAQ guidance.

Provided to you by **Kinloch Consulting Group, Inc. February 10, 2022**

Highlights

- The new FAQs amend the prior guidance on OTC COVID-19 tests to ensure that plans and issuers have significant flexibility in how they provide access to those tests.
- The Departments provide examples of steps that plans and issuers can take to prevent and address fraud and abuse.
- The cost of OTC COVID-19 tests can be reimbursed by a health FSA or health savings account (HSA), but not if the cost is paid for or reimbursed by another health plan.

Important Dates

Jan. 15, 2022

Plans and issuers must cover OTC COVID-19 tests without cost sharing, prior authorization or other medical management requirements during the public health emergency.

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Background

On Jan. 10, 2022, the Departments issued prior FAQs (FAQs Part 51) that clarified that the Families First Coronavirus Response Act (FFCRA) requirement to cover COVID-19 diagnostic tests applies with respect to OTC COVID-19 tests available without a prescription or individualized clinical assessment from a health care provider. Beginning Jan. 15, 2022, plans and issuers must cover these tests without cost-sharing requirements, prior authorization or other medical management requirements during the public health emergency.

FAQs Part 51 also established a safe harbor that allows plans and issuers to provide direct coverage of OTC COVID-19 tests through both its pharmacy network and a direct-to-consumer shipping program, and otherwise limit 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).

FAQs About FFCRA and CARES Act Implementation Part 52

Q1: Do plans and issuers have flexibility in how they establish a direct-to-consumer shipping program and direct coverage through an in-person network in order to qualify for the safe harbor established in FAQs Part 51, Q2?

Yes. In response to questions raised by stakeholders, the Departments are revising the requirements of the safe harbor established in FAQs Part 51, Q2, to **ensure** that plans and issuers have significant flexibility in how they provide access to OTC COVID-19 tests under those requirements.

> While this FAQ illustrates the flexibility plans and issuers have in providing direct coverage of OTC COVID-19 tests, it does not modify the requirement under the safe harbor in FAQs Part 51, Q2, that plans and issuers cover OTC COVID-19 tests obtained outside of their direct coverage program, but are permitted to limit reimbursement of these tests to no less than the actual price or $12 per test (whichever is lower). Note that, when providing coverage of OTC COVID-19 tests outside of a direct coverage pathway, the price of tests includes shipping and sales tax costs related to the purchase of OTC COVID-19 tests, so that plans and issuers must cover the total cost of the COVID-19 test (including shipping costs and sales tax) up to $12 per test.

In order to meet the requirements of the safe harbor, plans and issuers must provide direct coverage by ensuring participants, beneficiaries and enrollees have adequate access to OTC COVID-19 tests with no upfront out-of-pocket expenditure. For this purpose, whether a plan or issuer provides adequate access through its direct coverage program will depend on the facts and circumstances, but 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.

> The Departments recognize that there may be some limited circumstances in which a direct coverage program could provide adequate access—and therefore satisfy the safe harbor's requirements—without establishing both a direct-to-consumer shipping mechanism and an in-person mechanism. For example, if 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 to OTC COVID-19 tests without establishing a direct-to-consumer shipping mechanism.

"Direct coverage" may be provided through a number of mechanisms including, but not limited to, a direct-to-consumer shipping program that allows for orders to be placed online or by telephone; the plan's or issuer's pharmacy network; other nonpharmacy retailers (including through distribution of coupons for enrollees to receive tests from certain retailers without cost-sharing); and alternative OTC COVID-19 test distribution sites established by (or on behalf of) the plan or issuer (such as a standalone drive-through or walk-up distribution site, including a site that operates independently of a pharmacy or other retailer). In order to facilitate consumer access and provide for a seamless experience in obtaining OTC COVID-19 tests with no upfront out-of-pocket expenditure, plans and issuers should ensure that participants, beneficiaries and enrollees are aware of key information needed to access OTC COVID-19 testing, such as which tests are available under the direct coverage program and, if the plan or issuer offers different mechanisms for obtaining tests under its direct coverage program, which tests are available under each mechanism.

