

FAQS ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 43

June 23, 2020

Set out below are frequently asked questions (FAQs) regarding implementation of the Families First Coronavirus Response Act (the FFCRA), the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), and other health coverage issues related to Coronavirus Disease 2019 (COVID-19). These FAQs have been prepared jointly by the Department of Labor (DOL), the Department of Health and Human Services (HHS), and the Department of the Treasury (collectively, the Departments). Similar to 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 www.cms.gov/ccio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help individuals understand the law and benefit from it, as intended.

Under section 6001(c) of the FFCRA, the Departments are authorized to implement the requirements of section 6001 of the FFCRA, as amended by section 3201 of the CARES Act, through sub-regulatory guidance, program instruction, or otherwise. On April 11, 2020, the Departments issued FAQs to provide guidance on these FFCRA and CARES Act requirements and address other health coverage issues related to COVID-19 (FAQs Part 42).¹

Due to the urgent need to help facilitate the nation's response to the public health emergency posed by COVID-19, the Departments are adopting temporary policies to provide relief in connection with certain standards identified below under the conditions outlined in this guidance. The Departments therefore believe that this guidance is a statement of policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA).² 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.³

¹ 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>.

² 5 U.S.C. § 553(b)(A).

³ 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

The FFCRA and the CARES Act

The FFCRA was enacted on March 18, 2020.⁴ Section 6001 of the FFCRA generally requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits for certain items and services related to testing for the detection of SARS-CoV-2, the virus that causes COVID-19, or the diagnosis of COVID-19 (generally referred to collectively in this document as COVID-19) when those items or services are furnished on or after March 18, 2020, and during the applicable emergency period.⁵ 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.⁶

The CARES Act was enacted on March 27, 2020.⁷ 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.⁸ Section 3202(a) of the CARES Act generally requires plans and issuers providing coverage for these items and services to reimburse any provider of COVID-19 diagnostic testing an amount that equals the negotiated rate or, if the plan or issuer does not have a negotiated rate with the 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 requires 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.

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.

⁴ Pub. L. No. 116-127 (2020).

⁵ 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 Assistance 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 April 21, 2020, the HHS Secretary renewed the COVID-19 public health emergency declaration, effective April 26, 2020. *See* HHS Office of the Assistance 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/covid19-21apr2020.aspx>. The 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.

⁶ Medical management includes medical necessity review (including concurrent review) and step-therapy approaches, among other techniques.

⁷ Pub. L. No. 116-136 (2020).

⁸ References in this document to section 6001 of the FFCRA should be considered to include the amendments made to section 6001 by section 3201 of the CARES Act, unless otherwise specified.

Nothing in the FFCRA or the CARES Act prevents a state from imposing additional standards or requirements on health insurance issuers or providers with respect to the diagnosis or treatment of COVID-19, to the extent those standards or requirements do not prevent the application of a federal requirement.

Section 6001 of the FFCRA

Q1. Are self-insured group health plans required to comply with the requirements of section 6001 of the FFCRA?

Yes. In FAQs Part 42, Q1, the Departments addressed which types of group health plans and health insurance coverage are subject to the requirements of section 6001 of the FFCRA. The statute and FAQs make clear that the requirements apply to both insured and self-insured group health plans.⁹

The Departments will enforce the applicable provisions of the FFCRA (and the related provisions of the CARES Act), in conjunction with states, where applicable. If you are covered by a private-sector, employer-sponsored group health plan and have concerns about your plan's compliance with these requirements, you may contact DOL at askebsa.dol.gov or by calling toll free at 1-866-444-3272. If you are covered by a non-federal public-sector employer-sponsored plan (such as a state or local government employee plan) and have concerns about your plan's compliance with these requirements, you may contact HHS at 1-877-267-2323 extension 6-1565 or at phig@cms.hhs.gov. If you have insured coverage, you may contact your State Department of Insurance (For contact information, visit https://content.naic.org/state_web_map.htm).

Q2. How can a plan or issuer determine which COVID-19 tests are required to be covered under section 6001(a)(1) of the FFCRA?

Section 6001(a) of the FFCRA requires plans and issuers to provide coverage for an in vitro diagnostic test defined in section 809.3(a) of title 21, Code of Federal Regulations (or its successor regulations) for the detection of SARS-CoV-2 or the diagnosis of COVID-19, and the administration of such a test, that—

- A. Is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 360(k), 360c, 360e, 360bbb-3);
- B. The developer has requested, or intends to request, emergency use authorization

⁹ Section 6001 does not apply to a plan or coverage in relation to its provision of excepted benefits or to group health plans that do not cover at least two employees who are current employees (such as plans in which only retirees participate). It does, however, apply to health insurance coverage offered in connection with a group health plan maintained by a small employer, as defined in section 2791(e)(4) of the PHS Act, which term includes employers with as few as one common law employee.

under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb–3), 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. Is 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. Other tests that the Secretary of HHS determines appropriate in guidance.

