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BLOG

Departments Issue Further Guidance Under FFCRA and CARES Act Affecting Health Plans

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The Departments of Labor (DOL), Health and Human Services (HHS), and Treasury (collectively, the Departments) recently issued additional FAQ guidance regarding implementation of the health coverage provisions under the Families First Coronavirus Response Act (the FFCRA) and 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 build on previously issued FAQ guidance and shed light on a number of outstanding issues for employers, health insurance issuers, and other stakeholders.

Background

The FFCRA, as amended by the CARES Act, 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 or diagnosis of COVID-19 without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements (COVID-19 Coverage Requirements).

Specifically, the FFCRA, as amended by the CARES Act, requires plans and issuers to provide coverage for the following items and services:

- in vitro diagnostic testing (meeting certain criteria, see below) for the detection of SARS-CoV-2 or the diagnosis of COVID-19, and the administration of such testing; and
- items and services furnished to an individual during health care provider office visits (including in-person 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 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).

Group health plans and health insurance issuers are required to reimburse a provider of COVID-19 diagnostic testing in an amount that equals the negotiated rate with that provider or, if the plan or issuer does not have a negotiated rate with the provider (*i.e.*, an out-of-network provider), the cash price for such service listed by the

provider on a public website. (The plan or issuer may negotiate a rate with the provider that is lower than the listed cash price).

Plans and issuers may not impose any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization requirements, or other medical management requirements for these items and services, and they must be covered without cost-sharing when medically appropriate for the individual, as determined by the individual's attending health care provider in accordance with accepted standards of current medical practice.

The FAQs clarify the following with respect to COVID-19 Coverage Requirements and other health care issues:

Coverage of Diagnostic Testing

- The FFCRA, as amended by the CARES Act, requires coverage for certain in vitro diagnostic tests approved, cleared, or authorized under the Federal Food, Drug, and Cosmetic Act, as well as tests for which the developer has requested, or intends to request, emergency use authorization. States and territories may authorize laboratories within that state or territory to develop and perform a COVID-19 test. The FAQs announce that all in vitro diagnostic tests for COVID-19 that have received a Food and Drug Administration (FDA) emergency use authorization are listed on the emergency use authorization (EUA) page of the FDA website. Lists 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, as well as states and territories that have notified FDA that they may authorize laboratories to develop and perform COVID-19 tests, are also available through the FDA's COVID-19 testing FAQs page. The Departments advise that if a clinical laboratory or commercial manufacturer is listed, it is reasonable to assume that the laboratory or manufacturer has requested or intended to request an authorization, and therefore, plans and issuers must cover listed diagnostic tests. However, a plan or insurer may take reasonable steps to verify that a test offered by a developer meets the statutory criteria for tests for which emergency use authorization has been requested but not yet approved, such as to request a copy of the EUA request or pre-EUA submitted to FDA without violating the FFCRA's prohibition on medical management requirements. The FAQs also clarify that.
- COVID-19 tests intended for at-home testing (including tests where the individual performs self-collection of a specimen at home), when ordered by an attending health care provider who has determined that the test is medically appropriate, generally must be covered at no cost and without prior authorization or other medical management requirements.
- COVID-19 testing that is conducted to screen for general workplace health and safety (such as employee "return-to-work" programs), for public health surveillance for SARS-CoV-2 (the virus that causes COVID-19), or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition, is not required to be covered under the COVID-19 Coverage Requirements.
- Group health plans and issuers are required to cover multiple COVID-19 tests an individual receives, provided each test is diagnostic and medically appropriate for the individual, as determined by an attending health care provider. The FAQs encourage health care providers to consult guidance issued by the Center for Disease Control, as well as any other applicable health department, state, tribal, territorial, or professional societies, when determining whether COVID-19 testing is appropriate.
- Group health plans and health insurance issuers must cover a facility fee (a fee for the use of facilities or equipment an individual's provider does not own or that are owned by a hospital), but only to the extent that the facility fee is assessed in relation to items or services required to be covered under the COVID-19 Coverage Requirements.
- For purpose of the COVID-19 Coverage Requirements, the FAQs clarify that a health care provider need not be "directly" responsible for providing care to the patient to be considered an "attending health care 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.
- Individuals who have concerns about a private-sector group health plan's compliance with these COVID-19 Coverage Requirements should contact the DOL.

