COMPLIANCE BULLETIN

Agency FAQs on Coronavirus-related Changes for Health Plans

The Departments of Labor, Health and Human Services and the Treasury (Departments) have provided answers to frequently asked questions (FAQs) regarding health coverage issues related to COVID-19, including implementation of the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief and Economic Security Act (CARES Act).

These new laws require health plans and issuers to cover certain items and services related to the diagnosis of COVID-19 without imposing any cost-sharing requirements (including deductibles, copayments and coinsurance) or prior authorization or other medical management requirements. According to the Departments' FAQs, health plans and issuers must provide notice of the changes to plan participants **as soon as reasonably practicable**.

According to the Departments, their approach to implementation of the new coronavirus-related requirements will focus on assisting (rather than penalizing) group health plans, health insurance issuers and others who are working diligently and in good faith to comply with the new requirements.

This Compliance Bulletin contains the Departments' FAQs.

Action Steps

Employers that sponsor group health plans should become familiar with the FFCRA's and CARES Act's changes for their health plans. The Departments' FAQs clarify that the Affordable Care Act's 60-day advance notice requirement does not apply to these changes. However, health plans and issuers must notify plan participants of the changes as soon as reasonably practicable.

Highlights

- The FFCRA and the CARES Act include a number of changes for health plans and health insurance issuers.
- Health plans and issuers must cover COVID-19 testing without any cost-sharing requirements.
- HDHPs may cover telehealth and other remote care services without a deductible.
- The Departments have issued FAQs on these coverage changes.

Important Dates

March 18, 2020

Health plans and issuers must cover COVID-19 testing without imposing any cost-sharing requirements.

March 27, 2020

HDHPs can cover telehealth or other remote care services without a deductible.

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Overview of New Laws

The FFCRA

The FFCRA was enacted on March 18, 2020. 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 diagnostic testing for the detection of SARS-CoV-2 or the diagnosis of COVID-19 (referred to collectively as COVID-19) when those items or services are furnished on or after March 18, 2020, and during the applicable emergency period. Under the FFCRA, plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments and coinsurance) or prior authorization or other medical management requirements.

The CARES Act

The CARES Act was enacted on March 27, 2020. 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 or prior authorization or other medical management requirements.

Additionally, section 3202 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.)

State Laws

As discussed in Q9 below, nothing in the FFCRA or the CARES Act prevents a state from imposing additional standards or requirements on health insurance issuers 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.

FAQs

Q1. Which types of group health plans and health insurance coverage are subject to section 6001 of the FFCRA, as amended by section 3201 of the CARES Act?

Section 6001 of the FFCRA, as amended by section 3201 of the CARES Act, applies to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in section 1251(e) of the Patient Protection and Affordable Care Act).

The term “group health plan” includes both insured and self-insured group health plans. It includes private employment-based group health plans (ERISA plans), non-federal governmental plans (such as plans sponsored by states and local governments) and church plans.

“Individual health insurance coverage” includes coverage offered in the individual market through or outside of an Exchange, as well as student health insurance coverage (as defined in 45 CFR 147.145).

Section 6001 does not apply to short-term, limited-duration insurance (as defined in 26 CFR 54.9801-2, 29 CFR 2590.701-2, and 45 CFR 144.103), or to a plan or coverage in relation to its provision of excepted benefits (as defined in 26 CFR 54.9831-1(c), 29 CFR 2590.732(c), and 45 CFR 146.145(b) and 148.220). It also does not apply to group health

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plans that do not cover at least two employees who are current employees (such as plans in which only retirees participate).

Definitions

The terms "group health plan," "health insurance issuer," "group health insurance coverage," and "individual health insurance coverage" have the meanings given such terms in section 2791 of the PHS Act, section 733 of ERISA and section 9832 of the federal tax code, as applicable. Group and individual health insurance coverage includes certain non-grandfathered health insurance coverage in the individual and small group markets subject to an HHS non-enforcement policy (also known as "grandmothered" or "transitional" plans).

Compliance with section 6001 of the FFCRA, as amended by section 3201 of the CARES Act, will not cause a plan or coverage to cease to be a grandfathered health plan, provided that no other changes are made that would cause a loss of grandfather status under 26 CFR 54.9815-1251(g), 29 CFR 2590.715-1251(g), and 45 CFR 147.140(g), as applicable.

Q2. When are plans and issuers required to comply with section 6001 of the FFCRA and for how long?