For purposes of A above, all in vitro diagnostic tests for COVID-19 that have received an emergency use authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act are listed on the EUA page of the Food and Drug Administration (FDA) website, available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>. At this time, the FDA has not cleared or approved an in vitro diagnostic test for COVID-19 under the other regulatory pathways outlined in A above.

For purposes of B above, also available on the FDA website is a list of clinical laboratories and commercial manufacturers that have notified FDA that they have validated their own COVID-19 test and are offering the test as outlined in FDA guidance.¹⁰ The following scenarios are outlined in FDA guidance:

- Commercial manufacturers that develop COVID-19 diagnostic tests and serological tests should notify FDA prior to distribution that their test has been validated. Among other things, they should also be preparing a request for an EUA, and should submit a request for an EUA to FDA within a reasonable period of time thereafter, as described in FDA guidance.
- Laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing that develop a diagnostic test for COVID-19 should notify FDA prior to using the test for specimen testing that their test has been validated. Among other things, they should also be preparing an EUA request, and should submit an EUA request within a reasonable period of time thereafter, as described in FDA guidance. (This policy does not apply to tests being offered by such laboratories as referenced in C above.)
- Laboratories certified under CLIA to perform high-complexity testing that develop serology tests should, among other things, notify FDA prior to using the test for specimen testing that their test has been validated. FDA does not expect such laboratories to

¹⁰ U.S. Food and Drug Administration, Center for Devices and Radiological Health, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff (updated May 11, 2020), available at <https://www.fda.gov/media/135659/download>.

submit an EUA request, although they are encouraged to do so. (This policy does not apply to tests being offered by such laboratories as referenced in C above.)

FDA will post the names of entities that provide such notification on FDA's website at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#offeringtests>. If an expected EUA request is not submitted within a reasonable time after notifying the FDA, or if significant problems are identified with a test that cannot be or have not been addressed in a timely manner, FDA intends to remove the manufacturer/laboratory and test from the list, and may take additional actions as appropriate.

Accordingly, for purposes of B above, if a clinical laboratory or commercial manufacturer is listed on FDA's website as having provided notification under the FDA guidance, it can reasonably be assumed that the laboratory or manufacturer has requested or intends to request an EUA, except for laboratory-developed serology tests (as an EUA request is not currently expected in that case). Therefore, plans and issuers must cover in vitro diagnostic tests for COVID-19 that are included on this list. In addition, a plan or issuer may take reasonable steps to verify that a test offered by a developer meets the statutory criteria outlined in B. For example, a plan or issuer may request that a laboratory or commercial manufacturer provide documentation, such as a copy of the EUA request or pre-EUA submitted to FDA, to demonstrate that it has requested or intends to request an EUA. These requests will not be considered to violate FFCRA section 6001's prohibition on medical management requirements as long as they are reasonable and necessary to verify that a COVID-19 test meets the statutory criteria.

For purposes of C above, states and territories may authorize laboratories within that state or territory to develop and perform a test for COVID-19, as outlined in FDA guidance. States and territories that have notified FDA that they choose to use this flexibility are listed at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#offeringtests>.

For purposes of D above, no other tests have been specified in guidance by the Secretary of HHS at this time.

Q3. In FAQs Part 42, the Departments clarified that coverage for certain items and services must be provided consistent with the requirements of section 6001 of the FFCRA “when medically appropriate for the individual, as determined by the individual’s attending health care provider.” How should plans and issuers determine if a provider is the attending health care provider?

Given the critical importance of expanding the availability of COVID-19 testing through safe and accurate tests to combat the COVID-19 pandemic, the Departments clarify that a health care provider need not be “directly” responsible for providing care to the patient to be considered an attending provider, as long as the provider makes an individualized clinical assessment to

determine whether the test is medically appropriate for the individual in accordance with current accepted standards of medical practice. Therefore, an attending provider for purposes of section 6001 of the FFCRA is an individual who is licensed (or otherwise authorized) under applicable law, who is acting within the scope of the provider’s license (or authorization), and who is responsible for providing care to the patient. As stated in FAQs Part 42, a plan, issuer, hospital, or managed care organization is not an attending provider.¹¹

Q4. Are plans and issuers required to cover COVID-19 tests intended for at-home testing under section 6001 of the FFCRA?

Yes. COVID-19 tests intended for at-home testing¹² (including tests where the individual performs self-collection of a specimen at home) must be covered, 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 in section 6001(a)(1) of the FFCRA. 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.

Q5. Is COVID-19 testing for surveillance or employment purposes required to be covered under section 6001 of the FFCRA?

No. Section 6001 of the FFCRA requires coverage of items and services only for diagnostic purposes as outlined in this guidance. Clinical decisions about testing are made by the individual’s attending health care provider and may include testing of individuals with signs or symptoms compatible with COVID-19, as well as asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2, that is determined to be medically appropriate by the individual’s health care provider, consulting CDC guidelines as appropriate.¹³ However, testing conducted to screen for general workplace health and safety (such as employee “return to work” programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section 6001 of the FFCRA.

