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

Set out below are Frequently Asked Questions (FAQs) regarding implementation of the Families First Coronavirus Response Act (FFCRA), the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), and the Affordable Care 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.

COVID-19 DIAGNOSTIC TESTING

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

[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 October 15, 2021, the HHS Secretary renewed the COVID-19 public health emergency declaration, effective October 18, 2021, that was previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, and July 19, 2021. See HHS Office of the Assistant Secretary for Preparedness and Response, Renewal of Determination That A Public Health Emergency Exists, available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVDI-15Oct21.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.

(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 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 four 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 believe 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

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

[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); and 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).

[6] 5 U.S.C. § 553(b)(A).

good cause to issue this guidance without prior public comment and without a delayed effective date.[7]

In June 2020, the Departments issued FAQs Part 43. In FAQs Part 43, Q4, the Departments stated that plans and issuers are required under section 6001 of the FFCRA to cover COVID-19 tests intended for at-home testing, when the test is ordered by an attending health care provider who has determined that the test is medically appropriate for the individual based on current accepted standards of medical practice and the test otherwise meets the statutory criteria under the FFCRA.[8]

In issuing FAQs Part 43, the Departments noted that, as of the date of publication of that document, the Food and Drug Administration (FDA) had not yet authorized any COVID-19 diagnostic tests to be completely used and processed at home.[9] However, since June 2020, when FAQs Part 43 were issued, the FDA has authorized additional diagnostic tests for COVID-19, including tests that can be self-administered and self-read at home or elsewhere without the involvement of a health care provider, sometimes referred to as self-tests or at-home tests.[10] These at-home diagnostic tests are now available either by prescription or over-the-counter (OTC) (without either a prescription or individualized clinical assessment by a health care provider), through pharmacies, retail stores, and online retailers.

On December 2, 2021, President Biden announced that the Departments would issue guidance by January 15, 2022, to clarify that individuals who purchase OTC COVID-19 diagnostic tests (referred to as OTC COVID-19 tests throughout this document) during the public health emergency will be able to seek reimbursement from their plan or issuer.[11] These FAQs provide that guidance. The Departments have evaluated the requirements of section 6001 of the FFCRA and the implementing guidance issued to date and have determined that it is appropriate to issue these FAQs. Testing is critically important to help reduce the spread of SARS-CoV-2, as well as to quickly diagnose SARS-CoV-2 infection and COVID-19 so that it can be effectively treated. In light of FDA authorization of at-home tests available OTC, to remove financial barriers and expand access to COVID-19 testing, and to ensure consistency with section 6001 of the FFCRA, the Departments are issuing this guidance to clarify that individuals who purchase OTC COVID-

[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 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.

[8] See 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.

[9] Id. at footnote 8.

[10] The FDA provides information on which at-home tests are authorized for use at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

[11] President Biden Announces New Actions to Protect Americans Against the Delta and Omicron Variants as We Battle COVID-19 this Winter (Dec. 2, 2021), available at 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/.

19 tests during the public health emergency will be able to seek reimbursement from their plan or issuer. The Departments are updating their guidance to generally require coverage of 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, as described below.

Q1: Under section 6001 of the FFCRA, are plans and issuers required to cover OTC COVID-19 tests available without an order or individualized clinical assessment by a health care provider?

Yes. Plans and issuers must cover OTC COVID-19 tests that meet the statutory criteria under section 6001(a)(1) of the FFCRA,[12] including tests obtained without the involvement of a health care provider. Consistent with section 6001 of the FFCRA, this coverage must be provided without imposing any cost-sharing requirements, prior authorization, or other medical management requirements. In this context, with respect to OTC COVID-19 tests obtained without a health care provider's involvement, the Departments interpret the relevant FFCRA and CARES Act provisions to require coverage without out-of-pocket expense to the participant, beneficiary, or enrollee for the cost of the test (unless a plan or issuer meets the conditions for the safe harbors described in Q2 and Q3).