Plans and issuers are required to comply with section 6001 of the FFCRA as of **March 18, 2020**, the date of enactment of the FFCRA. This means that, beginning March 18, 2020, plans and issuers must provide coverage for the items and services described in section 6001(a) of the FFCRA and Q3 below that were furnished on or after March 18, 2020, and must not impose any cost-sharing requirements, prior authorization, or other medical management requirements with respect to those items and services.

Plans and issuers must continue to comply with section 6001 of the FFCRA for applicable items and services furnished during the public health emergency related to COVID-19.

Q3. What items and services must plans and issuers provide benefits for under section 6001 of the FFCRA?

Section 6001(a) of the FFCRA, as amended by section 3201 of the CARES Act, requires plans and issuers to provide coverage for the following items and services:

1. An in vitro diagnostic test as defined in section 809.3 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, 360bbb3);
    b. The developer has requested, or intends to request, emergency use authorization 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

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d. Other tests that the Secretary of HHS determines appropriate in guidance.

2. Items and services furnished to an individual during healthcare provider office visits (which includes 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 described in paragraph (1), but only to the extent 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 such product.

Q4. Do "in vitro diagnostic tests" described in section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act, include serological tests for COVID-19?

Yes. Serological tests for COVID-19 are used to detect antibodies against the SARS-CoV-2 virus, and are intended for use in the diagnosis of the disease or condition of having current or past infection with SARS-CoV-2, the virus which causes COVID-19. The Food and Drug Administration (FDA) currently believes such tests should not be used as the sole basis for diagnosis. The FDA has advised the Departments that serological tests for COVID-19 meet the definition of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19.14 Therefore, plans and issuers must provide coverage for a serological test for COVID-19 that otherwise meets the requirements of section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act.

Q5. The FFCRA requires plans and issuers to cover items and services provided during a visit that "relate to the furnishing or administration" of COVID-19 diagnostic testing or that relate "to the evaluation of such individual for purposes of determining the need" for diagnostic testing. What types of items and services must be covered pursuant to this requirement?

Plans and issuers must cover items and services furnished to an individual during visits that result in an order for, or administration of, a COVID-19 diagnostic test, but only to the extent that the items or services relate to the furnishing or administration of the test or to the evaluation of such individual for purposes of determining the need of the individual for the product, as determined by the individual's attending healthcare provider.

The Centers for Disease Control and Prevention (CDC) advises that clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. In addition, the CDC strongly encourages clinicians to test for other causes of respiratory illness. Therefore, for example, if the individual's attending provider determines that other tests (for example, influenza tests, blood tests, etc.) should be performed during a visit (which term here includes in-person visits and telehealth visits) to determine the need of such individual for COVID-19 diagnostic testing, and the visit results in an order for, or administration of, COVID-19 diagnostic testing, the plan or issuer must provide coverage for the related tests under section 6001(a) of the FFCRA. This coverage must be provided without cost sharing, when medically appropriate for the individual, as determined by the individual's attending healthcare provider in accordance with accepted standards of current medical practice. This coverage must also be provided without imposing prior authorization or other medical management requirements.

Q6. May a plan or issuer impose any cost-sharing requirements, prior authorization requirements or medical management requirements for benefits that must be provided under section 6001(a) of the FFCRA, as amended by section 3201 of the CARES Act?

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No. Section 6001(a) of the FFCRA provides that plans and issuers shall not impose any cost-sharing requirements (including deductibles, copayments and coinsurance), prior authorization requirements or other medical management requirements for these items and services. These items and services must be covered without cost sharing when medically appropriate for the individual, as determined by the individual's attending healthcare provider in accordance with accepted standards of current medical practice.

Q7. Are plans and issuers required to provide coverage for items and services that are furnished by providers that have not agreed to accept a negotiated rate as payment in full (that is, out-of-network providers)?

Yes. Section 3202(a) of the CARES Act provides that a plan or issuer providing coverage of items and services described in section 6001(a) of the FFCRA shall reimburse the provider of the diagnostic testing as follows:

1. If the plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the PHS Act, such negotiated rate shall apply throughout the period of such declaration.

2. If the plan or issuer does not have a negotiated rate with such provider, 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 public internet website, or the plan or issuer may negotiate a rate with the provider for less than such cash price.

Section 3202(b) of the CARES Act also 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. Section 3202(b) of the CARES Act also grants the Secretary of HHS authority to impose civil monetary penalties on any provider that does not comply with this requirement and has not completed a corrective action plan, in an amount not to exceed $300 per day that the violation is ongoing.

Q8. Section 6001(a)(2) of the FFCRA requires plans and issuers to provide benefits for certain items and services that are furnished during healthcare provider office visits, which include in-person and telehealth visits, as well as visits to urgent care centers and emergency rooms. Under what circumstances are items or services considered to be furnished during a visit?