¹¹ This guidance supersedes the definition of an “attending provider” in FAQs Part 42, footnote 16, which stated that “[a]n attending provider means an individual who is licensed under applicable state law, who is acting within the scope of the provider’s license, and who is directly responsible for providing care to a patient.”

¹² On April 20, 2020, the FDA authorized the first COVID-19 test for home collection of specimens to be sent to a laboratory for processing and test reporting. See U.S. Food and Drug Administration, Letter to Brian Krueger, Ph.D., Laboratory Corporation of America, Granting EUA Amendments (Apr. 20, 2020), available at <https://www.fda.gov/media/136148/download>. However, as of the publication of this document, the FDA has not authorized any COVID-19 test to be completely used and processed at home.

¹³ See Centers for Disease Control and Prevention, Overview of Testing for SARS-CoV-2 (June 13, 2020), available at <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>.

Q6. If an individual receives multiple diagnostic tests for COVID-19, are plans and issuers required to cover each test, as well as other applicable items and services?

Yes. The coverage required under section 6001 of the FFCRA for items and services described in section 6001(a) of the FFCRA is not limited with respect to the number of diagnostic tests for an individual, provided that the tests are diagnostic and medically appropriate for the individual, as determined by an attending health care provider in accordance with current accepted standards of medical practice.¹⁴ Although plans and issuers may not impose prior authorization or other medical management requirements to deny coverage for individuals who are tested multiple times, providers are urged to consult guidance issued by the CDC, as well as state, tribal, territorial, and local health departments or professional societies, when determining whether diagnostic testing is appropriate for a particular individual.¹⁵

Q7. If a facility fee is charged for a visit that results in an order for or administration of a COVID-19 diagnostic test, must the plan or issuer also cover the facility fee without imposing cost-sharing requirements?

Yes, to the extent the facility fee relates to the furnishing or administration of a COVID-19 test or to the evaluation of an individual to determine the individual's need for testing.

Section 6001(a)(2) of the FFCRA requires plans and issuers to provide coverage for items and services furnished to an individual during health care provider office visits (including in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product, but only to the extent that the items and services relate to the furnishing or administration of the product or to the evaluation of the individual for purposes of determining the need of the individual for that product. A facility fee is a fee for the use of facilities or equipment an individual's provider does not own or that are owned by a hospital. Therefore, to the extent a facility fee is assessed in relation to items or services required to be covered under section 6001, the plan or issuer must provide coverage for the facility fee.¹⁶ 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.

For example, if an individual is treated in the emergency room and the attending provider orders a number of services to determine whether a COVID-19 diagnostic test is appropriate, such as diagnostic test panels for influenza A and B and respiratory syncytial virus, as well as a chest x-

¹⁴ Since the Departments are not aware of any professional society recommendations for confirmatory or repeat testing on the same sample, the Departments expect plans and issuers to be billed once per sample.

¹⁵ See Centers for Disease Control and Prevention, Overview of Testing for SARS-CoV-2 (June 13, 2020), available at <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html>.

¹⁶ Section 6001 of the FFCRA does not preempt state laws that prohibit providers from billing facility fees, or require coverage of facility fees for in-network providers, if the plan and issuer and the provider have entered into a contractual arrangement under which the plan or issuer does not pay facility fees for any service furnished by the in-network provider.

ray, and ultimately orders a COVID-19 test, the plan or issuer must cover those related items and services without cost sharing, prior authorization, or other medical management requirements, including any physician fee charged to read the x-ray and any facility fee assessed in relation to those items and services.

Section 3202 of the CARES Act

Q8. Do the reimbursement requirements of section 3202(a) of the CARES Act apply to any items and services other than diagnostic testing for COVID-19?

No. Section 3202(a) of the CARES Act describes the amount a plan or issuer must reimburse a provider for COVID-19 testing, but does not address the reimbursement rate for any other items and services.

Q9. Does section 3202 of the CARES Act protect participants, beneficiaries, and enrollees from balance billing for a COVID-19 diagnostic test?

The Departments read the requirement to provide coverage without cost sharing in section 6001 of the FFCRA, together with section 3202(a) of the CARES Act establishing a process for setting reimbursement rates, as intended to protect participants, beneficiaries, and enrollees from being balance billed for an applicable COVID-19 test. Section 3202(a) contemplates that a provider of COVID-19 testing will be reimbursed either a negotiated rate or an amount that equals the cash price for such service that is listed by the provider on a public website. In either case, the amount the plan or issuer reimburses the provider constitutes payment in full for the test, with no cost sharing to the individual or other balance due. Therefore, the statute generally precludes balance billing for COVID-19 testing. However, section 3202(a) of the CARES Act does not preclude balance billing for items and services not subject to section 3202(a), although balance billing may be prohibited by applicable state law and other applicable contractual agreements.¹⁷

Q10. How do the requirements of section 3202(a)(2) of the CARES Act interact with state balance billing laws regarding reimbursement for items and services furnished by out-of-network providers or providers that do not have a negotiated rate with a plan or issuer for COVID-19 tests?

