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Authors
Richard Stover, FSA, MAAA
Leslye Laderman, JD, LLM

Guidance issued on COVID-19 diagnostic testing and vaccine requirements

The Departments of Labor, Health & Human Services, and the Treasury recently issued a new set of FAQs that provide additional guidance to group health plan sponsors on various questions related to coverage of COVID-19 diagnostic testing and vaccines. Of particular note, the guidance allows employers to offer benefits for COVID-19 vaccinations through an EAP or onsite medical clinic without affecting their status as excepted benefits.

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 expanded the COVID-19 diagnostic testing mandate provisions. (See our March 31, 2020 *FYI Alert*.)

On April 11, 2020, and June 23, 2020, the Departments of Labor, Health & Human Services, and the Treasury (the departments) issued 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* and our July 1, 2020 *FYI*.)

HOLD THE DATE: COVID relief legislation webinar

On March 30 at 1:00 p.m. ET, Buck's team of compliance experts will explore the impact of the latest and most far-reaching COVID legislation.

Departments' FAQs

On February 26, 2021, the departments issued an additional set of FAQs and a press release to supplement earlier guidance on coverage of COVID-19 diagnostic testing and preventive services, including vaccinations.

The FAQs address the following items.

COVID-19 diagnostic testing

The FFCRA included a requirement that group health plans, including grandfathered plans, cover COVID-19 diagnostic testing with no cost-sharing both in-network and out-of-network. The CARES Act expanded those requirements. (See our March 31, 2020 *FYI Alert*.) This requirement applies during the public health emergency that was first effective for 90 days starting on January 31, 2020 and has been extended several times. On January 22, 2021, Acting HHS Secretary Norris Cochran announced that HHS had determined that the public health emergency will likely remain in place through the end of 2021. HHS will provide a 60 day notice when a decision is made to terminate the public health emergency or let it expire.

Can plans use medical screening criteria to deny or impose cost-sharing on a claim for COVID-19 diagnostic testing for an asymptomatic person with no known or suspected exposure to COVID-19?
No. A plan cannot require the presence of symptoms or a recent known or suspected exposure.

Can plans distinguish between COVID-19 diagnostic testing of asymptomatic people that must be covered and testing for general workplace health and safety, for public health surveillance, or for other purposes not primarily intended for individualized diagnosis or treatment of COVID-19?
Yes. While plans are required to cover diagnostic testing where the purpose of the testing is for individualized diagnosis or treatment of COVID-19, they are not required to provide coverage of testing for public health surveillance or employment purposes. However, there is no prohibition or limitation on plans providing this coverage.

Are plans required to cover COVID-19 diagnostic tests provided through state or locally administered testing site?
Yes.

Are plans required to cover point-of-care tests for COVID-19 without cost-sharing?
Yes.

What items and services associated with COVID-19 diagnostic testing are plans required to cover?
Plans must "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."

What should plans do if they identify providers who are not complying with the CARES Act requirements related to cash price posting, or who are otherwise acting in bad faith?
Plans can give participants information about providers who have negotiated rates for testing with the plan as well as other providers who adhere to best practice standards. Plans can also report violations to COVID19CashPrice@cms.hhs.gov.

Expedited coverage of preventive services for coronavirus

The CARES Act requires non-grandfathered health plans to cover, without cost-sharing, any qualifying coronavirus preventive service both in-network and out-of-network. (See our *FYI* from December 9, 2020.) This includes any item, service, or immunization that is intended to prevent or mitigate COVID-19 and that is:

- An evidence-based item or service that has a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF), or
- An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

Currently three COVID-19 vaccines have received recommendations from the ACIP — the Pfizer-BioNTech, Moderna, and Johnson & Johnson vaccines.

Do plans have to cover all COVID-19 vaccines with a recommendation in effect from ACIP?
Yes. Coverage must be provided with no cost-sharing. Plans are not permitted to exclude coverage for any qualifying coronavirus preventive service.

When must plans begin providing coverage for qualifying coronavirus preventive services?
Qualifying coronavirus preventive services must be covered, without cost-sharing, no later than 15 business days after the date that the USPSTF or ACIP make a recommendation.

Do plans have to cover the administration fee when the plan is not billed for the vaccine?
Yes, it's true regardless of how the administration fee is billed and regardless of whether the vaccine requires multiple doses. This includes covering the cost of the administration of a vaccine where a third party, such as the federal government, pays for the vaccine.

The CDC and ACIP have made recommendations regarding the categories of individuals to prioritize for COVID-19 vaccination during the initial phases of the vaccination program while the vaccine supply is limited. Can a plan deny coverage of the vaccine because the participant is not in a category recommended for early vaccination?

No. Plans must provide coverage based on the recommendations of ACIP, regardless of prioritization.

Enforcement of notice requirements

Will the departments take enforcement action when a plan covers qualifying preventive services before it satisfies the summary of benefits and coverage (SBC) notice of modification requirements?
No. The departments will not take enforcement action against any plan that does not provide at least 60 days' advance notice of a material modification regarding the addition of coverage for qualifying coronavirus preventive services. However, plans must provide any required notice of changes as soon as reasonably practical.

> **Buck comment**. Employers should include information about enhanced COVID-related coverage in plan SBCs. For example, while diagnostic testing is usually subject to cost-sharing, diagnostic testing for COVID-19 must be covered without cost-sharing both in-network and out-of-network. Similarly, while non-grandfathered plans are only required to cover ACA preventive services without cost-sharing in-network, they must also cover COVID-19 vaccines without cost-sharing out-of-network.

Coverage of COVID-19 vaccines under an EAP or onsite medical clinic

May an employer offer benefits for COVID-19 vaccines (and their administration) under an EAP that constitutes an excepted benefit?
Yes.

May an employer offer benefits for COVID-19 vaccines (and their administration) at an onsite medical clinic that constitutes an excepted benefit?
Yes.

> **Buck comment.** Prior guidance clarified that an employer could offer benefits for diagnosis and testing for COVID-19 under an EAP or at an onsite medical clinic without affecting its status as an excepted benefit. (See our April 15, 2020 *FYI Alert*.) As vaccine supplies become available, the ability for employers to also offer vaccines under an EAP or onsite clinic will help them encourage the vaccination of all employees, regardless of benefit enrollment or eligibility.

In closing

These FAQs provide important new guidance for plan sponsors on coverage of COVID-19 diagnostic testing and vaccinations, as employers continue to implement strategies to address the pandemic.

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