FAQS ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 52

February 4, 2022

Set out below are Frequently Asked Questions (FAQs) regarding implementation of the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#Affordable_Care_Act), these FAQs answer questions from stakeholders to help people understand the law and benefit from it, as intended.

The FFCRA was enacted on March 18, 2020.[1] Section 6001 of the FFCRA generally requires group health plans and health insurance issuers offering group or individual health insurance coverage, including grandfathered health plans, to provide benefits for certain items and services related to testing for the detection of SARS-CoV-2 (the virus that causes coronavirus disease 2019 (COVID-19)) or the diagnosis of COVID-19, when those items or services are furnished on or after March 18, 2020, and during the applicable emergency period.[2] Under the FFCRA, plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements.

The CARES Act was enacted on March 27, 2020.[3] Section 3201 of the CARES Act amended section 6001 of the FFCRA to include a broader range of diagnostic items and services that plans

[1] Pub. L. No. 116-127 (2020).

[2] On January 31, 2020, HHS Secretary Alex M. Azar II declared that as of January 27, 2020, a public health emergency exists nationwide as the result of the 2019 novel coronavirus. See HHS Office of the Assistant Secretary for Preparedness and Response, Determination of the HHS Secretary that a Public Health Emergency Exists, available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx. On January 14, 2022, the HHS Secretary renewed the COVID-19 public health emergency declaration, effective January 16, 2022, that was previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 20, 2021, and October 18, 2021. See HHS Office of the Assistant Secretary for Preparedness and Response, Renewal of Determination That A Public Health Emergency Exists, available at https://aspr.hhs.gov/legal/PHE/Pages/COVID19-14Jan2022.aspx. The HHS Secretary may extend the public health emergency declaration for subsequent 90-day periods for as long as the public health emergency continues to exist, and may terminate the declaration whenever he determines that the public health emergency has ceased to exist. On January 22, 2021, Acting HHS Secretary Norris Cochran sent a letter to governors announcing that HHS has determined that the public health emergency will likely remain in place for the entirety of 2021, and when a decision is made to terminate the declaration or let it expire, HHS will provide states with 60 days' notice prior to termination.

[3] Pub. L. No. 116-136 (2020).

and issuers must cover without any cost-sharing requirements, prior authorization, or other medical management requirements.[4] Section 3202(a) of the CARES Act requires plans and issuers providing coverage to reimburse a provider that has a negotiated rate with the plan or issuer for COVID-19 diagnostic testing an amount that equals that negotiated rate; or, if the plan or issuer does not have a negotiated rate with such provider, the cash price for such service that is listed by the provider on a public website. (The plan or issuer may negotiate a rate with the provider that is lower than the cash price.) Additionally, during the public health emergency related to COVID-19 declared under section 319 of the Public Health Service Act (PHS Act), section 3202(b) of the CARES Act and implementing regulations at 45 CFR Part 182 require providers of diagnostic tests for COVID-19 to make public the cash price of a COVID-19 diagnostic test on the provider's public internet website or face potential enforcement action including civil monetary penalties.

Under section 6001(c) of the FFCRA, the Departments are authorized to implement the requirements of section 6001 of the FFCRA through sub-regulatory guidance, program instruction, or otherwise. The Departments have previously issued several sets of FAQs to implement provisions of the FFCRA and CARES Act and to address other health coverage issues related to COVID-19.[5] Due to the urgent need to continue to facilitate the nation's response to the public health emergency posed by COVID-19, the Departments are of the view that this guidance is a statement of policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA).[6] For the same reasons, the Departments additionally find that, even if this guidance were subject to the public participation provisions of the APA, prior notice and comment for this guidance is impracticable and/or contrary to the public interest, and there is good cause to issue this guidance without prior public comment and without a delayed effective date.[7]

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[4] For purposes of this document, references to section 6001 of the FFCRA include the amendments made by section 3201 of the CARES Act, unless otherwise specified.

[5] See FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42 (Apr. 11, 2020), available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-42.pdf and https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf (FAQs Part 42); FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43 (June 23, 2020), available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf and https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf (FAQs Part 43); FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 44 (Feb. 26, 2021), available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-44.pdf and https://www.cms.gov/files/document/faqs-part-44.pdf (FAQs Part 44); FAQs about Affordable Care Act Implementation Part 50, Health Insurance Portability and Accountability Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (Oct. 4, 2021), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-50.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-50.pdf (FAQs Part 50); and FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (January 10, 2022), available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf (FAQs Part 51).

[6] 5 U.S.C. § 553(b)(A).

[7] 5 U.S.C. § 553(b)(B) and (d)(3). Good cause exists for the same reasons underlying the issuance of the March 13, 2020 Proclamation on Declaring a National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Outbreak and the determination, under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency

On January 10, 2022, the Departments issued FAQs about Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (FAQs Part 51).[8] FAQs Part 51 clarified that the requirement to cover COVID-19 diagnostic tests under section 6001 of the FFCRA applies with respect to over-the-counter (OTC) COVID-19 tests[9] available without a prescription or individualized clinical assessment from a health care provider. Plans and issuers must provide coverage for such tests without cost-sharing requirements, prior authorization, or other medical management requirements in accordance with section 6001 of the FFCRA with respect to such tests purchased on or after January 15, 2022, during the public health emergency.