Section 3202(a)(2) of the CARES Act provides that, if a plan or issuer does not have a negotiated rate with a provider of COVID-19 diagnostic testing, the plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a

¹⁷ See e.g., the terms and conditions for certain payments for provider relief (Provider Relief Fund) under Division B of Public Law 116-136 (providing that, as a condition of accepting a payment from the Provider Relief Fund for all care for a presumptive or actual case of COVID-19, a recipient certifies that it will not seek to collect from the patient out-of-pocket expenses that are greater than what the patient would have otherwise been required to pay if the care had been provided by an in-network provider). See Department of Health and Human Services, Provider Relief Fund Payments Terms and Conditions, available at <https://www.hhs.gov/sites/default/files/relief-fund-payment-terms-and-conditions.pdf>.

public internet website, or the plan or issuer may negotiate a rate with the provider that is lower than the cash price. Plans and issuers that do not already have a negotiated rate with a provider may nevertheless seek to negotiate to determine a rate, and state laws governing reimbursements may apply. For example, many states have balance billing laws that establish dispute resolution processes for issuers and providers to determine reimbursement rates for certain items and services. Such dispute resolution processes would continue to apply in these states to the issuers and providers that do not already have a negotiated rate. Additionally, to the extent that a state law does not prevent the application of the requirements of section 3202(a) of the CARES Act, the state law is not preempted and continues to apply.

Q11. How should plans and issuers determine a reimbursement rate for providers of COVID-19 testing if they do not have a negotiated rate with the provider and the provider has not made available on a public internet website the cash price of a COVID-19 diagnostic test, as required by section 3202(b) of the CARES Act?

The requirement imposed by section 3202(a) of the CARES Act to reimburse the provider an amount that equals the cash price of a COVID-19 test is contingent upon the provider making public the cash price for the test, as required by section 3202(b) of the CARES Act. If the provider has not complied with this requirement, and the plan or issuer does not have a negotiated rate with the provider, the plan or issuer may seek to negotiate a rate with the provider for the test. However, section 3202(a) is silent with respect to the amount to be reimbursed for COVID-19 testing in circumstances where the provider has not made public the cash price for a test and the plan or issuer and the provider cannot agree upon a rate that the provider will accept as payment in full for the test. The Departments note that section 3202(b) of the CARES Act grants the Secretary of HHS authority to impose civil monetary penalties on any provider of a diagnostic test for COVID-19 that does not comply with the requirement to publicly post the cash price for the COVID-19 diagnostic test on the provider's website and has not completed a corrective action plan, in an amount not to exceed \$300 per day that the violation is ongoing.¹⁸

If the method for determining reimbursement for out-of-network services (or services for which there is no negotiated rate) is governed by applicable state law, then state law continues to apply as described in Q10 above.

Q12. If an individual receives a COVID-19 test in an emergency department of a hospital that is out-of-network, how do the requirements of section 3202(a) of the CARES Act interact with PHS Act section 2719A?

Under PHS Act section 2719A and its implementing regulations, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage cannot impose cost sharing (expressed as a copayment amount or

¹⁸ See also Centers for Medicare & Medicaid Services, Price Transparency: Requirements for Providers to Make Public Cash Prices for COVID-19 Diagnostic Testing (May 12, 2020), available at <https://www.cms.gov/files/document/covid-ffs-price-transparency-faqs.pdf>.

coinsurance rate) on out-of-network emergency services in a greater amount than what is imposed for in-network emergency services. Additionally, the Departments' regulations provide that a plan or issuer satisfies the cost-sharing limitations in the statute if it provides benefits for out-of-network emergency services in an amount at least equal to the greatest of the following three amounts (adjusted for in-network cost-sharing requirements): (1) the median amount negotiated with in-network providers for the emergency service; (2) the amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount); or (3) the amount that would be paid under Medicare for the emergency service (collectively, minimum payment standards).¹⁹ The minimum payment standards do not prohibit a group health plan or health insurance issuer from paying an amount for an emergency service that is greater than the amounts specified in the regulations.

Because the Departments interpret the provisions of section 3202 of the CARES Act as specifying a rate that generally protects participants, beneficiaries, and enrollees from balance billing for a COVID-19 test (see Q9 above), the requirement to pay the greatest of three amounts under the regulations implementing section 2719A of the PHS Act is superseded by the requirements of section 3202(a) of the CARES Act with regard to COVID-19 diagnostic tests that are out-of-network emergency services. For these services, the plan or issuer must reimburse an out-of-network provider of COVID-19 testing an amount that equals the cash price for such service that is listed by the provider on a public website, or the plan or issuer may negotiate a rate that is lower than the cash price.

For all other out-of-network emergency services, which are not subject to the requirements of section 3202(a) (see Q8 above), the minimum payment standards under section 2719A of the PHS Act continue to apply.

