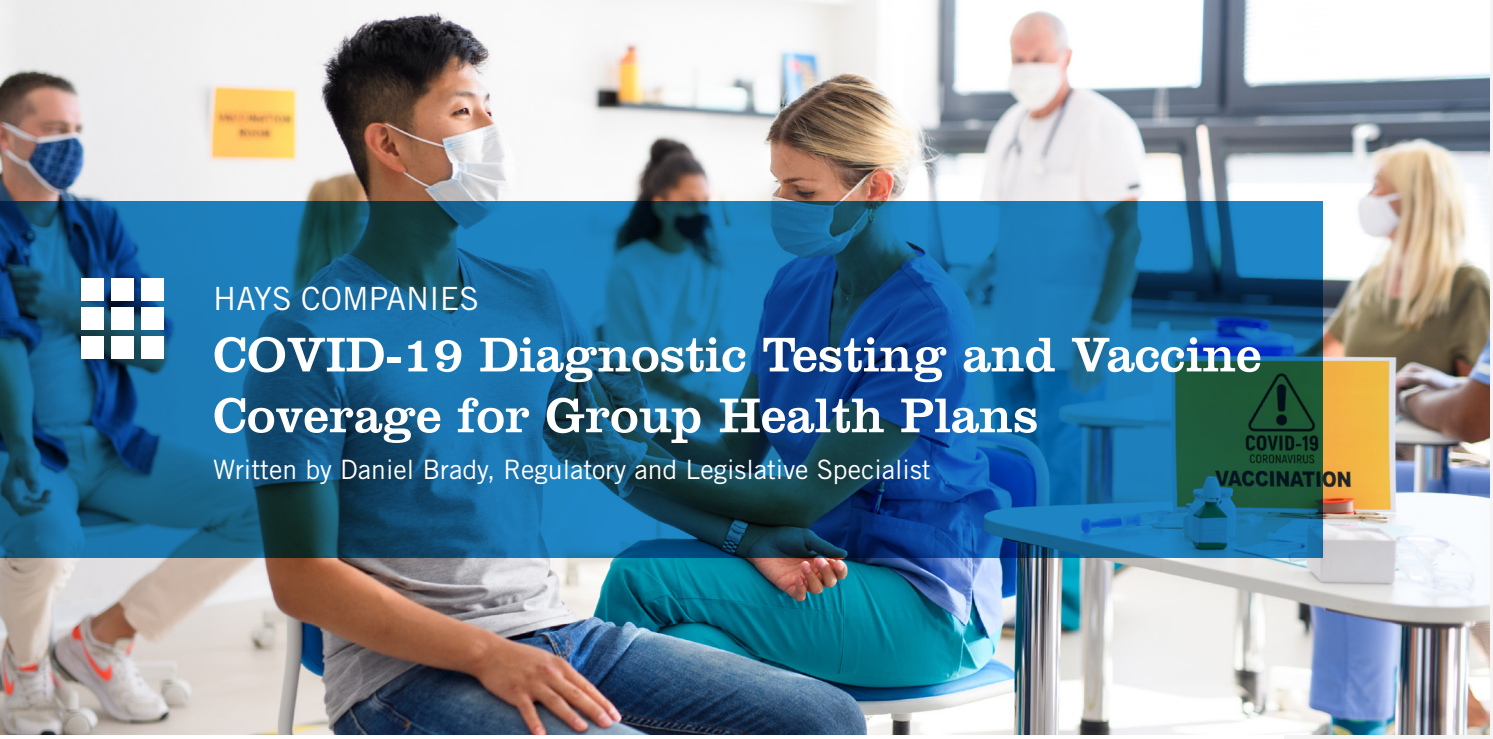

HAYS COMPANIES

COVID-19 Diagnostic Testing and Vaccine Coverage for Group Health Plans

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On February 26, 2021, the Departments of Labor, Health and Human Services (HHS) and the Treasury (collectively, the Departments) issued a new set of FAQs addressing the obligations of health plans and issuers to provide benefits for certain COVID-19 related-services. FAQ Part 44 further expands upon and clarifies recent guidance issued by the Departments regarding requirements under the Families First Coronavirus Response Act (FFCRA) and Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

The following outline is intended to highlight the Department's guidance for employers offering group health plans with respect to:

1. Coverage of items and services related to diagnostic testing for COVID-19, and
2. Coverage of qualifying coronavirus preventive services, including recommended COVID-19 vaccines.