Section 6001 of the FFCRA does not require a plan or issuer to provide coverage by reimbursing sellers of OTC COVID-19 tests directly (also referred to in this document as "direct coverage"); a plan or issuer may instead require a participant, beneficiary, or enrollee who purchases an OTC COVID-19 test to submit a claim for reimbursement to the plan or issuer (in accordance with the plan's or issuer's reasonable internal claims procedures, consistent with applicable federal and state law). However, plans and issuers are strongly encouraged to provide direct coverage for OTC COVID-19 tests to participants, beneficiaries, and enrollees by reimbursing sellers directly without requiring participants, beneficiaries, or enrollees to provide upfront payment and seek reimbursement.

This FAQ modifies guidance previously provided by the Departments[13] such that the requirement to cover COVID-19 tests under section 6001 of the FFCRA with respect to OTC COVID-19 tests is no longer limited only to situations in which the individual has an order or individualized clinical assessment from a health care provider. This updated guidance requires coverage, without an order or individualized clinical assessment from a health care provider, only with respect to OTC COVID-19 tests that do not require a health care provider's order

[12] Section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act, describes in vitro diagnostic tests for the detection of SARS-CoV-2 or the diagnosis of COVID-19 that (A) are approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act; (B) the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act, unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe; (C) are developed in and authorized by a state that has notified the Secretary of HHS of its intention to review tests intended to diagnose COVID–19; or (D) are other tests that the Secretary of HHS determines appropriate in guidance.

[13] FAQs Part 43, Q4 is superseded. FAQs Part 42, Q6 and FAQs Part 43, Q3 and Q6 continue to apply with respect to tests that require the order of a health care provider under the applicable FDA authorization or approval, but are superseded to the extent inconsistent with this guidance with respect to OTC COVID-19 tests or other tests that do not require a health care provider's order.

under the applicable FDA authorization, clearance, or approval. This FAQ does not modify previous guidance[14] addressing coverage for purposes not primarily intended for individualized diagnosis or treatment of COVID-19, including the guidance that states that plans and issuers are not required to provide coverage of testing (including an OTC COVID-19 test) that is for employment purposes.

Q2: If a plan or issuer provides direct coverage of OTC COVID-19 tests, may it limit coverage to only tests that are provided through preferred pharmacies or other retailers?

No. However, a plan or issuer may limit reimbursement for OTC COVID-19 tests in a manner that meets the conditions of the safe harbor described in this Q2. A reimbursement structure that removes barriers associated with upfront costs will facilitate access to COVID-19 tests and, therefore, also improve health equity. At the same time, the Departments are of the view that it is important to ensure that participants, beneficiaries, and enrollees can receive reasonable reimbursement for OTC COVID-19 tests purchased from pharmacies or other retailers of their choice.

Therefore, 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 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 non-preferred pharmacies or other retailers to no less than the actual price, or $12 per test (whichever is lower).[15] Plans and issuers may elect to provide more generous reimbursement up to the actual price of the test. Additionally, under this safe harbor, the direct-to-consumer shipping program may be provided through one or more in-network provider(s) or another entity designated by the plan or issuer.

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 the direct-to-consumer shipping program) with no upfront out-of-pocket expenditure by the participant, beneficiary, or enrollee. Under this safe harbor (and consistent with the general requirement as stated in Q1), plans or issuers may not impose any prior authorization or other medical management requirements on participants, beneficiaries, or enrollees that obtain applicable OTC COVID-19 tests via such a direct coverage program, or otherwise. In providing OTC COVID-19 tests through its direct coverage program, a plan or issuer must take reasonable steps to ensure

[14] See FAQs Part 44, Q2, 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.

[15] 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 Q2, the plan or issuer must calculate the reimbursement based on the number of tests in a package.

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).

The Departments note that whether there is adequate access should be determined based on all relevant facts and circumstances, such as the locality of participants, beneficiaries, and enrollees under the plan or coverage and current utilization of the plan's or issuer's pharmacy network by its participants, beneficiaries, and enrollees. Furthermore, in implementing this safe harbor, plans and issuers should keep in mind the general purpose of the safe harbor – which is to facilitate consumer access and provide for a seamless experience in obtaining free OTC COVID-19 tests. Accordingly, plans and issuers should ensure that participants, beneficiaries, and enrollees are aware of key information needed to access OTC COVID-19 testing, such as dates of availability of the direct coverage program and participating retailers or other locations.