The Departments construe the term "visit" in section 6001(a)(2) of the FFCRA broadly to include both traditional and non-traditional care settings in which a COVID-19 diagnostic test described in section 6001(a)(1) of the FFCRA is ordered or administered, including COVID-19 drive-through screening and testing sites where licensed healthcare providers are administering COVID-19 diagnostic testing. Therefore, the items and services described in section 6001(a) of the FFCRA, as amended by section 3201 of the CARES Act, must be covered when furnished in non-traditional settings, as well as when provided in traditional settings.

Q9. In light of the COVID-19 public health emergency, will the Departments 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?

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Yes. 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 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 to enrollees not later than 60 days prior to the date on which the modification will become effective. However, to help facilitate the nation's response to COVID-19, the Departments will not take enforcement action against any plan or issuer that makes such modification to provide greater coverage related to the diagnosis and/or treatment of COVID-19, without providing at least 60 days advance notice. **Plans and issuers must provide notice of the changes as soon as reasonably practicable**. Plans and issuers may either provide an updated SBC reflecting the modification or provide a separate notice describing the material modifications.

HHS encourages states to take a similar approach and will not consider a state to have failed to substantially enforce section 2715(d)(4) of the PHS Act if it takes such an approach.

Additionally, issuers are generally not permitted to modify the health insurance coverage for a product mid-year under section 2703 of the PHS Act and 45 CFR 147.106, subject to certain exceptions. However, HHS will not take enforcement action against any health insurance issuer that changes the benefits or cost-sharing structure of its plans mid-year to provide increased coverage for services related to the diagnosis and/or treatment of COVID-19. HHS encourages states to take a similar approach, and will not consider a state to have failed to substantially enforce section 2703 of the PHS Act if it takes such an approach.

These non-enforcement policies will apply with respect to changes made during the period during 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. Although enforcement relief is being provided during this period for the advance notice requirements of section 2715(d)(4) of the PHS Act, to the extent a plan or issuer maintains any such changes beyond the emergency period, plans and issuers must comply with all other applicable requirements to update plan documents or terms of coverage.

The Departments would continue to take enforcement action against any health insurance issuer or plan that attempts to limit or eliminate other benefits, or to increase cost sharing, to offset the costs of increasing the generosity of benefits related to the diagnosis and/or treatment of COVID19.

Q10. May states impose additional requirements on health insurance issuers to respond to the COVID-19 public health emergency?

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

Excepted Benefits

Sections 2722 and 2763 of the PHS Act, section 732 of ERISA and section 9831 of the Code provide that the respective requirements of title XXVII of the PHS Act, part 7 of ERISA and Chapter 100 of the Code generally do not apply to the provision of certain types of benefits, known as "excepted benefits." Excepted benefits are described in section 2791(c)

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of the PHS Act, section 733(c) of ERISA and section 9832(c) of the Code. The parallel statutory provisions establish four categories of excepted benefits, of which only the first and second are relevant here.

The first category, under section 2791(c)(1) of the PHS Act, section 733(c)(1) of ERISA and section 9832(c)(1) of the Code, includes benefits that are generally not health coverage, including on-site medical clinics. The benefits in this category are excepted in all circumstances.

The second category of excepted benefits is limited excepted benefits, which may include limited scope vision or dental benefits, and benefits for long-term care, nursing home care, home healthcare or community-based care. The benefits in this category are excepted only if certain conditions are met. Section 2791(c)(2)(C) of the PHS Act, section 733(c)(2)(C) of ERISA and section 9832(c)(2)(C) of the Code authorize the Secretaries of HHS, Labor and the Treasury (collectively, the Secretaries) to issue regulations establishing other, similar limited benefits as excepted benefits. The Secretaries exercised this authority previously with respect to certain employee assistance programs (EAPs). Under the Departments' final regulations, EAPs are excepted if they satisfy all of the following requirements:

1. The EAP does not provide significant benefits in the nature of medical care. For this purpose, the amount, scope and duration of covered services are taken into account.
2. The benefits under the EAP are not coordinated with benefits under another group health plan:
    a. Participants in the other group health plan must not be required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the other group health plan; and
    b. Participant eligibility for benefits under the EAP must not be dependent on participation in another group health plan.
    c. No employee premiums or contributions are required as a condition of participation in the EAP.
    d. There is no cost sharing under the EAP.

Q11. May an employer offer benefits for diagnosis and testing for COVID-19 under an EAP that constitute an excepted benefit?

