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Guidance on OTC COVID-19 Tests; 2022 Medical Mileage Rates and PCORI Fees

The following general summary is intended to educate employers and plan sponsors on the potential effects of recent government guidance on employee benefit plans. This summary is not and should not be construed as legal or tax advice. The government's guidance is complex and very fact specific. As always, we strongly encourage employers and plan sponsors to consult competent legal or benefits counsel for all guidance on how the actions apply in their circumstances.

Tri-Agency Guidance Regarding Over-the-Counter COVID-19 Tests

On December 2, 2021, President Biden announced a nine-point plan[1] to further battle the ongoing COVID-19 pandemic considering the recent rise of the latest (as of the date of this writing) variant: Omicron.

Among the items listed in the White House's published strategy was the expansion of "Free At-Home Testing for Americans." In response, the Departments of Labor, Health and Human Services, and the Treasury (collectively, the "Agencies") issued guidance on January 10, 2022 in the form of Frequently Asked Questions[2] clarifying that group health plans and issuers must provide coverage of over-the-counter ("OTC") home COVID-19 tests without participant cost-sharing, preauthorization, or medical management.

By way of background, the Families First Coronavirus Response Act (FFCRA)[3], as amended by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act")[4], generally requires – among other things - group health plans and insurers (including grandfathered plans) and government programs to cover – without "any cost sharing (including deductibles, copayments and coinsurance) requirements or prior authorization or other medical management requirements" - FDA-approved COVID-19 diagnostic testing products. Previously, such at-home diagnostic tests were covered only when ordered by a health care provider who had determined the test was medically necessary for that individual and otherwise met the requirements of FFCRA.[5]

With the advent of FDA-approved at-home COVID-19 diagnostic tests that could be self-administered and without the interpretation or involvement of a health care provider, it was unclear if group health plans and issuers were required to cover these associated costs, as well.

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[1] https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/02/fact-sheet-president-biden-announces-new-actions-to-protect-americans-against-the-delta-and-omicron-variants-as-we-battle-covid-19-this-winter/

[2] https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf

[3] https://www.congress.gov/bill/116th-congress/house-bill/6201

[4] https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf

[5] https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf; https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-44.pdf

The Agencies' published guidance now requires insurers and plans to reimburse OTC COVID-19 diagnostic tests that have authorized, cleared, or approved by the FDA beginning January 15, 2022 and throughout the public health emergency.

Group health plans and insurers will be required to cover these OTC diagnostic tests – irrespective of whether a health care provider ordered the test. This coverage must be provided without participant cost sharing, preauthorization, or medical management. Group health plans and insurers can provide the coverage by reimbursing sellers of OTC COVID-19 diagnostic tests directly (which the Agencies encourage) or by requiring individuals who purchase a test to submit a claim for reimbursement.

The Agencies' guidance includes a limited safe-harbor that, for OTC diagnostic tests purchased outside of direct coverage, group health plans and insurers may limit reimbursement to $12 per test or – if less – the total cost of the test.

Group health plans and insurers may also limit the number of reimbursements for OTC COVID-19 diagnostic tests purchased without the involvement of a health care provider to no fewer than eight tests per covered individual per 30-day period (or per calendar month).

With respect to this guidance and its impact on healthcare Flexible Spending Accounts (health FSAs), Health Savings Accounts (HSAs), and Health Reimbursement Arrangements (HRAs), the Internal Revenue Service issued a reminder on September 10, 2021 that the cost of home testing for COVID-19 is an eligible medical expense that may be paid or reimbursed under an FSA, HSA, or HRA.[6]

Currently, the cost for diagnosing COVID-19 through home testing is an eligible medical expense that may be paid or reimbursed under healthcare Flexible Spending Accounts (health FSAs), Health Savings Accounts (HSAs), Health Reimbursement Arrangements (HRAs). In the case of health FSAs and HRAs, the plan document must permit the reimbursement. Plans with provisions allowing reimbursement of any expense that qualifies as a medical expense under the Internal Revenue Code and applicable regulations will automatically permit reimbursement of home COVID-19 tests. However, plan sponsors are encouraged to review their plan documents to determine if additional plan amendments are needed if they wish to permit such reimbursements.

It is noteworthy that, for an OTC COVID-19 diagnostic test to be eligible for reimbursement under an FSA, HSA, or HRA, the expense cannot be reimbursed from other health coverage. As previously stated,[7] an individual's HSA eligibility will not be impacted if an HSA-compatible health plan provides health benefits associated with testing for and treatment of COVID-19 before the minimum statutory High Deductible Health Plan deductible is met. This includes any testing or treatment provided without cost-sharing.

2022 Medical Mileage Rates

On December 17, 2021, the Internal Revenue Service (IRS) announced the 2022 standard medical mileage rate.[8] The 2022 rate for when an automobile is used to obtain medical care—which may be deductible under Internal Revenue Code § 213 if it is primarily for, and essential to, the medical care—is 18 cents per mile for 2022, which is a slight increase from 2021's rate of 16 cents per mile.

Mileage to and from a medical service is generally an eligible expense under an FSA, HRA, or HSA.

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[6] https://www.irs.gov/newsroom/irs-cost-of-home-testing-for-covid-19-is-eligible-medical-expense-reimbursable-under-fsas-hsas

[7] https://drq94yec07kda.cloudfront.net/cares/Compliance-Alert-IRS-Update-HDHP-COVID19.pdf

[8] https://www.irs.gov/pub/irs-drop/n-22-03.pdf;

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New Indexed PCORI Fees Issued

Under the Affordable Care Act (ACA), a fund for a nonprofit corporation to assist in clinical effectiveness research was created, with certain health insurance carriers and health plan sponsors required to pay fees based on the average number of lives covered by welfare benefits plans. These fees are referred to as either Patient-Centered Outcome Research Institute (PCORI) or Comparative Effectiveness Research (CER) fees.

On December 22, 2021, IRS published Notice 2022-04[9] updating the amount of these PCORI fees that must be paid by self-insured health plans for plan years ending on or after October 1, 2021 and before October 1, 2022. For plan years ending on or after October 1, 2021 and before October 1, 2022, the fee is increased to $2.79, up from $2.66.

As previously stated[10], the PCORI fee had expired on October 1, 2019; this was subsequently extended by the Further Consolidated Appropriations act of 2020 (Pub. L. 116-94).

Fees are reported and paid annually through IRS Form 720 (Quarterly Federal Excise Tax Return). These fees are due by July 31 of the year following the end of the plan year along with IRS Form 720.

Indexed each year, the fee amount is determined by the value of national health expenditures. The fee phases out for plan years ending after September 30, 2029.

As a reminder, fees are required for all group health plans including HRAs but are not required for FSAs that are considered excepted benefits. To be an excepted benefit, health FSA participants must be eligible for their employer's group health insurance plan and may include employer contributions in addition to employee salary reductions. However, the employer contributions may only be $500 per participant or up to a dollar-for-dollar match of each participant's election.

HRAs exempt from other regulations would be subject to the CER fee. For instance, an HRA that only covered retirees would be subject to this fee, but those covering dental or vision expenses only would not be, nor would employee EAPs, disease management programs and wellness programs be required to pay CER fees.

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[9] https://www.irs.gov/pub/irs-drop/n-22-04.pdf
[10] https://healthequity.com/doclib/compliance/Reminders-for-Cafeteria-Plans.pdf