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FYI®
For Your Information®

Volume 43

Issue 37

July 1, 2020

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Additional guidance on COVID-19 diagnostic testing coverage mandate

The Departments of Labor, Health & Human Services, and the Treasury recently issued a new set of FAQs that provide guidance to group health plan sponsors on various questions related to implementation of the COVID-19 diagnostic testing mandate.

Background

On March 18, 2020, the president signed the Families First Coronavirus Response Act (FFCRA), which included a requirement that group health plans and other entities cover COVID-19 diagnostic testing and related items and services without cost-sharing, prior authorization, or other medical management requirements ("coverage mandate"). (See our March 19, 2020 *FYI Alert*.) The following week, he signed the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which expands the COVID-19 diagnostic testing mandate provisions. (See our March 31, 2020 *FYI Alert*.)

On April 11, 2020, the Departments of Labor, Health & Human Services, and the Treasury (the departments) issued a set of FAQs that provided guidance to group health plan sponsors on implementation of the COVID-19 diagnostic testing coverage mandate. (See our April 15, 2020 *FYI Alert*.) At that time, the departments indicated that they would release additional guidance.

Departments' FAQs

On June 23, 2020, the departments issued an additional set of FAQs to supplement the earlier guidance. Most of the FAQs seem to reflect questions raised by group health plan sponsors and insurers. The FAQs address the following.

Scope of COVID-19 diagnostic testing coverage mandate

The first seven FAQs address issues related to the scope of the coverage mandate.

Are self-insured group health plans subject to the coverage mandate? Most group health plans, including self-insured group health plans, are subject to the mandate. This includes grandfathered plans under the Affordable Care Act (ACA), non-federal governmental plans, and church plans. The mandate does not apply to retiree-only plans or plans that only provide excepted benefits, such as dental and vision plans.

How can a plan determine which COVID-19 tests are required to be covered without cost-sharing? In addition to tests that determine whether an individual has the virus based on the presence of COVID-19 virus genetic material in the body, a group health plan must also cover serological testing to detect COVID-19 antibodies. All tests must be either: (1) authorized by the Food and Drug Administration (FDA), (2) under review by the FDA, (3) developed and authorized by a state, or (4) determined appropriate by the Secretary of Health & Human Services.

The FAQ provides links to the FDA website that plan sponsors may use to obtain information on tests that satisfy these criteria. The guidance also states that a plan may request that a laboratory or commercial manufacturer provide documentation to demonstrate that it has requested or intends to request an emergency use authorization from the FDA. These requests will not be considered to violate the prohibition on medical management requirements as long as they are reasonable and necessary to verify that a COVID-19 test meets the statutory criteria.

Are plans required to cover COVID-19 tests intended for at-home testing without cost-sharing? COVID-19 tests intended for at-home use (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 it otherwise meets the criteria described above.

Who is an "attending health provider" for purposes of the coverage mandate? Generally, the coverage mandate only applies to items and services "when medically appropriate for the individual, as determined by the individual's attending health care provider." In the new FAQ, the departments clarify that an attending provider for purposes of the coverage mandate is an individual who is: (1) licensed or otherwise authorized under applicable law, (2) acting within the scope of his or her license or authorization, and (3) responsible for providing care to the patient. The guidance notes that a health care provider does not have to be directly responsible for providing care to the patient to be considered an attending provider — what is key is that the provider makes an individualized clinical assessment to determine whether the test is medically appropriate for the individual in accordance with current accepted medical practice standards. The guidance also reiterates that a plan, issuer, hospital, or managed care organization is not an attending provider.

Is COVID-19 testing for surveillance or employment purposes subject to the coverage mandate? The FAQ states that testing conducted to screen for general workplace health and safety (such as employee "return to work" programs), for public health surveillance, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 is not subject to the coverage mandate. The FAQ reiterates that clinical decisions about testing must be made by the individual's attending health care provider and may include testing of individuals with signs or symptoms compatible with COVID-19.

Can an employer require antibody testing as a condition for re-entering the workplace?

No. In guidance issued on June 17, the EEOC clarified that employers cannot require employees to undergo antibody or serology testing as a condition of re-entering the workplace. (See our **June 24, 2020** *FYI*.)

Are plans required to cover multiple COVID-19 diagnostic tests for the same individual as well as other applicable items and services? The FAQ states that there is no limit to the number of diagnostic tests subject to the coverage mandate. Thus, a plan may be required to cover multiple tests for the same individual if 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.