Notice Requirements

Q13. In FAQs Part 42, the Departments announced temporary enforcement relief that allows plans and issuers to make changes to coverage to increase benefits, or reduce or eliminate cost sharing, for the diagnosis and treatment of COVID-19 or for telehealth and other remote care services more quickly than they would otherwise be able to under current law.²⁰ May a plan or issuer also revoke these changes upon the expiration of the

¹⁹ 26 CFR 54.9815-2719A(b)(3); 29 CFR 2590.715-2719A(b)(3); 45 CFR 147.138(b)(3).

²⁰ With respect to any change that adds benefits, or reduces or eliminates cost-sharing requirements, for the diagnosis and treatment of COVID-19 or telehealth and other remote care services, the Departments will not enforce requirements that generally require plans and issuers to provide 60 days' advance notice of a material modification to the terms of the plan or coverage. However, under the enforcement relief policy, a plan or issuer must provide notice of the changes as soon as reasonably practicable. This non-enforcement relief applies with respect to changes made during the period in which a public health emergency declaration under section 319 of the PHS Act related to COVID-19 or a national emergency declaration under the National Emergencies Act related to COVID-19 is in effect. See FAQs Part 42, Q9 and Q14, (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>.

public health emergency related to COVID-19 without satisfying advance notice requirements?

Section 2715(d)(4) of the PHS Act and final rules issued by the Departments regarding the Summary of Benefits and Coverage (SBC) provide that if a plan or issuer makes a material modification (as defined under section 102 of the Employee Retirement Income Security Act (ERISA)) in any of the terms of the plan or coverage that would affect the content of the SBC, that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification not later than 60 days prior to the date on which the modification will become effective. In FAQs Part 42, Q9 and Q14, the Departments announced temporary enforcement relief that generally applies with respect to changes made to increase benefits, or reduce or eliminate cost-sharing requirements, for the diagnosis and/or treatment of COVID-19 and telehealth or other remote care services during the public health emergency or national emergency declaration period related to COVID-19.

If a plan or issuer reverses these changes once the COVID-19 public health emergency or national emergency declaration is no longer in effect, the Departments will consider a plan or issuer to have satisfied its obligation to provide advance notice of a material modification under section 2715(d)(4) of the PHS Act and its implementing regulations with respect to a participant, beneficiary, or enrollee if the plan or issuer had previously notified the participant, beneficiary, or enrollee of the general duration of the additional benefits coverage or reduced cost sharing (such as, that the increased coverage applies only during the COVID-19 public health emergency) or notifies the participant, beneficiary, or enrollee of the general duration of the additional benefits coverage or reduced cost sharing within a reasonable timeframe in advance of the reversal of the changes.²¹

Telehealth and Other Remote Care Services

Q14. In light of the COVID-19 pandemic, may a large employer offer coverage only for telehealth and other remote care services to employees who are not eligible for any other group health plan offered by the employer?

Yes. In general, a plan, fund, or program established or maintained by an employer (or employee organization) that provides medical care (including telehealth or other remote care services) to employees or their dependents is a group health plan subject to federal requirements applicable to group health plans. Nonetheless, in light of the critical need to minimize the risk of

²¹ The DOL has issued guidance providing additional time to furnish notices, disclosures, and other documents required by provisions of Title I of ERISA that would be required to be furnished between March 1, 2020, and 60 days after the announced end of the COVID-19 National Emergency or such other date announced by DOL in a future notice, if the plan and responsible fiduciary act in good faith and furnish the notice, disclosure, or document as soon as administratively practicable under the circumstances. See EBSA Disaster Relief Notice 2020-01 (Apr. 28, 2020), available at <https://www.dol.gov/agencies/ebsa/employers-and-advisers/plan-administration-and-compliance/disaster-relief/ebsa-disaster-relief-notice-2020-01>.

exposure to and community spread of SARS-CoV-2, for the duration of any plan year beginning before the end of the public health emergency related to COVID-19, the Departments are providing relief for a group health plan (and health insurance coverage offered in connection with a group health plan) that solely provides benefits for telehealth or other remote care services from the group market reforms under part 7 of ERISA, title XXVII of the PHS Act, and chapter 100 of the Internal Revenue Code (the Code), except as specified below. This relief is limited to telehealth and other remote care service arrangements that are sponsored by a large employer (as defined under section 2791(e)(2) of the PHS Act) and that are offered only to employees (or their dependents) who are not eligible for coverage under any other group health plan offered by that employer.

Under this temporary relief, the Departments will continue to apply otherwise applicable federal non-discrimination standards. The specified market reforms that these arrangements must continue to satisfy are the following provisions of the PHS Act (and corresponding provisions of ERISA and the Code):

- Section 2704 (relating to prohibition of pre-existing condition exclusions or other discrimination based on health status);
- Section 2705 (relating to prohibition of discrimination against individual participants and beneficiaries based on health status);
- Section 2712 (relating to prohibition of rescissions); and
- Section 2726 (relating to parity in mental health or substance use disorder benefits).