Winston Takeaways: *The FAQs clarify and further expand the types of items and services related to the diagnosis and testing for COVID-19 that must be covered with no cost-sharing, prior authorization, or medical management criteria, and rely on the health care clinician's medical judgment, whether he or she is directly or indirectly responsible for providing care to the patient, to determine whether COVID-19 testing is appropriate.*

If an attending health care provider orders a number of services, in determining whether a COVID-19 diagnostic test is appropriate (such as diagnostic test panels for influenza A and B and respiratory syncytial virus and x-rays), 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. Many hospitals and care networks require preoperative/preadmission COVID-19 testing in advance of scheduled surgeries and procedures. Reports of large numbers of positive COVID-19 tests for patients entering the emergency room for car accident injuries and other urgent conditions indicates that COVID-19 tests are being ordered for patients who may not be complaining of symptoms. Under the current guidance, it is unclear whether diagnostic tests performed in these types situations are subject to the COVID-19 Coverage Requirements.

Out-of-Network Coverage and Negotiated Rates

- Providers are generally prohibited from balance billing for COVID-19 diagnostic testing. However, the COVID-19 Coverage Requirements do not preclude balance billing for other items and services which may be furnished during the same visit, although such balance billing may be prohibited by applicable state law and other applicable contractual agreements.
- The FAQs clarify that the CARES Act does not address the reimbursement rates for items or services other than diagnostic testing for COVID-19. Accordingly, a plan or issuer can apply its out-of-network reimbursement rates for other out-of-network items and services furnished in connection with the COVID-19 testing.
- For tests administered in an out-of-network hospital emergency department, the CARES Act supersedes the Affordable Care Act (ACA) regulatory requirement to pay the greatest of three amounts, requiring the plan or issuer to reimburse out-of-network emergency providers an amount that equals the cash price listed by the provider on a public website, or a negotiated lower rate. For all other out-of-network emergency services, the ACA payment standards continue to apply.
- Group health plans and health insurance issuers that do not already have a negotiated rate with a provider may nevertheless seek to negotiate to determine a rate with a provider of COVID-19 diagnostic testing, and state laws governing reimbursements may apply.

Winston Takeaway: *The FAQs caution that the COVID-19 Coverage Requirements generally preclude balance billing for mandated diagnostic testing. However, a plan or issuer can apply its out-of-network reimbursement rates for other out-of-network items and services furnished in connection with the COVID-19 testing. Plans and issuers will need to reimburse out-of-network providers for COVID-19 diagnostic testing the cash price listed by the provider on a public website, or a negotiated rate, rather than a greater amount that the ACA may require. The FAQs do not provide any further guidance as to determining the amount to be reimbursed for COVID-19 testing where the provider has not made public the cash price for a test and the plan or issuer and provider cannot agree upon a rate. The Departments note that the Secretary of HHS has authority to impose civil monetary penalties of up to $300 per day 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.*

Relief of SBC Notice and Individual Coverage HRA Notice Requirements

- In previous FAQ guidance, the Departments announced temporary relief to allow 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 without providing the minimum 60-day advance notice to enrollees required for material modifications to the Summary of Benefits and Coverage (SBC). These FAQs add that if a plan or issuer reverses these changes once the COVID-19 public health emergency or national emergency declaration ends, the Departments will consider the plan or issuer to have satisfied its obligation to

provide advance notice, if it notified participants, beneficiaries, and enrollees of the general duration of the additional benefits coverage or reduced cost-sharing (such as by reference to the duration of the public health emergency declaration) within a reasonable time in advance of the reversal of the changes.

- An individual coverage health reimbursement arrangement (HRA) is required to provide employees with a notice, generally at least 90 days before the start of the plan year, that includes important information about the individual coverage HRA, terms of the HRA, and certain consequences of enrollment, among other information. Under the DOL's Employee Benefits Security Administration 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.