Is a facility fee charged for a visit that results in an order for or administration of a COVID-19 diagnostic test subject to the coverage mandate? A facility fee that 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 must be covered at 100% without cost-sharing, prior authorization, or other medical management requirements.

Provider reimbursements

The CARES Act sets out specific rules for determining the amount that a health provider must be reimbursed for providing COVID-19 diagnostic testing and related services subject to the coverage mandate. Basically, the CARES Act provides that a plan must pay the provider either the provider's negotiated rate for those services or an amount that equals the cash price for such service that is listed by the provider on a public website. The FAQs discuss several issues related to how these provider reimbursement rules are applied.

Do the CARES Act reimbursement requirements apply to any items and services other than diagnostic testing for COVID-19? The FAQ confirms that the CARES Act rules only apply for determining the amount a plan or issuer must reimburse a provider for COVID-19 testing and related services subject to the coverage mandate, not to any other items and services.

Can plan participants be balanced billed for COVID-19 diagnostic tests related services subject to the coverage mandate? The FAQ states that the CARES Act reimbursement rules generally preclude balance billing for COVID-19 testing and services subject to the coverage mandate. It notes, however, that the CARES Act does not preclude balance billing for items and

services not subject to the rules, although balance billing may be prohibited by applicable state law and other applicable contractual agreements.

How do the CARES Act reimbursement rules interact with state balance billing laws for charges by providers that do not have a negotiated rate with a plan or issuer for COVID-19 tests? The FAQ notes that if a plan or issuer does not have a negotiated rate with a provider for COVID-19 diagnostic testing, it must reimburse the provider in an amount that equals the cash price for such service as listed by the provider on its "public internet website," or it may negotiate a rate with the provider that is lower than the cash price. The guidance states that the rate negotiation may be subject to state balance billing laws that establish dispute resolution processes for issuers and providers to determine reimbursement rates for certain items and services. It also notes that to the extent state law does not prevent the application of the CARES Act requirements, the state law is not preempted and continues to apply.

How should plans 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 posted the cash price of the test on a public internet website? If the provider has not posted a cash price on its website and the plan does not have a negotiated rate with the provider, the plan may try to negotiate a rate with the provider for the test. However, the FAQ notes that the CARES Act is silent with respect to the amount to be reimbursed for COVID-19 testing where the provider has not made the cash price for a test public and the plan and the provider cannot agree on a rate that the provider will accept as payment in full. It also notes that 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 would continue to apply.

What if a provider does not publicly post the cash price for the COVID-19 diagnostic test on its website?

The FAQ notes that HHS has the authority to impose a penalty of up to $300 per day on any provider of a COVID-19 diagnostic test that does not comply with the requirement to publicly post the cash price for such a test on its website.

How do the CARES Act reimbursement requirements interact with the ACA emergency room coverage mandate if an individual receives COVID-19 diagnostic testing at an out-of-network emergency room? The ACA prohibits non-grandfathered group health plans from imposing copayment amounts or coinsurance rates on out-of-network emergency services that are greater than those imposed for in-network emergency services. Regulations under the ACA also prescribe the method for determining the provider rates to which the cost-sharing is applied. Under these rules, a plan satisfies the cost-sharing limitations for out-of-network emergency services if it applies these rates to an amount that is at least equal to the greatest of the following: (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.

The FAQ states that because the CARES Act reimbursement requirements preclude an individual from being balance-billed for COVID-19 testing subject to the coverage mandate, the CARES Act rules for determining provider rates supersede the ACA rules described above for COVID-19 diagnostic tests that are out-of-network emergency services. However, for all other out-of-network emergency services not subject to the CARES Act reimbursement requirements, the minimum payment standards under the ACA apply.

Issues related to reversal of COVID-19 benefits at end of emergency period

Under the ACA, if a mid-year material modification is made to any of the terms of a plan or coverage that would affect the content of the most recently provided Summary of Benefits and Coverage (SBC), the plan must provide notice of the modification no later than 60 days prior to the date on which the modification will become effective. In the previous COVID-19 FAQ, the departments announced that they temporarily would not enforce this advance notice requirement 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.

Will a plan have to provide 60 days' advance notice if it reverses these changes once the COVID-19 public health emergency period expires? The FAQ states that the departments will consider a plan to have satisfied its obligation to provide advance notice of a material modification to information included in the most recently issued SBC if the plan had previously notified affected individuals of the general duration of the additional benefits coverage or reduced cost-sharing (e.g., that the increased coverage applies only during the COVID-19 public health emergency) or notifies the affected individuals 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.

