Agencies issue new FAQs on COVID-19 testing, vaccines

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In this article

In FAQs Part 44 and Part 50 on COVID-19 testing and vaccines, the departments of Labor (DOL), Health and Human Services (HHS), and Treasury provide information on the requirement for group health plans to cover these items and related services without cost sharing (including deductibles, copayments and coinsurance). While breaking little new ground, FAQs Part 44 clarify that plans cannot require enrollees to have COVID-19 symptoms or recent exposure to receive coverage of virus testing without cost sharing. The guidance also provides more information on the coverage requirement for COVID vaccines and opportunities for plans to provide the vaccine as an excepted benefit. Updates to this GRIST reflect guidance in FAQs Part 50, which clarifies that group health plans must cover without cost sharing any new COVID-19 vaccines or amended vaccine recommendations (for example an additional dose for certain individuals, booster shots, or expansion to younger populations) immediately after adoption by the Centers for Disease Control and Prevention (CDC), rather than 15 days later.

Coverage of COVID-19 testing

Pandemic relief enacted in 2020 (Pub. L. Nos. 116-127 and 116-136) requires all group health plans, including grandfathered plans, to cover COVID-19 testing and related services at no cost to plan participants during the public health emergency. The public health emergency, currently set to expire on Oct. 17, is renewed in 90-day increments by the HHS secretary. HHS has indicated informally that the public health emergency will likely continue through all of 2021.

In April 2020, the departments issued FAQs (Part 42) interpreting the COVID-19 testing coverage provisions for group health plans and issuers. The guidance explained what items related to COVID-19 testing plans must cover, how the mandated coverage extends to out-of-network providers, how testing

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can be covered as an excepted benefit, and what temporary telehealth flexibilities apply during the public health emergency. FAQs (Part 43) issued in June 2020 provided additional clarification about testing coverage and reimbursement requirements. (For discussion of these earlier sets of FAQs, see the Mercer Law and Policy resources at the end of this article.)

FAQs Part 44 underscore that the COVID testing mandate applies regardless of a plan's medical-screening criteria or the test location. The agencies also urge plans to safeguard enrollees from inappropriate cost sharing or abusive billing practices.

Plans can't use medical-screening criteria to deny a claim for COVID-19 testing (Q1 & Q2)

The law requires plans to cover COVID-19 testing without cost sharing, prior authorization or other medical-management requirements. An earlier FAQ (Q5 for FAQ Part 43) clarified that plans must cover COVID-19 testing for diagnostic purposes only. That FAQ also stated that the attending healthcare provider should conduct an individualized clinical assessment to decide about the medical appropriateness of testing someone with COVID-19 symptoms or exposure.

Scope of COVID-19 diagnostic testing clarified. FAQs Part 44 clarify that plans can't limit coverage of diagnostic testing without cost sharing to individuals who have COVID-19 symptoms or a known or suspected exposure to the disease. Plans *must assume* that a COVID-19 test received from a licensed or authorized provider demonstrates that an "individualized clinical assessment" took place and must cover the test without cost sharing. According to the guidance, only state and local public health authorities — not group health plans or insurers — can direct providers to limit eligibility for COVID-19 testing for groups to manage testing access and supplies.

Coverage of COVID-19 testing for workplace health & safety still not required. Like earlier guidance, FAQs Part 44 distinguish between individual diagnostic testing and general testing for public health surveillance or employment purposes. Although plans don't have to cover testing for public health or employment purposes, the guidance adds that nothing prevents a plan from voluntarily covering this kind of testing. The agencies encourage plans to clearly communicate when testing is covered.

Plans must cover COVID-19 testing, regardless of where received (Q3 & Q4)

FAQs Part 44 reiterate earlier guidance that when a licensed or authorized provider conducts a COVID-19 test, plans must assume an individualized clinical assessment occurred and cover the test without cost sharing. This hold true whether the test is provided at a state or local government site, a drive-through site, another site that doesn't require appointments, or the point of care. Presumably, the point of care refers to a doctor's office or any other health provider's location where a person receives care in addition to the testing.

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Plans should protect participants from inappropriate cost sharing (Q5)

The law also bans cost sharing for items and services provided during a visit that results in an order for or administration of a COVID-19 test. For the cost-sharing ban to apply, the item or service must relate to the "furnishing or administration" of the test or the "evaluation" of an individual's need for the test. This statutory language leaves some room for interpretation. Agency FAQs have provided some specifics, but questions remain.