HHS encourages states to take a similar approach and will not consider a state to have failed to substantially enforce applicable PHS Act requirements if it takes such an approach.

Grandfathered Health Plans

Section 1251 of the Patient Protection and Affordable Care Act (PPACA) provides that grandfathered health plans are subject to only certain provisions of PPACA, for as long as they maintain their status as grandfathered health plans. Implementing regulations issued by the Departments specify certain changes to the terms of a group health plan or health insurance coverage offered in the group or individual market that will cause the plan or coverage to cease to be a grandfathered health plan. Among other changes that could cause a loss of grandfather status, a plan or coverage will generally lose its grandfather status if it eliminates all or substantially all benefits to diagnose or treat a particular condition or increases cost-sharing requirements above certain thresholds, as compared to the terms of the plan or coverage that were in effect on March 23, 2010.²²

²² 26 CFR 54.9815-1251(g)(i) and (ii); 29 CFR 2590.715.1251(g)(i) and (ii); 45 CFR 147.140(g)(i) and (ii).

Q15. If a grandfathered group health plan or issuer of grandfathered group or individual health insurance coverage adds benefits, or reduces or eliminates cost-sharing requirements, for the diagnosis and treatment of COVID-19 or for telehealth and other remote care services during the public health or national emergency period related to COVID-19, will the plan or coverage lose its grandfather status solely because it later reverses these changes upon the expiration of the COVID-19 emergency period?

No. In general, for purposes of determining whether changes to the terms of a plan or coverage would cause a loss of grandfather status under regulations issued by the Departments, the revised terms are compared to the terms that were in effect as of March 23, 2010. To the extent that a plan or issuer added benefits or reduced or eliminated cost sharing pursuant to the Departments' safe harbor outlined in FAQs Part 42, Q9 and Q14, only for the period in which a public health emergency or national emergency related to COVID-19 is in effect, the plan or coverage would not lose its grandfather status solely because these changes are later reversed (which could involve an elimination of all or substantially all benefits to diagnose or treat a particular condition or increases in cost-sharing requirements) and the terms of the plan or coverage that were in effect prior to the applicable emergency period are restored.

Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)

In general, in the case of a group health plan or health insurance issuer offering group or individual health insurance coverage that provides both medical/surgical benefits and mental health or substance use disorder (MH/SUD) benefits, MHPAEA requires that the financial requirements (such as coinsurance and copays) and quantitative treatment limits (such as visit limits) imposed on MH/SUD benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all medical/surgical benefits in a particular benefit classification.²³

A financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification if it applies to at least 2/3 of all medical/surgical benefits in the classification.²⁴ If it does not apply to at least 2/3 of medical/surgical benefits, it cannot be applied to MH/SUD benefits in that classification. If the financial requirement or quantitative treatment limitation applies to at least 2/3 of medical/surgical benefits, the level (such as 80% or 70% coinsurance) of the financial requirement or quantitative treatment limitation that may be applied to MH/SUD benefits in a classification may not be more restrictive than the predominant level that applies to medical/surgical benefits (defined as the level that applies to more than one half of

²³ The six classifications of benefits defined in final rules implementing MHPAEA are: (1) inpatient, in-network; (2) inpatient, out-of-network; (3) outpatient, in-network; (4) outpatient, out-of-network; (5) emergency care; and (6) prescription drugs. 26 CFR 54.9812-1(c)(2)(ii)(A)(1)-(6); 29 CFR 2590.712(c)(2)(ii)(A)(1)-(6); 45 CFR 146.136(c)(2)(ii)(A)(1)-(6) and 147.160.

²⁴ 26 CFR 54.9812-1(c)(3)(i)(A); 29 CFR 2590.712(c)(3)(i)(A); 45 CFR 146.136(c)(3)(i)(A) and 147.160.

medical/surgical benefits subject to the requirement or limitation in the classification).²⁵ In performing these calculations, the determination of the portion of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation is generally based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year. A plan or issuer is not required to perform the parity analysis each plan year unless there is a change in plan benefit design, cost-sharing structure, or utilization that would affect a financial requirement or quantitative treatment limitation within a classification (or sub-classification).²⁶

Q16. When performing the “substantially all” and “predominant” tests for financial requirements and quantitative treatment limitations under the MHPAEA regulations, may plans and issuers disregard benefits for items and services required to be covered without cost sharing under section 6001 of the FFCRA?

Yes. The coverage requirements of section 6001 of the FFCRA went into effect immediately upon enactment of the FFCRA and apply with respect to items and services furnished only while the public health emergency related to COVID-19 is in effect. In consideration of the temporary nature of these requirements, and given that plans and issuers were not able to anticipate these requirements when designing their plans and coverage, the Departments will temporarily exercise enforcement discretion under which the Departments will not take enforcement action against any plan or issuer that disregards benefits for the items and services that are covered without cost sharing under section 6001 of the FFCRA for purposes of the “substantially all” and “predominant” tests for financial requirements and quantitative treatment limitations.