The Departments note that, if a plan or issuer is relying on this safe harbor to meet its obligation to cover OTC COVID-19 tests, but is at any time unable to meet the requirements of this safe harbor (for example, if there are delays that are significantly longer than the amount of time it takes to receive other items under the plan's or issuer's direct-to-consumer shipping program), the plan or issuer would be required to provide coverage for OTC COVID-19 tests in a manner that is otherwise consistent with the requirements described in this guidance. Specifically, a plan or issuer that is unable to meet the requirements of this safe harbor could not deny coverage or impose cost sharing (including setting limits on the amount of reimbursement for OTC COVID-19 tests) with respect to any OTC COVID-19 tests, obtained by participants, beneficiaries, or enrollees, that meet the statutory criteria under section 6001(a)(1) of the FFCRA during this period, including those purchased from non-preferred sellers. Furthermore, this safe harbor applies only with respect to the requirement to provide coverage of OTC COVID-19 tests that are administered without a provider's involvement or prescription; plans and issuers must continue to provide coverage for COVID-19 tests that are administered with a provider's involvement or prescription, as required by section 6001 of the FFCRA and the Departments' guidance, even when relying on this safe harbor. HHS encourages states to take an approach similar to this safe harbor and will not consider a state to have failed to substantially enforce section 6001 of the FFCRA if it takes such an approach.

Q3: If a plan or issuer otherwise provides coverage without cost sharing for COVID-19 diagnostic tests, may a plan or issuer set limits on the number or frequency of OTC COVID-19 tests covered without cost sharing under a plan or coverage?

Yes, but only if the plan or issuer meets the conditions for the safe harbor described in this Q3. The Departments are of the view that it is important to allow plans and issuers to implement certain safeguards against problematic behaviors and ensure OTC COVID-19 tests are accessible to everyone who needs them, when they need them. Furthermore, the Departments recognize an individualized clinical assessment or a health care provider's involvement in the administration of a COVID-19 test may play a role in ensuring the appropriateness and proper utilization of COVID-19 testing for diagnostic purposes and are of the view that additional safeguards are warranted for OTC COVID-19 tests that are covered without such an assessment or provider's involvement.

Therefore, with respect to OTC COVID-19 tests purchased by participants, beneficiaries, and enrollees during the public health emergency that are available without such an assessment or provider's involvement, the Departments will not take enforcement action 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, if the plan or issuer limits the number of OTC COVID-19 tests covered for each participant, beneficiary, or enrollee to no less than 8 tests[16] per 30-day period (or per calendar month).

Although the Departments are adopting this safe harbor, in part, to discourage behaviors that could lead to future shortages, the Departments recognize that individuals may reasonably purchase more OTC COVID-19 tests in a single day than they would use that day or week. The Departments also recognize that multiple individuals covered as a family or household under the same plan or coverage may need to be tested in a short period of time (for example, during a quarantine period following exposure) and that individuals within a family may also experience multiple needs for diagnostic testing in short periods of time. For these reasons, under this safe harbor, a plan or issuer would be required to set the limit for at least 8 individual tests per 30-day period (or per calendar month) per participant, beneficiary, or enrollee, but must not limit participants, beneficiaries, or enrollees to a smaller number of these tests over a shorter period (for example, limiting individuals to 4 tests per 15-day period), though plans and issuers may set more generous limits.

The Departments note that this safe harbor applies only with respect to the coverage of OTC COVID-19 tests that are administered without a provider's involvement or prescription; plans and issuers must continue to provide coverage for COVID-19 tests that are administered with a provider's involvement or prescription, as required by section 6001 of the FFCRA and the Departments' guidance, even when relying on this safe harbor. HHS encourages states to take an approach similar to this safe harbor and will not consider a state to have failed to substantially enforce section 6001 of the FFCRA if it takes such an approach.

Q4: When providing coverage of OTC COVID-19 tests, are plans and issuers permitted to address suspected fraud and abuse?