Feedback sought to address inappropriate cost sharing. In FAQs Part 44, the agencies invite feedback on steps plans can take to protect participants from inappropriate cost sharing for related services. Plans are advised to maintain claim-processing and information-technology systems designed to protect enrollees from having to pay cost sharing when prohibited by the law. The agencies did not provide specific best practices in this area but will take enforcement action when appropriate.

Agencies encourage plans to communicate and report (Q6)

The Part 44 guidance addresses protecting participants and beneficiaries from price gouging and other abusive billing practices associated with COVID-19 testing. While saying that most providers have priced COVID tests at reasonable levels, the agencies are seeking feedback on how best to monitor abusive practices, such as out-of-network providers that may improperly balance-bill participants and beneficiaries for COVID tests. Regulators invite input on ways to encourage enrollees to use test providers that are not overcharging. The agencies recommend two steps to guard against abusive billing:

- **Steer to in-network providers.** Plans should provide information to participants and beneficiaries about providers that have negotiated rates with the plan or meet best-practice standards.

- **Report to HHS.** If a plan had a negotiated rate with a diagnostic test provider in effect before the public health emergency, the provider must receive that rate for the COVID-19 testing throughout the emergency. If a plan has no prenegotiated rate with the test provider (referred to as an out-of-network provider in an earlier FAQ), the plan must reimburse the "cash price for such service" listed on the provider's public website or negotiate a lesser price. The law requires all testing providers to post the cash price for a COVID-19 diagnostic test or risk a civil penalty of up to $300 per day. The guidance provides an email address (COVID19CashPrice@cms.hhs.gov) where plans and issuers can identify providers that are violating this posting requirement.

Coverage of COVID-19 vaccines

The 2020 pandemic relief also requires coverage of COVID-19 vaccines (and other COVID-19 preventive items and services) without cost sharing. Unlike the testing mandate, the vaccine coverage mandate has no expiration date. An interim final rule published in November 2020 addressed the

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COVID-19 preventive-services coverage requirement. (For discussion of the rule and related vaccine considerations, see Mercer Law and Policy resources at the end of this article.)

The law requires nongrandfathered group health plans and issuers to cover COVID-19 vaccines and other preventive services without cost sharing on an expedited time frame. COVID-19 preventive services must be covered without cost sharing beginning just 15 business days after a recommendation is in effect from the CDC's Advisory Committee on Immunization Practices (ACIP) or an "A" or "B" recommendation from US Preventive Services Task Force (USPSTF). In contrast, the Affordable Care Act (ACA) requires coverage of other new preventive services without cost sharing by the first plan year starting on or after one year from the end of the month when USPSTF or ACIP made the recommendation.

FAQs Part 44 reiterate portions of the November 2020 regulation and apply some of the earlier interpretive guidance on testing to COVID-19 vaccinations. FAQs Part 50 clarify that new COVID-19 vaccines and their administration costs must be covered without cost sharing immediately upon authorization. Coverage must be consistent with the scope of the authorization, including any amendments regarding an additional dose for certain individuals, booster shots or expansion to younger populations.

Plans must expedite coverage of *all* COVID-19 vaccines (FAQs Part 44 Q7–Q8 and Part 50 Q1–Q2)

FAQs Part 44 restates the provisions in the November 2020 regulation: Plans must cover all COVID-19 vaccines and associated administration costs without cost sharing within 15 business days (not including weekends and holidays) after the USPSTF or ACIP recommendation takes effect. An ACIP recommendation is considered "in effect" after the CDC director has adopted it. Plans can't exclude any vaccine that has met the criteria set out in the law.

Effective date clarification. As FAQs Part 50 notes, on Dec. 12, 2020, ACIP recommended and the CDC adopted "the use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine." According to the guidance, this adoption took effect for group health plans on Jan. 5, 2021, and means that any COVID-19 vaccine recommendation adopted by the CDC must be covered immediately (not 15 business days later). Earlier guidance detailing the effective date to cover a specific vaccine is superseded (i.e., FAQs Part 44 Q8, in part). The departments intend to enforce the immediate coverage requirement going forward. Employers that previously did not immediately cover a newly authorized vaccine will not face enforcement action, but should confirm immediate coverage for any new COVID-19 vaccines or amended vaccine recommendations.