HHS encourages states to adopt a similar approach with respect to health insurance issuers offering coverage in the group and individual markets. Under this temporary exercise of enforcement discretion, HHS also will not consider a state to have failed to substantially enforce MHPAEA and its implementing regulations insofar as the state adopts such an approach for plan years with respect to which section 6001 applies.

The Departments remain committed to enforcement of MHPAEA and will take action as appropriate to the extent violations occur that are not within this limited exercise of enforcement discretion.

Wellness Programs

Under PHS Act section 2705, ERISA section 702, Code section 9802, and the Departments’ implementing regulations, plans and issuers are generally prohibited from discriminating against participants, beneficiaries, and individuals in eligibility, benefits, or premiums based on a health

²⁵ 26 CFR 54.9812-1(c)(3)(i)(B); 29 CFR 2590.712(c)(3)(i)(B); 45 CFR 146.136(c)(3)(i)(B) and 147.160.

²⁶ 78 FR 68240, 68243 (Nov. 13, 2013).

factor.²⁷ With respect to group health plans, an exception to this general prohibition allows premium discounts, rebates, or modification of otherwise applicable cost-sharing requirements (including copayments, deductibles, or coinsurance) in return for adherence to certain programs of health promotion and disease prevention, commonly referred to as wellness programs.

On June 3, 2013, the Departments issued final regulations that address the requirements for wellness programs provided in connection with group health plans.²⁸ These regulations include certain requirements for “health-contingent wellness programs,” which are defined as any “program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward).” Among other requirements, a health-contingent wellness program must provide a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining any reward to individuals for whom it is unreasonably difficult due to a medical condition, or medically inadvisable, to satisfy the otherwise applicable standard.²⁹

Q17. May a plan or issuer waive a standard for obtaining a reward (including any reasonable alternative standard) under a health-contingent wellness program if participants or beneficiaries are facing difficulty in meeting the standard as a result of circumstances related to COVID-19?

Yes. Plans and issuers are permitted to waive a standard (including a reasonable alternative standard) for obtaining a reward under a health-contingent wellness program. However, to the extent the plan or issuer waives a wellness program standard as a result of the COVID-19 public health emergency, the waiver must be offered to all similarly situated individuals, as described in the implementing regulations.³⁰

²⁷ The Health Insurance Portability and Accountability Act of 1996 (HIPAA) nondiscrimination provisions and the implementing regulations published by the Departments on December 13, 2006 (the 2006 HIPAA regulations) set forth eight health status-related factors, which the 2006 HIPAA regulations refer to as “health factors” for simplicity. Under the statute and the regulations, the eight health factors are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), and disability. 71 FR 75014, 75030 (Dec. 13, 2006). In the Departments’ view, “[t]hese terms are largely overlapping and, in combination, include any factor related to an individual’s health.” 66 FR 1378, 1379 (Jan. 8, 2001).

²⁸ See 78 FR 33158 (Jun. 3, 2013). These regulations update the 2006 HIPAA regulations. The PPACA amended the statutory nondiscrimination and wellness provisions to in large part reflect the 2006 HIPAA regulations regarding wellness programs.

²⁹ 26 CFR 54.9802-1(f)(3)(iv) and (f)(4)(iv); 29 CFR 2590.702(f)(3)(iv) and (f)(4)(iv); 45 CFR 146.121(f)(3)(iv) and (f)(4)(iv).

³⁰ 26 CFR 54.9802-1(d); 29 CFR 2590.702(d); 46 CFR 146.121(d).

Individual Coverage Health Reimbursement Arrangements

Individual coverage health reimbursement arrangements are a new form of health reimbursement arrangement (HRA) that provide employers with an alternative to offering traditional group health plan coverage, subject to certain conditions. An individual coverage HRA reimburses employees for their medical expenses (and sometimes their family members' medical care expenses), up to a maximum dollar amount that the employer makes available each year. Employees must be enrolled in individual health insurance (or Medicare Parts A and B, or Part C) for each month the employee (or the employee's family member) is covered by the individual coverage HRA. The individual coverage HRA is required to provide employees with a notice, generally at least 90 days before the start of the plan year,³¹ that includes important information about requirements for individual coverage HRAs, the terms of the HRA, and certain consequences of accepting or not accepting the individual coverage HRA, among other information.³²

On April 28, 2020, DOL released EBSA Disaster Relief Notice 2020-01 (EBSA Notice 2020-01),³³ which extends the time for plan officials impacted by the COVID-19 outbreak to furnish certain notices and disclosures required by ERISA so long as they make a good faith effort to furnish the documents as soon as administratively practicable under the circumstances.³⁴ HHS concurred with that relief and is adopting a temporary policy of relaxed enforcement that is consistent with that relief with respect to non-Federal governmental plans, Small Business Health Options Programs (SHOPs), health insurance issuers offering coverage in connection with group health plans, and their participants and beneficiaries covered by these arrangements under applicable provisions of the PHS Act.³⁵