A "direct-to-consumer shipping mechanism" is any program that provides direct coverage of OTC COVID-19 tests for participants, beneficiaries or enrollees without requiring the individual to obtain the test at an in-person location. This can include online or telephone ordering and may be provided through a pharmacy or other retailer, the plan or issuer directly, or any other entity on behalf of the plan or issuer. A direct-to-consumer shipping program does not have to provide exclusive access through one entity, as long as it allows a participant, beneficiary or enrollee to place an order for OTC COVID-19 tests to be shipped to them directly. For example, if a plan or issuer has opted to provide direct in-person coverage of OTC COVID-19 tests through specified retailers, and those retailers maintain online platforms where individuals can also order tests to be delivered to them, the Departments will consider the plan or issuer to have provided a direct-to-consumer shipping mechanism. 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.

When implementing an in-person mechanism, a plan or issuer must ensure that participants, beneficiaries or enrollees have access to OTC COVID-19 tests through an adequate number of locations (which could include pharmacies and other retailers or independent distribution sites set up by or on behalf of a plan or issuer). Whether there is adequate access should be determined based on all relevant facts and circumstances, such as:

- The locality of participants, beneficiaries or enrollees under the plan or coverage;
- Current utilization of the plan's or issuer's pharmacy network by its participants, beneficiaries or enrollees when making this coverage available through a pharmacy network; and
- How the plan or issuer notifies participants, beneficiaries or enrollees of the retail locations, distribution sites or other mechanisms for distributing tests, as well as which tests are available under the direct coverage program.

The Departments note that they may request information from plans and issuers to ensure that participants, beneficiaries and enrollees have adequate access to OTC COVID-19 tests, such as the number and location of in-person options. Adequate access under this safe harbor does not require a plan or issuer to make all OTC COVID-19 tests that meet the statutory criteria under section 6001(a)(1) of the FFCRA available to its participants, beneficiaries or enrollees through its direct coverage program. For example, depending on all relevant facts and circumstances, a plan or issuer may be considered to provide adequate access to OTC COVID-19 tests through its direct coverage program if that coverage consists of tests from a limited number of manufacturers, such as those with whom the plan or issuer has a contractual relationship or from whom the plan or issuer has been able to obtain OTC COVID-19 tests directly. The Departments note

that although not all OTC COVID-19 tests must be available through a direct coverage program, a plan or issuer must cover all OTC COVID-19 tests that meet the statutory criteria under the FFCRA, subject to certain limitations under safe harbors.

The Departments note that the guidance in this Q1 applies prospectively and is effective Feb. 4, 2022.

Q2: Will the Departments take enforcement action against a plan or issuer that is temporarily unable to provide adequate access to OTC COVID-19 tests through its direct coverage program due to a supply shortage?

No. The Departments will not consider a plan or issuer to be out of compliance with the safe harbor in FAQ Part 51, Q2, if it has established a direct coverage program that meets the requirements of that safe harbor as revised by Q1 of these FAQs Part 52, but is temporarily unable to provide adequate access through the program due to a supply shortage. In that circumstance, a plan or issuer that otherwise meets the requirements of the safe harbor may continue to limit reimbursement to $12 per test (or the full cost of the test, whichever is lower) for OTC COVID-19 tests purchased outside of the direct coverage program.

The Departments also note that a plan or issuer would not be out of compliance with the FFCRA because an individual is unable to obtain at least eight OTC COVID-19 tests per 30-day period (or per month), and is therefore unable to submit claims for those tests for reimbursement. However, if a consumer is able to obtain eligible tests despite a supply shortage, the plan or issuer must reimburse the participant, beneficiary or enrollee for at least eight tests per 30-day period (or per month), subject to reasonable restrictions on the purveyors from which tests are obtained to prevent fraud and abuse, as discussed in FAQs Part 51, Q4, and these FAQs Part 52, Q3.

Q3: Is a plan or issuer permitted to address suspected fraud and abuse related to the reimbursement of OTC COVID-19 tests purchased by a participant, beneficiary or enrollee from a private individual or via online auctions, resale marketplaces or resellers?

Yes. While the FFCRA prohibits medical management of coverage of COVID-19 diagnostic testing, including OTC COVID-19 tests, FAQs Part 44, Q2, and FAQs Part 51, Q4, clarify that plans and issuers are permitted to take reasonable steps to prevent, detect and address fraud and abuse.