Recognizing that some employers are considering offering individual coverage HRAs 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.

Winston Takeaway: *The FAQs confirm that group health plan sponsors will not be penalized for failing to provide advance notice if the sponsor reverses the additional benefit changes made in response to COVID-19 after the COVID-19 public health emergency ends, as long as the sponsor provided previous notice of the duration of the additional benefits coverage within a reasonable time in advance of the reversal of the changes. For example, a plan that previously announced greater coverage or reduced cost-sharing for COVID-19 testing or treatment for the duration of the COVID-19 public health emergency will meet this requirement for relief. HHS Secretary Azar previously extended the public health emergency declaration until July 25, 2020, and may further extend the public health emergency declaration for subsequent 90-day periods (and may terminate the declaration whenever he determines that the public health emergency has ceased to exist).*

The FAQs encourage employers to consider providing the individual coverage HRA notice as far in advance as the first day on which the individual coverage HRA may take effect, so that eligible employees can make an informed decision about enrollment, 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.

Enforcement Relief of Telehealth and Remote Care Services and the Mental Parity Act

- While an employer program that provides medical care, such as telehealth, will generally be considered a group health plan subject to federal requirements, the FAQs clarify that group health plans (and health insurance coverage offered in connection with a group health plan) that solely provide benefits for telehealth or other remote-care services are exempt from certain ACA group market requirements (*e.g.*, the prohibition on annual and lifetime limits) and mandates (*e.g.*, preventative services mandate), for the duration of any plan year beginning before the end of the COVID-19 public health emergency. This relief is limited to telehealth and other remote-care service arrangements sponsored by a large employer (as defined under the ACA) and offered only to employees or dependents who are not eligible for coverage under any other group health plan offered by that employer (*e.g.*, to part-time employees who do not satisfy eligibility requirements for the employer's group medical plan). Other federal law requirements and mandates continue to apply, such as the prohibitions of pre-existing condition exclusions and discrimination based on health status, the prohibition of rescissions, and the requirements of parity in mental health or substance use disorder benefits.
- The Departments will temporarily provide enforcement relief for any plan or issuer that disregards benefits for items and services that are covered without cost-sharing under the COVID-19 Coverage Requirements for purposes of compliance with the "substantially all" and "predominant" tests for financial requirements and quantitative treatment limitations under the Mental Health Parity and Addiction Equity Act.

Winston Takeaway: *While the FAQs provide temporary relief from the ACA group health plan mandates for programs that provide telehealth and other remote care services to employees not otherwise covered by the employer's group health plan, such programs may still be considered ERISA plans that are subject to COBRA and would have to comply with general ERISA requirements, including plan document, summary plan description, and*

Form 5500 annual reporting requirements. In addition, the guidance does not address whether such arrangements qualify as ACA excepted benefits. Further clarification would be welcomed.

Grandfathered Health Plan Status

To the extent that a group health plan or health insurance issuer added benefits or reduced or eliminated cost-sharing pursuant to the agencies' safe harbor in previous FAQ guidance, only for the period in which the COVID-19 public health emergency is in effect, the plan will not lose its grandfathered status solely because these changes are later reversed and the terms of the plan or coverage that were in effect prior to the start of the COVID-19 public health emergency are restored.

Wellness Program Waivers

Due to the inability of participants to access on-site screenings and general well-being appointments with providers during the COVID-19 public health emergency, the FAQs provide that a group health plan or health insurance issuer may waive a standard (including a reasonable alternative standard) for obtaining a reward under a health-contingent wellness program if participants or beneficiaries are having difficulty meeting the standard because of circumstances related to COVID-19. However, the waiver must be offered to all similarly situated individuals, as described in the ACA wellness regulations.

Winston Takeaway: *While not required, the FAQs confirm that a group health plan or health insurance issuer may 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. We anticipate guidance shortly from the EEOC regarding its wellness rules.*

Please contact a member of the Winston & Strawn Employee Benefits and Executive Compensation Practice Group for further information.

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