Yes. The Departments' final regulations provide that for the purpose of determining whether an EAP provides benefits that are significant in the nature of medical care, the amount, scope and duration of covered services are taken into account. An EAP will not be considered to provide benefits that are significant in the nature of medical care solely because it offers benefits for diagnosis and testing for COVID-19 while 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.

Q12. May an employer offer benefits for diagnosis and testing for COVID-19 at an on-site medical clinic that constitute an excepted benefit?

Yes. Coverage of on-site medical clinics is an excepted benefit in all circumstances.

Telehealth and Other Remote Care Services

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Q13. How can plans and issuers use telehealth and other remote care services to mitigate the impact of the COVID-19 public health emergency?

The widespread availability and use of telehealth and other remote care services are vital to combat the COVID-19 public health emergency. By using these services, patients are able to seek treatment from a healthcare professional in their home, without having to go to a medical office or hospital, helping minimize the risk of exposure to and community spread of COVID-19.

The Departments recognize that many plans and issuers are currently offering benefits for telehealth and/or other remote care services in some form. Many states have encouraged issuers to cover robust telehealth and other remote care services without cost sharing, and many plans and issuers have taken steps to promote the use of these services by providing expanded access to them without cost sharing. The Departments strongly encourage all plans and issuers to promote the use of telehealth and other remote care services, including by notifying consumers of their availability, by ensuring access to a robust suite of telehealth and other remote care services, including mental health and substance use disorder services, and by covering telehealth and other remote care services without cost sharing or other medical management requirements.

Section 3701 of the CARES Act amends the laws applicable to high deductible health plans (HDHPs) and Health Savings Accounts (HSAs) to provide flexibility with respect to telehealth and other remote care services. Specifically, section 3701 of the CARES Act amends section 223(c) of the Code to provide a temporary safe harbor for providing coverage for telehealth and other remote care services. As added by section 3701 of the CARES Act, section 223(c)(2)(E) of the Code allows HSA-eligible HDHPs to cover telehealth and other remote care services without a deductible or with a deductible below the minimum annual deductible otherwise required by section 223(c)(2)(A) of the Code. Section 3701 also amends section 223(c)(1)(B)(ii) of the Code to include telehealth and other remote care services as categories of coverage that are disregarded for purposes of determining whether an individual who has other health plan coverage in addition to an HDHP is an eligible individual who may make tax-favored contributions to his or her HSA under section 223 of the Code. Thus, an otherwise eligible individual with coverage under an HDHP may also receive coverage for telehealth and other remote care services outside the HDHP and before satisfying the deductible of the HDHP and still contribute to an HSA. The amendments to section 223 of the Code under section 3701 of the CARES Act are effective March 27, 2020, and apply to plan years beginning on or before December 31, 2021.

The Departments expect that the flexibilities provided through the amended provisions under section 223 of the Code will increase healthcare access for patients who may have signs or symptoms compatible with COVID-19 and protect other individuals from potential exposure. However, the Departments note that the amendments to section 223 of the Code apply generally to coverage for healthcare provided through telehealth and other remote care services and are not limited to coverage for COVID-19-related telehealth and other remote care services.

The Departments also encourage states to support efforts to increase access to telehealth and other remote care services. In particular, the Departments urge states to consider whether state licensing laws could be relaxed 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, 50 U.S.C. section, 1601 *et seq*., related to COVID-19 is in effect, to enable more in-state and out-of-state providers to offer telehealth and other remote care services in the state.

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Q14. In light of the public health emergency posed by COVID-19, will the Departments allow plans and issuers to add benefits, or reduce or eliminate cost sharing, for telehealth and other remote care services prior to satisfying any applicable notice of modification requirements and without regard to restrictions on mid-year changes to provide coverage for telehealth services?

Yes. The Departments will apply the same non-enforcement policies described in Q8 to situations where a plan or issuer adds benefits, or reduces or eliminates cost sharing, for telehealth and other remote care services. These non-enforcement policies will apply with respect to changes made for the period during 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**. Plans and issuers must provide notice of the changes as soon as reasonably practicable**. Although enforcement relief is being provided for the advance notice requirements of section 2715(d)(4) of the PHS Act, to the extent a plan or issuer maintains any such changes beyond the emergency period, plans and issuers must comply with all other applicable requirements to update plan documents or terms of coverage.

The Departments would continue to take enforcement action against any health insurance issuer or plan that attempts to limit or eliminate other benefits, or to increase cost sharing, to offset the costs of increasing the generosity of benefits related to the diagnosis and/or treatment of COVID19.

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