FAQs Part 51 also established two safe harbors intended to facilitate consumer access without cost sharing to OTC COVID-19 tests available without an order or individualized clinical assessment by a health care provider that meet the statutory criteria under section 6001(a)(1) of the FFCRA:

- FAQs Part 51, Q2: The Departments will not take enforcement action related to coverage of OTC COVID-19 tests against any plan or issuer that provides coverage of OTC COVID-19 tests purchased by participants, beneficiaries, and enrollees without an order or individualized clinical assessment by a health care provider during the public health emergency by arranging for direct coverage of OTC COVID-19 tests through both its pharmacy network and a direct-to-consumer shipping program, and otherwise limits reimbursement for OTC COVID-19 tests from non-preferred pharmacies or other retailers to no less than the actual price, or $12 per test (whichever is lower).[10] For purposes of this safe harbor, direct coverage of OTC COVID-19 tests means that a participant, beneficiary, or enrollee is not required to seek reimbursement post-purchase; instead, the plan or issuer 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 via a direct-to-consumer shipping program) with no upfront out-of-pocket expenditure by the participant, beneficiary, or enrollee.

Assistance Act, 42 U.S.C. § 5121 et seq., that a national emergency exists nationwide as a result of the COVID-19 pandemic, and the same reasons underlying the issuance of the January 31, 2020 declaration that a public health emergency exists, under section 319 of the PHS Act. The Departments note that the reasons underlying these issuances persist as evidenced by the World Health Organization designating the Omicron variant as a Variant of Concern on November 26, 2021, see https://www.who.int/news/item/28-11-2021-update-on-omicron. In addition, on December 20, 2021, the Centers for Disease Control and Prevention stated that the Omicron variant likely would spread more easily than the original SARS-CoV-2 virus and that breakthrough infections in people who were fully vaccinated were likely to occur. https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html.

[8] See https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf.

[9] FAQs Part 51 states that OTC COVID-19 tests include those that can be self-administered and self-read at home or elsewhere without the involvement of a health care provider, without either a prescription or individualized clinical assessment by a health care provider.

[10] As stated in FAQs Part 51, the Departments recognize that some OTC COVID-19 tests are sold in packages containing more than one test. If a plan or issuer limits reimbursement for OTC COVID-19 tests from non-preferred sellers, pharmacies, or retailers to $12 per test, as allowed under FAQs Part 51, Q2, the plan or issuer must calculate the reimbursement based on the number of tests in a package.

- FAQs Part 51, Q3: The Departments will not take enforcement action related to coverage of OTC COVID-19 tests purchased without an order or individualized clinical assessment by a health care provider against any 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 and limits the number of OTC COVID-19 tests covered for each participant, beneficiary, or enrollee to no less than 8 tests[11] per 30-day period (or per calendar month).[12]

The Departments have received a number of questions from stakeholders regarding FAQs Part 51. These FAQs Part 52 modify the safe harbor in FAQs Part 51, Q2 in certain respects and further clarify the coverage requirements during the public health emergency related to coverage of OTC COVID-19 tests available without an order or individualized clinical assessment by a health care provider in response to those questions.

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.[13] 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.[14] "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 non-pharmacy retailers (including through distribution of coupons for enrollees to receive tests from certain

[11] If applying a quantity limit of at least 8 tests, plans and issuers may count each test separately, even if multiple tests are sold in one package.

[12] The Departments note that the 30-day period may be a rolling 30-day period and does not have to coincide with the calendar month.

[13] 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 such 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.

[14] The Departments recognize that there may be some limited circumstances in which a direct coverage program could provide adequate access, and therefore satisfy the requirements of the safe harbor, 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.

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.

This FAQ clarifies that 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. A direct-to-consumer shipping mechanism 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). As the Departments noted in FAQs Part 51, Q2, 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 such 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.[15]

The Departments note that the guidance in this Q1 applies prospectively and is effective February 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.[16]

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 that are 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. Such a 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 section 6001 of FFCRA, or a requirement that the participant, beneficiary, or enrollee attest that the test has not

[15] 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 section 6001(a)(1) of the FFCRA, subject to certain limitations under safe harbors.

[16] The Departments also note that a plan or issuer would not be out of compliance with section 6001 of FFCRA because an individual is unable to obtain at least 8 OTC COVID-19 tests per 30-day period (or per month), and is therefore unable to submit claims for such 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 8 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.

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 that 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.[17] To the extent 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, such a test must be covered in accordance with section 6001 of the FFCRA when the test is ordered by an attending health care provider and otherwise meets the statutory criteria in section 6001(a)(1) of 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

[17] FAQs Part 51 referred to these tests as self-tests or at-home tests.

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 section 223(d)(2) of the Code, 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 (1) include the distribution in gross income, or (2) if and as permitted under Q&A-37 and -76 of IRS Notice 2004-50, repay the distribution to the HSA.[18]

[18] IRS Notice 2004-50 (Revised August 9, 2004), available online at https://www.irs.gov/pub/irs-drop/n-04-50.pdf.