Yes. As stated in FAQs Part 44, Q2, although the FFCRA prohibits medical management of coverage of COVID-19 diagnostic testing, plans and issuers may act to prevent, detect, and address fraud and abuse. Examples of permissible activities include the following:

- A plan or issuer may take reasonable steps to ensure that an OTC COVID-19 test for which a covered individual seeks coverage under the plan or coverage was purchased for the individual's own personal use (or use by another participant, beneficiary, or enrollee who is covered under the plan or coverage as a member of the individual's family), provided that such steps do not create significant barriers for participants, beneficiaries, and enrollees to obtain these tests. For example, a plan or issuer could require an

[16] The Departments recognize that some OTC COVID-19 tests are sold in packages containing more than one test. In applying the quantity limit of 8, plans and issuers may count each test separately, even if multiple tests are sold in one package.

attestation, such as a signature on a brief attestation document, that the OTC COVID-19 test was purchased by the participant, beneficiary, or enrollee for personal use, not for employment purposes, has not been (and will not be) reimbursed by another source, and is not for resale. In contrast, the Departments are of the view that fraud and abuse programs that require an individual 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.

- A plan or issuer may require reasonable documentation of proof of purchase with a claim for reimbursement for the cost of an OTC COVID-19 test. Examples of such documentation could include the UPC code for the OTC COVID-19 test to verify that the item is one for which coverage is required under section 6001 of FFCRA, and/or a receipt from the seller of the test, documenting the date of purchase and the price of the OTC COVID-19 test.

Q5: How can plans and issuers facilitate access to, effective use of, and prompt payment for OTC COVID-19 tests?

The Departments recognize that participants, beneficiaries, and enrollees may benefit from education, as well as other forms of consumer support, in order to access and use OTC COVID-19 tests as intended. Plans and issuers may provide education and information resources to support consumers seeking OTC COVID-19 testing, as long as such resources make clear that the plan or issuer provides coverage for, including reimbursement of, all OTC COVID-19 tests that meet the statutory criteria under section 6001(a)(1) of the FFCRA (subject to the safe harbors in Q2 and Q3), and such information is consistent with the test's emergency use authorization (EUA), including:

- Guidance to support consumers' efforts to access and effectively use OTC COVID-19 tests and information to explain the differences between OTC COVID-19 tests and tests performed or ordered by a health care provider and/or processed in a laboratory (including when different types of COVID-19 tests are appropriate based on guidance from scientific entities like FDA, the National Institutes of Health, and the Centers for Disease Control and Prevention (CDC));

- Quality information (including shelf life and expiration dates) for specific OTC COVID-19 testing products, or information about reliability of OTC COVID-19 test results, such as information from the test's labeling or EUA summary about the expected test performance (i.e., rate of false positives and false negatives) of specific tests and active recalls of FDA-authorized, cleared, or approved OTC COVID-19 tests;

- How to obtain OTC COVID-19 tests directly from the plan or issuer or from designated sellers that offer those tests at a lower cost, or that receive reimbursement directly from the plan or issuer for the cost of an OTC COVID-19 test, resulting in no charges for the participant, beneficiary, or enrollee at the time of purchase (such as those directly covered by a plan or issuer through its pharmacy network and a direct-to-consumer shipping program, pursuant to the enforcement safe harbor described in Q2); and

- How to submit a claim for reimbursement, including electronic and paper filing options, the required information needed for such a claim, and a description of the documentation that must be submitted in order for the plan or issuer to be able to process the claim promptly and accurately.

Q6: When must plans and issuers 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?

Plans and issuers must provide coverage without cost-sharing requirements, prior authorization, or other medical management requirements in accordance with the requirements under section 6001 of the FFCRA with respect to 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. Coverage may, but is not required to, be provided for OTC COVID-19 tests purchased without a provider order or individualized clinical assessment before January 15, 2022.

The non-enforcement policies set forth in FAQs Part 42, Q9,[17] which permit plans and issuers to amend the terms of a plan or coverage to add benefits, or reduce or eliminate cost sharing, for the diagnosis and treatment of COVID-19 prior to satisfying any applicable notice-of-modification requirements and without regard to otherwise applicable restrictions on mid-year changes to health insurance coverage in the group and individual markets, continue to apply with respect to changes made to comply with these updates related to coverage of OTC COVID-19 tests.

COVERAGE OF PREVENTIVE SERVICES

PHS Act section 2713 and its implementing regulations relating to coverage of preventive services[18] require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover, without the imposition of any cost-sharing requirements, the following items or services:[19]

[17] See 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.