Diagnostic Testing

Use of medical screening criteria for asymptomatic individuals

- The FAQ clarifies prior guidance in FAQ Part 43, stating that health plans and issuers may not use medical screening criteria to deny or impose cost-sharing for COVID-19 testing on individuals even when the individual has no known or suspected exposure to COVID-19 or is asymptomatic.
- Health plans must assume when an individual seeks diagnostic testing from a licensed health care provider or is referred by a licensed provider for testing, they are seeking "individualized clinical assessment," and the test should be covered without cost-sharing.

Diagnostic testing for individualized diagnosis or treatment vs. general workplace health and safety

- If the purpose of the testing is for individualized diagnosis or treatment, health plans may not impose cost-sharing.
- Plans and issuers may, but are not required to, provide coverage for testing if the purpose is for public health surveillance or employment purposes (e.g., employee "return to work" programs).

  i. Health plans are encouraged to provide communication clarifying for what purposes COVID-19 testing will be covered. Plans may develop programs to detect and address fraud related to testing purposes so long as those programs are consistent with the FFCRA.

Diagnostic testing provided through state – or locality – administered testing sites

- The guidance clarifies that a licensed or authorized health care provider includes state- or locality-administered testing sites so long as the sites act within the scope of their license or authorization.
- Examples of state- or locality-administered sites include drive-through sites or other sites that do not require appointments.

Point-of-care tests

- Point-of-care and other tests meeting one of the criteria in the FFCRA must be covered without cost-sharing, prior authorization, or medical management. This includes testing for asymptomatic individuals.

Coverage for items and services associated with diagnostic testing

- The guidance does not provide additional information beyond what is included in section 6001(a)(2) of the FFCRA, which 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 the evaluation of the individual for purposes of determining the need of the individual for that product."
- To maintain compliance, the FAQ states health plans and issuers should maintain claims processing systems in ways that protect participants and beneficiaries. It is recommended they document these efforts.

Providers not complying with cash pricing requirements of CARES Act

- Health plans must provide coverage for COVID-19 testing based on the negotiated rate or if the plan 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 FAQ says plan sponsors can encourage participants to use in-network providers to avoid situations in which participants receive testing from out-of-network providers charging unreasonably high prices for testing. However, the FAQs do not provide an exception to the coverage requirement for situations in which a provider charges unreasonably high prices for testing (i.e., the plan must pay the price listed on the provider's website).
- If health plans and issuers identify providers of diagnostic testing who are not in compliance with the cash price posting requirements under section 3202(b) of the CARES Act or are otherwise acting in bad faith, they should report those violations to COVID19CashPrice@cms.hhs.gov.

Rapid Coverage of Preventive Services – COVID-19 Vaccines

Non-grandfathered group health plans and issuers offering non-grandfathered group or individual health insurance coverage are required to cover, without cost-sharing, qualifying coronavirus preventive services. Section 2713(a) of the PHS Act defines "qualifying coronavirus preventive services" as an item, service, or immunization intended to prevent or mitigate COVID-19 and that is, with respect to the individual involved:

1. An evidence-based item or service that has in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF); or
2. 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) (regardless of whether the immunization is recommended for routine use).

What vaccines must be covered?

- Plans and issuers must cover all COVID-19 vaccines with a recommendation in effect from the Advisory Committee on Immunization Practices (ACIP), making them a qualifying coronavirus preventive service.