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Vaccine coverage. To date, the CDC has adopted ACIP recommendations for three vaccines:

- The Pfizer vaccine for people age 16 and older, adopted on Dec. 12, 2020; expanded to adolescents age 12 and older adopted on May 12, 2021; amended to include booster shots for people aged 65 and older and other high-risk populations, adopted Sept. 24, 2021
- The Moderna vaccine for people age 18 and older, adopted on Dec. 20, 2020
- The Johnson & Johnson vaccine for people age 18 and older, adopted on Feb. 28, 2021

As of the date of this updated GRIST, Moderna and Johnson & Johnson have requested approval for booster shots, and Pfizer has requested approval for use with children ages 5 to 12. Each application is expected to be authorized by the end of October. Group health plans are required to provide cost-free coverage immediately upon the CDC's adoption.

Plans must cover the vaccine administration fee (Q9)

Plans must cover both the vaccine and its administration, regardless of how the vaccine is billed and whether multiple doses are required. Like the November 2020 regulation, this FAQ in Part 44 state that even when a third party (such as the federal government) covers the cost of vaccine itself, plans must cover the administration fee without cost sharing.

Plans can't deny coverage based on timing of vaccine receipt (Q10)

Although states and localities have set out prioritization categories for who gets the vaccine, plans must cover the vaccine for individuals receiving it, even if they received the vaccine earlier than their locality recommends. On the other hand, a healthcare provider's refusal to give the vaccine to someone who is not in a priority category is not an adverse benefit determination subject to appeal or external review.

Advance-notice safe harbor reiterated, expanded (Q11)

Plans usually must provide an updated summary of benefits and coverage (SBC) reflecting any change to prior SBC content at least 60 days *before* the change will take effect. In an earlier FAQ, the agencies acknowledged that this requirement was impractical for the COVID-19 testing mandate and created safe harbor: A plan that communicated the mandated COVID-19 coverage terms as soon as possible — via an updated SBC or a separate communication — would not face enforcement action for failing to provide 60 days' advance notice of the change. In FAQs Part 44, the agencies apply the same safe harbor for required coverage for COVID-19 vaccines.

Employer EAPs and onsite clinics can offer COVID-19 vaccines (Q13)

FAQs from last year provided some flexibility for plans to offer COVID-19 testing as an excepted benefit. FAQs Part 44 apply the same standards to COVID-19 vaccines.

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Coverage through an excepted-benefit EAP. Under current regulations, employee assistance programs (EAPs) are excepted benefits if they do not provide "significant benefits in the nature of medical care" and meet certain other criteria. The agencies won't consider an EAP to provide significant benefits solely because it offers COVID-19 vaccines (and COVID-19 testing and diagnosis). This means an EAP can provide the vaccines if it does not charge any cost sharing and meets the other excepted-benefit criteria. Earlier guidance limited COVID-19 testing through an excepted-benefit EAP to the public health emergency. Part 44 guidance on providing COVID-19 vaccines through an excepted-benefit EAP does not appear to be limited to the public health emergency. Clarification of this point would be helpful.

Permanent coverage through an on-site medical clinic. Employer-sponsored on-site medical clinics are excepted benefits in all circumstances, according to earlier guidance. Care at the clinic does not have to satisfy other criteria required for excepted-benefit EAPs. Employers can provide COVID-19 vaccines, testing and even treatment through an on-site clinic to all employees — regardless of health plan enrollment — without the clinic having to meet all of the ERISA or ACA rules for group health plans.

Employer issues

Compliance standards for plans concerning COVID testing and vaccines are evolving as the public health and national emergencies continue. In light of the FAQs, employers sponsoring group health plans should pay attention to several items:

- **Check coverage of COVID testing.** Confirm with third-party administrators (TPAs) or insurers that coverage of COVID-19 testing continues without cost sharing. Insurers and TPAs also should have a consistent and clear process to evaluate claims and audit instances when plan participants have been balance-billed for COVID-19 testing and related items and services. Check that employees are accessing COVID-19 testing either from in-network providers or else from out-of-network providers that are charging a reasonable price for the test. Since agencies are prepared to enforce these requirements, ensure the plan documents all compliance activities. Keep in mind that group health plans do not have to cover COVID-19 testing without cost sharing if the testing isn't done for diagnostic purposes but instead is part of general workplace or public health screening. Employees covered by a health plan could still get tested on their own without cost sharing on an ongoing basis.