[18] 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; 45 CFR 147.130.

[19] In addition, under section 3203 of the CARES Act and its implementing regulations, plans and issuers must cover, without cost-sharing requirements, any qualifying coronavirus preventive service pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). The term "qualifying coronavirus preventive service" means an item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is, with respect to the individual involved (1) an evidence-based item or service that has in effect a rating of "A" or "B" in the current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP (regardless of whether the immunization is recommended for routine use). On November 6, 2020, the Departments published interim final rules with a request for comments regarding this requirement, *Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* (85 FR 71142).

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009, which are not considered in effect for this purpose;[20]
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the CDC with respect to the individual involved;
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women, preventive care and screenings provided for in comprehensive guidelines supported by HRSA, to the extent not included in certain recommendations of the USPSTF.[21]

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations.[22]

Coverage of Colonoscopies Pursuant to USPSTF Recommendations

In 2016, the USPSTF recommended with an "A" rating screening for colorectal cancer starting at age 50 years and continuing until age 75 years. The Departments have issued several FAQs clarifying that if a colonoscopy is scheduled and performed as a screening procedure pursuant to the USPSTF recommendation, cost sharing may not be imposed for items and services that are an integral part of performing the colonoscopy.[23] These items and services include:

- Required specialist consultation prior to the screening procedure;[24]
- Bowel preparation medications prescribed for the screening procedure;[25]

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[20] The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of Division H of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2023.

[21] For accommodations and religious and moral exemptions with respect to coverage of certain recommended contraceptive services, see 26 CFR 54.9815-2713A; 29 CFR 2590.715-2713A; 45 CFR 147.131 through 147.133.

[22] See 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); 45 CFR 147.130(a)(4).

[23] See citations on bullet points below. See also 85 FR 71142, 71174 (Nov. 6, 2020) (stating "plans and issuers subject to section 2713 of the PHS Act must cover, without cost sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately.").

[24] See FAQs about Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation (Oct. 23, 2015), Q7, available at www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxix.pdf and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf

[25] See FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation (Apr. 20, 2016), Q1, available at www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.

- Anesthesia services performed in connection with a preventive colonoscopy;[26]
- Polyp removal performed during the screening procedure;[27] and
- Any pathology exam on a polyp biopsy performed as part of the screening procedure.[28]

On May 18, 2021, the USPSTF updated its recommendation for colorectal cancer screening. The USPSTF continues to recommend with an "A" rating screening for colorectal cancer in all adults aged 50 to 75 years and extended its recommendation with a "B" rating to adults aged 45 to 49 years. In its "Practice Considerations" section detailing screening strategies, the Final Recommendation Statement provides: "When stool-based tests reveal abnormal results, follow-up with colonoscopy is needed for further evaluation…. Positive results on stool-based screening tests require follow-up with colonoscopy for the screening benefits to be achieved."[29] Additionally, the Final Recommendation Statement provides with respect to direct visualization tests: "Abnormal findings identified by flexible sigmoidoscopy or CT colonography screening require follow-up colonoscopy for screening benefits to be achieved."[30]

Q7: Are plans and issuers required to cover, without the imposition of any cost sharing, a follow-up colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization test (e.g., sigmoidoscopy, CT colonography)?

Yes. A plan or issuer must cover and may not impose cost sharing with respect to a colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization screening test for colorectal cancer for individuals described in the USPSTF recommendation. As stated in the May 18, 2021 USPSTF recommendation, the follow-up colonoscopy is an integral part of the preventive screening without which the screening would not be complete.[31] The follow-up colonoscopy after a positive non-invasive stool-based screening test or direct visualization screening test is therefore required to be covered without cost sharing in accordance with the requirements of PHS Act section 2713 and its implementing regulations.

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[26] See FAQs about Affordable Care Act Implementation (Part XXVI) (May 11, 2015), Q7, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

[27] See FAQs about Affordable Care Act Implementation (Part XII) (Feb. 20, 2013), Q5, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.

[28] See FAQs about Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation (Oct. 23, 2015), Q8, available at www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxix.pdf and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf.

[29] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.