When must plans begin providing coverage for preventive services?

- Plans and issuers must cover qualifying coronavirus preventive services without cost-sharing starting no later than 15 business days (not including weekends or holidays) after a recommendation for the qualifying coronavirus preventive service is made.
- At the time the FAQ was released, the ACIP recommended vaccines included the Pfizer BioNTech COVID-19 vaccine (must be covered effective 1/5/21) and the Moderna COVID-19 vaccine (must be covered effective 1/12/21).
- **Note:** The ACIP recommended the Johnson & Johnson COVID-19 vaccine on 2/28/21 after the FAQ was published. Plans will be required to cover that vaccine no later than 15 business days after that date.

Coverage of vaccine administration fees when plan or issuer is not billed for the vaccine

- Plans and issuers must provide coverage of administration fees without cost-sharing regardless of how the fee is billed or whether the preventive immunization requires multiple doses, including instances where the immunization is paid for by a third-party such as the Federal Government.

Coverage of individuals outside of recommended vaccination category

- Plans and issuers may not deny coverage of a COVID-19 vaccine to a participant or beneficiary because the individual is not in a specified category recommended for early vaccination. Coverage must be provided without cost-sharing in accordance with the vaccine-specific recommendations of ACIP and CDC, regardless of priority.
- Plans and issuers should not communicate to participants and beneficiaries that coverage is limited only to those recommended for early vaccination under state, local, or CDC recommendations. They may, however, communicate to participants and beneficiaries about which individuals would be vaccinated first when supplies are limited.
- A provider's decision to decline to vaccinate an individual based on the individual's prioritization category will not be considered an adverse benefit determination made by a group health plan or issuer and is not subject to the internal claims and appeals review process under ERISA.

SBC Notice Requirements

- Plans and issuers must provide notice of material modifications to enrollees not later than 60 days prior to the date on which a material modification will become effective. This is the standard rule applicable in all cases unless the Departments provide specific relief as they have done so here.
  - A material modification (as defined under section 102 of ERISA) is a modification to the terms of the plan or coverage affecting the content of the summary of benefits and coverage (SBC) that is not included in the most recently provided SBC, and that occurs with a renewal or reissuance of coverage.

Enforcement Relief

- Temporary enforcement relief was provided to plans and issuers who added benefits or reduced or eliminated cost-sharing for the diagnosis and treatment of COVID-19 or for telehealth and other remote care services and who failed to meet the 60-day advance notice requirement so long as notice was provided as soon as reasonably practicable. The relief applies during the public health emergency for COVID-19 or national emergency declaration period.

Expected Benefits

Employee Assistance Programs (EAPs)

- Plans and issuers may offer benefits for COVID-19 vaccines and their administration under an EAP that constitutes an excepted benefit so long as there is no cost-sharing and the EAP complies with other applicable requirements.
- The guidance notes that an EAP will not jeopardize its status as an excepted benefit solely because it offers benefits for COVID-19 vaccines and their administration (including when offered in combination with benefits for diagnosis and testing for COVID-19).

On-Site Medical Clinics

- An employer may offer benefits for COVID-19 vaccines and administration at an on-site medical clinic that constitutes an excepted benefit.

The Hays Research and Compliance team will continue to monitor the situation and provide updates as they are received.

Please be advised that any and all information, comments, analysis, and/or recommendations set forth above relative to the possible impact of COVID-19 on potential insurance coverage or other policy implications are intended solely for informational purposes and should not be relied upon as legal or medical advice. As an insurance broker, we have no authority to make coverage decisions as that ability rests solely with the issuing carrier. Therefore, all claims should be submitted to the carrier for evaluation. The positions expressed herein are opinions only and are not to be construed as any form of guarantee or warranty. Finally, given the extremely dynamic and rapidly evolving COVID-19 situation, comments above do not take into account any applicable pending or future legislation introduced with the intent to override, alter or amend current policy language.

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