> **Buck comment**. Under ERISA, if changes are made to a group health plan that would be considered by a participant to be a material reduction in benefits (e.g., an increase in participant cost-sharing or the elimination of a benefit), a summary of material modifications (SMM) must be provided no more than 60 days after the adoption of the change or modification. Although the FAQ does not address the ERISA requirement, a footnote points out that the time for providing an SMM would be affected by the relief applicable for providing required notices under ERISA. (See our May 7, 2020 *FYI*.)

Will a grandfathered plan that added benefits or reduced cost-sharing in connection with COVID-19 lose its grandfather status solely because it later reverses these changes when the COVID-19 emergency period expires? The FAQ states that if a plan added benefits or reduced or eliminated cost-sharing only for the period in which a public health emergency or national emergency related to COVID-19 is in effect, it will not lose its grandfather status solely because these changes are later reversed if the terms of the plan in effect prior to the applicable emergency period are restored.

> **Buck comment.** Any reversal would be subject to the notice requirements described above.

Other issues

The FAQs also address other discrete issues on telehealth services, mental health parity, wellness programs, and individual coverage health reimbursement arrangements.

May a large employer offer coverage only for telehealth and other remote care services to employees not eligible for any other group health plan offered by the employer? Generally, an employer-sponsored program that provides medical care to employees or their dependents is a group health plan subject to the ACA and other federal mandates. However, the FAQ states that, for the duration of any plan year beginning before the end of the public health emergency related to COVID-19, the departments will not require a group health plan that only provides telehealth and other remote care services to employees or their dependents who are otherwise ineligible for the employer's group health plan coverage to satisfy most of the ACA market reforms and other requirements set out in part 7 of ERISA, title XXVII of the Public Health Service Act (PHS), and chapter 100 of the Internal Revenue Code. The plan is still required to satisfy the following:

- The prohibition of pre-existing condition exclusions or other discrimination based on health status
- The prohibition of discrimination against individual participants and beneficiaries based on health status
- The prohibition of rescissions
- The requirement that a plan provide parity in mental health or substance use disorder benefits

This relief is limited to plans or programs sponsored by a large employer as defined under the ACA, i.e., an employer that has at least 50 full-time or full-time equivalent employees on the last day of the prior calendar year.

What requirements are included in part 7 of ERISA, title XXVII of the PHS Act, and chapter 100 of the Internal Revenue Code?

In addition to the ACA market reform, the requirements include:

- HIPAA portability and nondiscrimination rules
- Standards relating to hospital stays for mothers and newborns
- Parity in mental health and substance use disorder benefits
- Mandated coverage of post-mastectomy reconstructive surgery

May plans disregard benefits for COVID-19 diagnostic testing required to be covered without cost-sharing when testing for parity in financial requirements and quantitative treatment limitations under the Mental Health Parity and Addiction Equity Act? The FAQ states that the departments will temporarily exercise enforcement discretion under which they will not take enforcement action against any plan that disregards benefits for the items and services that are covered without cost-sharing under the coverage mandate for purposes of the "substantially all" and "predominant" tests for financial requirements and quantitative treatment limitations.

May a plan waive a standard for obtaining a reward (including any reasonable alternative standard) under a health-contingent wellness program if individuals are facing difficulty in meeting the standard due to circumstances related to COVID-19? The FAQ confirms that plans

may waive a standard (including a reasonable alternative standard) for obtaining a reward under a health-contingent wellness program, provided the waiver is offered to all similarly situated individuals.

What are the potential consequences of delaying the individual coverage health reimbursement arrangement (ICHRA) notice to employees? Generally, an ICHRA notice must be provided to employees at least 90 days before the beginning of the applicable plan year. However, earlier guidance provides that an individual coverage HRA notice, otherwise 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 FAQ urges employers to consider whether they can provide a timely ICHRA notice. It notes that the ICHRA notice includes important information to help employees understand how accepting an ICHRA may impact their eligibility for the premium tax credit if they purchase coverage offered through the Health Insurance Marketplaces and is also useful to employees for other purposes, such as verifying eligibility for a special enrollment period in the Marketplace.

In closing

The FAQs provide important guidance for employers on practical issues related to the COVID-19 diagnostic testing requirements and how it may affect their benefit programs.

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