Under EBSA Notice 2020-01, an individual coverage HRA notice that would otherwise be required to be furnished between March 1, 2020, and 60 days after the announced end of the COVID-19 National Emergency, generally may be furnished as soon as administratively practicable under the circumstances. The question below addresses issues employers may want

³¹ For participants not eligible to participate at the beginning of the plan year (or not eligible when the notice is otherwise provided to plan participants), the notice must be provided by no later than the date on which the HRA may first take effect for the participant. 26 CFR 54.9802-4(c)(6)(i); 29 CFR 2590.702-2(c)(6)(i); 45 CFR 146.143(c)(6)(i).

³² A model notice can be found at <https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/rules-and-regulations/completed-rulemaking/1210-AB87/individual-coverage-model-notice.pdf> and <https://www.cms.gov/files/document/hra-model-notice.pdf>.

³³ See EBSA Disaster Relief Notice 2020-01 (Apr. 28, 2020), available at <https://www.dol.gov/agencies/ebsa/employers-and-advisers/plan-administration-and-compliance/disaster-relief/ebsa-disaster-relief-notice-2020-01>.

³⁴ The guidance specifies that good faith acts include use of electronic alternative means of communicating with plan participants and beneficiaries who the plan fiduciary reasonably believes have effective access to the electronic means of communication, including email, text messages, and continuous access websites.

³⁵ Centers for Medicare & Medicaid Services, Insurance Standards Bulletin Series – INFORMATION: Temporary Period of Relaxed Enforcement of Certain Timeframes Related to Group Market Requirements under the Public Health Service Act in Response to the COVID-19 Outbreak (May 14, 2020), available at <https://www.cms.gov/files/document/Temporary-Relaxed-Enforcement-Of-Group-Market-Timeframes.pdf>.

to consider if they are not able between March 1, 2020, and 60 days after the announced end of the COVID-19 national emergency to provide the notice 90 days in advance of the plan year or when otherwise required to provide such notice.

Q18. What are the potential consequences of delaying the individual coverage HRA notice to the extent permitted by EBSA Notice 2020-01?

Because individual coverage HRAs are different from traditional group health plans in many respects, the individual coverage HRA regulations require employers to provide employees with certain information to help employees understand what actions they must take to accept the offer of the individual coverage HRA, the potential effect that the offer of and enrollment in the individual coverage HRA might have on their eligibility for the premium tax credit, and the terms of the individual coverage HRA offer.

Requirement to Enroll in Individual Health Insurance Coverage (or Medicare). Individuals must be enrolled in individual health insurance coverage (or Medicare Parts A and B, or Part C) for each month during which they are covered by an individual coverage HRA.³⁶ Individuals cannot receive reimbursement from their individual coverage HRA for medical care expenses that were incurred during a month when they were not enrolled in such coverage, and must forfeit their individual coverage HRA if they are not enrolled in such coverage. Employers should ensure notices are provided with sufficient time to allow individuals to weigh their coverage options and enroll in individual health insurance coverage.

The individual coverage HRA notice provides individuals with important information about how to enroll in individual health insurance coverage through an open enrollment or special enrollment period for individuals who newly gain access to an individual coverage HRA.³⁷ An individual to whom this special enrollment period applies generally has 60 days before the first day on which coverage for the individual coverage HRA can take effect to select an individual health insurance plan.³⁸

Impact on Eligibility for the Premium Tax Credit. The offer or acceptance of an individual coverage HRA may have consequences for eligibility for the premium tax credit available to qualified individuals purchasing individual health insurance coverage offered through the Health Insurance Marketplaces.³⁹ The individual coverage HRA notice includes important information to help employees understand this. It also includes the information consumers need to present to a Marketplace when applying for advance payments of the premium tax credits, or to verify eligibility for a special enrollment period.

³⁶ 26 CFR 54.9802-4(c)(1)(i); 29 CFR 2590.702-2(c)(1)(i); 45 CFR 146.123(c)(1)(i).

³⁷ 45 CFR 155.420(d)(14). This special enrollment period also applies to individuals who are newly provided a qualified small employer health reimbursement arrangement (QSEHRA).

³⁸ 45 CFR 155.420(c)(3).

³⁹ 84 FR 28888, 28943 (Jun. 20, 2019).

The Departments recognize that some employers are considering offering an individual coverage HRA for the first time. The Departments encourage employers affected by the COVID-19 pandemic to consider whether they can provide the individual coverage HRA notice at least early enough in advance of the first day on which the individual coverage HRA may take effect so that eligible employees have sufficient time to read and understand the notice, make an informed decision whether or not to enroll in the individual coverage HRA, and exercise their special enrollment right to individual health insurance coverage so that the coverage would start no later than the first day of the individual coverage HRA plan year.