[30] In addition, in its "Supporting Evidence" section, the USPSTF Full Recommendation Statement states: "Several comments requested that colonoscopy to follow up an abnormal noncolonoscopy screening test result be considered part of screening. The USPSTF recognizes that the benefits of screening can only be fully achieved when follow-up of abnormal screening test results is performed. The USPSTF added language to the Practice Considerations section to clarify this."

[31] Id.

Q8: When must plans and issuers begin providing coverage without cost sharing for a follow-up colonoscopy after a positive non-invasive stool-based screening test or direct visualization test based on the new USPSTF recommendation?

Plans and issuers must provide coverage without cost sharing consistent with the May 18, 2021 USPSTF recommendation regarding colorectal cancer screening and in accordance with the requirements under PHS Act section 2713 for plan years (in the individual market, policy years) beginning on or after the date that is one year after the date the recommendation was issued. In this case, the recommendation is considered to have been issued as of May 31, 2021, so plans and issuers must provide coverage without cost sharing for plan or policy years beginning on or after May 31, 2022.[32]

Coverage of FDA-approved Contraceptive Products Pursuant to HRSA Guidelines

The currently applicable HRSA Women's Preventive Services Guidelines (HRSA Guidelines), as updated on December 17, 2019, include a guideline that adolescent and adult women have access to the full range of female-controlled FDA-approved contraceptive methods,[33] effective family planning practices and sterilization procedures to prevent unintended pregnancy and improve birth outcomes.[34] The currently applicable HRSA Guidelines state that contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management and evaluation as well as changes to, and removal or discontinuation of, the contraceptive method), and that instruction in fertility awareness-based methods, including the lactation amenorrhea method, should be provided for women desiring an alternative method.

On February 20, 2013, the Departments issued an FAQ stating that the HRSA Guidelines ensure women's access to the full range of FDA-approved contraceptive methods including, but not limited to barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a health care provider.[35] The FAQ further clarified that plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care, such as covering a generic drug without cost sharing and imposing cost sharing for equivalent branded drugs. However, in these instances, the FAQ stated that a plan or issuer must accommodate any individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.

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[32] 26 CFR 54.9815-2713(b); 29 CFR 2590.715-2713(b); 45 CFR 147.130(b). Generally, for purposes of section 2713 of the PHS Act, USPSTF recommendations are considered to be issued on the last day of the month in which the USPSTF publishes or otherwise releases the recommendation. 75 FR 41726, 41729 (July 19, 2010).

[33] The Departments note that the FDA approves, clears, and grants contraceptive products and not methods.

[34] https://www.hrsa.gov/womens-guidelines-2019.

[35] See FAQs about Affordable Care Act Implementation Part XII (Feb. 20, 2013), Q14, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf and www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

On May 11, 2015, the Departments issued an FAQ clarifying that plans and issuers must cover, without cost sharing, at least one form of contraception in each method that is identified by the FDA in its Birth Control Guide.[36] The FAQ further clarified that, to the extent plans and issuers use reasonable medical management techniques within a specified method of contraception, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exception process that is not unduly burdensome on the individual (or provider or other individual acting as a patient's authorized representative) to ensure coverage without cost sharing of any service or FDA-approved item within the specified method of contraception. An additional FAQ stated that if an individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The FAQ makes clear that a plan or issuer must defer to the determination of the attending provider. The FAQs stated that medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider. The FAQs also clarified that the exception process must provide for making a determination of the claim according to a timeframe and in a manner that takes into account the nature of the claim (e.g., pre-service or post-service) and the medical exigencies involved for a claim involving urgent care.

On April 20, 2016, the Departments issued an FAQ stating that if a plan or issuer utilizes reasonable medical management techniques within a specified method of contraception, the plan or issuer may develop and utilize a standard exception form and instructions as part of its steps to ensure that it provides an easily accessible, transparent, and sufficiently expedient exception process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative).[37] The FAQ suggested that the Medicare Part D Coverage Determination Request Form may serve as a model for plans and issuers when developing a standard exception form.[38]

The Departments are issuing the following FAQ in response to complaints and public reports of potential violations of the contraceptive coverage requirement. This FAQ makes clear that all FDA-approved cleared, or granted contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual must be covered without-cost sharing, whether or not specifically identified in the current FDA Birth Control Guide.