In order to further discourage problematic behaviors that could limit access to consumers, a plan or issuer may establish a policy that limits coverage of OTC COVID-19 tests purchased without the involvement of a health care provider to tests purchased from established retailers that would typically be expected to sell OTC COVID-19 tests. Specifically, plans and issuers may disallow reimbursement for tests purchased by a participant, beneficiary or enrollee from a private individual via an in-person or online person-to-person sale or from a seller that uses an online auction or resale marketplace. This type of policy could include requiring reasonable documentation of proof of purchase that clearly identifies the product and seller, such as a UPC code or other serial number, original receipt from the seller of the test or other documentation for the OTC COVID-19 test to verify that the item qualifies for coverage under the FFCRA, or a requirement that the participant, beneficiary or enrollee attest that the test has not been (and will not be) reimbursed by another source (including through resale). If a plan or issuer implements a policy that disallows reimbursement for OTC COVID-19 tests from certain resellers, the plan or issuer should provide information to participants, beneficiaries or enrollees regarding the retailers from which purchased tests are generally covered by the plan or issuer and general information about the types of resellers for which participants, beneficiaries and enrollees are not eligible for reimbursement of purchased tests under the plan or coverage. This does not modify the requirement of FAQs Part 51, Q4, which prohibits a plan or issuer

from requiring individuals to submit multiple documents or implementing numerous steps that unduly delay a participant's, beneficiary's or enrollee's access to, or reimbursement for, OTC COVID-19 tests.

Q4: Do the coverage requirements specified in FAQs Part 51 apply to COVID-19 tests that use a self-collected sample but require processing by a laboratory or other health care provider to return results (such as home-collection PCR tests that can be purchased directly by consumers)?

No. The guidance in FAQs Part 51 applies to OTC COVID-19 tests that are approved, cleared or authorized for use by the Food and Drug Administration (FDA) and that can be obtained without a prescription and completely used and processed without the involvement of a laboratory or other health care provider (sometimes referred to as self-tests or at-home tests). To the extent that a COVID-19 test is not approved or authorized to be self-administered and self-read without the involvement of a health care provider (such as a test where a consumer collects a specimen at home and sends the specimen to be processed in a laboratory), the guidance in FAQs Part 51 and these FAQs Part 52 is not applicable. However, to the extent the guidance in FAQs Part 51 and these FAQs Part 52 is not applicable to an OTC COVID-19 test, that test must be covered in accordance with the FFCRA when the test is ordered by an attending health care provider and otherwise meets the statutory criteria in the FFCRA, as explained in prior guidance.

Q5: How does a plan's or issuer's coverage of OTC COVID-19 tests impact health flexible spending arrangements and similar account-based plans?

The cost of OTC COVID-19 tests purchased by an individual is a medical expense; thus, it has generally been reimbursable by health flexible spending arrangements (health FSAs) and health reimbursement arrangements (HRAs). However, FAQs Part 51, Q1 and Q2, now require plans and issuers to cover OTC COVID-19 tests, subject to certain limitations under safe harbors.

An individual cannot be reimbursed more than once for the same medical expense. Therefore, the cost (or the portion of the cost) of OTC COVID-19 tests paid or reimbursed by a plan or issuer cannot be reimbursed by a health FSA or HRA. In connection with notifying individuals about any direct coverage or reimbursement process, plans and issuers may wish to advise individuals not to seek reimbursement from a health FSA or HRA for the cost (or the portion of the cost) of OTC COVID-19 tests paid or reimbursed by the plan or issuer and not to use a health FSA or HRA debit card to purchase OTC COVID-19 tests for which the individual intends to seek reimbursement from the plan or issuer. If an individual mistakenly receives reimbursement from a health FSA or HRA for OTC COVID-19 test costs covered by a plan or issuer, the individual should contact the health FSA or HRA administrator regarding correction procedures.

In addition, under section 223(f) of the Internal Revenue Code (Code), a distribution from an individual's health savings account (HSA) is not included in the individual's gross income if the distribution is used to pay for qualified medical expenses. Under Code section 223(d)(2), qualified medical expenses are medical expenses incurred by an individual (or the individual's spouse or dependent) "but only to the extent such amounts are not compensated for by insurance or otherwise." Therefore, expenses incurred for OTC COVID-19 tests paid or reimbursed by a plan or issuer are not qualified medical expenses. If an individual mistakenly takes a distribution from an HSA for OTC COVID-19 test costs paid or reimbursed by a plan or issuer, the individual must either:

- Include the distribution in gross income; or
- Repay the distribution to the HSA, if and as permitted under Q&A-37 and -76 of IRS Notice 2004-50.