- **Make sure to cover all future COVID-19 vaccines and amended recommendations immediately after CDC adoption.** Do the same due diligence with TPAs and insurers to confirm COVID-19 vaccine coverage without cost sharing. How — or whether — the group health plan processes a COVID-19 vaccine claim for a participant or beneficiary may differ depending on where the vaccine is administered, such as a state- or locality-administered site for priority groups or at a healthcare or other facility with essential workers. In some cases, an individual could receive a vaccine for free from a provider that does not bill any charges to health coverage. While a safe harbor waives advance notice of SBC changes to cover the vaccines, plans must still provide a notice about vaccine coverage as soon as possible if they have not already done so.

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- **Consider options for uninsured employees.** FAQs Part 44 (Q14) includes information about available sources of federal funding to reimburse providers for COVID-19-related services provided to the uninsured. To obtain reimbursement for these services, providers must agree not to balance-bill patients. Consider encouraging uninsured employees to seek testing and vaccination from these providers or to take advantage of the extended open enrollment and special enrollment opportunities in the federal and most state health insurance marketplaces.

- **Monitor for more guidance.** Continue to assess and implement mechanisms to encourage employees to obtain the vaccine. Watch to see if agencies issue any guidance limiting employer options in this area. Some employers that can access the vaccine directly from the government or manufacturers may want to offer the vaccines directly to employees as an excepted benefit.

- **Continue to communicate with employees.** As the situation evolves, continue to communicate with employees — even those working remotely or not covered by the group health plan — about how to access COVID testing and vaccines. This will go a long way toward getting back to normal.

Related resources

Non-Mercer resources

- COVID-19 ACIP vaccine recommendations (CDC)

- FAQs about Affordable Care Act implementation Part 50, Health Insurance Portability and Accountability Act, and Coronavirus Aid, Relief, and Economic Security Act implementation (DOL/HHS/Treasury, Oct. 4, 2021)

- How CDC is making COVID-19 vaccine recommendations (CDC, Sept. 30, 2021)

- COVID-19 vaccine toolkit for health and drug plans (CMS, Aug. 19, 2021)

- What you should know about COVID-19 and the ADA, the Rehabilitation Act and other EEO laws (EEOC, May 28, 2021)

- FAQs about Families First Coronavirus Response Act (FFCRA) and Coronavirus Aid, Relief, and Economic Security (CARES) Act, part 44 (DOL/HHS/Treasury, Feb. 26, 2021)

- Updated and new 2021 special enrollment period for COVID-19 public health emergency: technical stakeholder guidance (HHS, March 23, 2021)

- Interim final rule, Additional policy and regulatory revisions in response to the COVID-19 public health emergency (Federal Register, Nov. 6, 2020)

- FFCRA and CARES Act FAQs, Part 43 (DOL/HHS/Treasury, June 23, 2020)

- FFCRA and CARES Act FAQs, Part 42 (DOL/HHS/Treasury, April 11, 2020)

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- Pub. L. No. 116-136, the CARES Act (Congress, March 27, 2020)
- Pub. L. No. 116-127, the FFCRA (Congress, March 18, 2020)
- Final regulation on excepted benefits (Federal Register, Oct. 1, 2014)

Mercer Law & Policy resources

- Top 10 compliance issues for health, fringe and leave benefits in 2022 (Sept. 7, 2021)
- COVID-19 vaccine considerations for group health plans (Dec. 21, 2020)
- Plan coverage of COVID-19 testing: Issues remain after June guidance (Sept. 15, 2020)
- Employer health plans have to meet new COVID-19 coverage mandate (April 21, 2020)
- CARES Act boosts telehealth, makes other health, paid leave changes (March 27, 2020)

Other Mercer resources

- Navigating coronavirus (regularly updated)
- On the vaccine mandate path, start where you are (Sept. 30, 2021)
- Vaccine tracking and verification: Your questions addressed! (Sept. 23, 2021)
- Public employers: Does the president's vaccine mandate apply? (Sept. 23, 2021)
- Vaccine incentives, surcharges and mandates, oh my! (Aug. 19, 2021)
- Mercer joins coalition backing COVID-19 vaccine efforts (Feb. 25, 2021)
- Employers can mandate the covid-19 vaccine, but should they? (Dec. 10, 2020)

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