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[36] See FAQs about Affordable Care Act Implementation Part XXVI (May 11, 2015), Q2 and Q3, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.

[37] See FAQs about Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation (Apr. 20, 2016), Q2, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.

[38] A copy of the Medicare Part D Coverage Determination Request Form is available at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminations-.

Q9: What is expected of non-exempt[39] plans and issuers regarding compliance with the requirement to cover contraceptive services under PHS Act section 2713?

The Departments have received a number of complaints and reports that participants, beneficiaries, and enrollees are being denied contraceptive coverage in violation of the requirements under PHS Act section 2713. Examples include plans and issuers, as well as their pharmacy benefits managers:

- Denying coverage for all or particular brand name contraceptives, even after the individual's attending provider determines and communicates to the plan or issuer that a particular service or FDA-approved, cleared, or granted contraceptive product is medically necessary with respect to that individual;
- Requiring individuals to fail first using numerous other services or FDA-approved, cleared, or granted contraceptive products within the same method of contraception before the plan or issuer will approve coverage for the service or FDA-approved, cleared, or granted contraceptive product that is medically appropriate for the individual, as determined by the individual's attending health care provider;
- Requiring individuals to fail first using other services or FDA-approved, cleared, or granted contraceptive products in other contraceptive methods before the plan or issuer will approve coverage for a service or FDA-approved, cleared, or granted contraceptive product in the contraceptive method that is medically appropriate for the individual, as determined by the individual's attending health care provider; and
- Failing to provide an easily accessible, transparent, and sufficiently expedient exception process that is not unduly burdensome (for example, requiring individuals to appeal an adverse benefit determination using the plan's or issuer's internal claims and appeals process as the means to obtain an exception).

The Departments are actively investigating these complaints and reports and may take enforcement or other corrective actions. The Departments are also assessing what types of changes to existing guidance or regulations may need to be made to better ensure individuals receive the coverage to which they are entitled under the law and will issue additional guidance, as warranted.

The Departments have also received stakeholder feedback that while the current 2019 version of the HRSA Guidelines recommends coverage of the full range of female-controlled FDA-approved contraceptive methods, the current FDA Birth Control Guide referenced in the Departments' prior guidance may not identify all and/or newer contraceptive products approved,

[39] On November 15, 2018, the Departments published final regulations concerning religious exemptions at 83 FR 57536 and moral exemptions at 83 FR 57592, as well as accommodations regarding this coverage. On August 16, 2021, the Departments issued FAQs about Affordable Care Act Implementation Part 48, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-48.pdf and https://www.cms.gov/files/document/faqs-part-48.pdf, in which the Departments indicated their intent to initiate rulemaking within six months of that date to amend these final regulations.

cleared, or granted by FDA, such as mobile apps for contraception based on fertility awareness.[40] As a result, plans and issuers may not be providing coverage for the full range of FDA-approved, cleared, or granted contraceptive products in accordance with the current 2019 HRSA Guidelines.

Plans and issuers subject to these requirements are reminded of their responsibility to fully comply with the requirements under PHS Act section 2713 and the HRSA Guidelines, as interpreted in the Departments' implementing regulations and guidance, including the requirement that, if an individual and their attending provider determine that a particular service or FDA-approved, cleared, or granted contraceptive product is medically appropriate for the individual (whether or not the item or service is identified in the current FDA Birth Control Guide), the plan or issuer must cover that service or product without cost sharing.

Consumers that are covered by a private-sector, employer-sponsored group health plan and have concerns about their plan's compliance with these requirements may contact the Department of Labor at askebsa.dol.gov or by calling toll free at 1-866-444-3272. Consumers that are covered by a non-federal public-sector employer-sponsored plan (such as a state or local government employee plan) and have concerns about their plan's compliance with these requirements may contact the Health Insurance Assistance Team of the U.S. Center for Consumer Information and Insurance Oversight at (888) 393-2789 or phig@cms.hhs.gov for further assistance with a question or issue.

[40] FDA News Release, "FDA allows marketing of first direct-to-consumer app for contraceptive use to prevent pregnancy," (Aug. 10, 2018), available at https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-app-contraceptive-use-prevent-pregnancy.