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Regulators Issue Further Guidance on Mandatory Coverage of Over-the-Counter COVID-19 Tests

by Martha L. Sewell

As we previously discussed, federal regulators released FAQs on January 10, 2022 ("January FAQs"), requiring health plans to cover over-the-counter (OTC) COVID-19 tests for all participants during the pandemic, without requiring an order from a health care provider. On February 4, 2022, additional FAQs were released which provide further details regarding how certain safe harbors under this new rule apply ("New FAQs"). The New FAQs also address how the new coverage requirements affect health flexible spending arrangements, health savings accounts, and similar arrangements.

The January FAQs announced safe harbors permitting health plans to impose (1) quantity limitations no less generous than 8 tests per 30-day period or per calendar month for each participant, beneficiary or enrollee, and (2) a $12 limit on the amount reimbursable for tests purchased outside of a "direct coverage program" ("$12 Safe Harbor"). The January FAQs also permitted health plans to take certain actions to minimize the risk of fraud.

The New FAQs impose certain specific requirements and stress that the overall reimbursement process should not involve so many required forms or steps that access to tests is unduly delayed, but generally characterize health plans as having "significant flexibility" regarding how direct coverage and reimbursement programs may be structured.

To satisfy the $12 Safe Harbor, a plan must ensure that direct coverage of COVID-19 tests is reasonably available to participants. While this is a facts and circumstances test, the New FAQs clarify that it generally will require availability of at least one direct-to-consumer shipping mechanism and at least one in-person mechanism with direct coverage, and that plans should cover shipping costs to the same extent that other mail-ordered items are covered. In addition, the New FAQs note that on audit, regulators may ask questions about the breadth of this coverage and review, for example, how close most participants are to a physical location where direct coverage is available.

Helpfully, the New FAQs clarify that plans are *not* required to *directly* cover *all* OTC COVID-19 tests. Thus, for example, if a plan provides direct coverage for a reasonable number of manufacturers' versions of each kind of test, then it would generally be able to exclude direct coverage for the same kinds of tests when provided by one particularly expensive manufacturer without failing to satisfy the $12 Safe Harbor. Note, however, that up to $12 would still generally need to be reimbursable if a participant purchases a test from the expensive

manufacturer outside of the direct coverage program. The New FAQs also clarify that no failure will occur solely because a supply shortage results in temporary unavailability of tests.

To discourage fraud, the New FAQs permit plans to limit coverage to tests that have been purchased from established retailers that would ordinarily be expected to sell OTC COVID-19 tests. For example, a plan can require submission of receipts showing certain information, and may refuse to reimburse for tests purchased from private individuals, online auctions, or resale markets.

Last, the New FAQs clarify that coverage is not required for tests that require processing by a healthcare professional (even if purchased over-the-counter) unless actually ordered by a health care provider, and if a plan imposes a limitation regarding the brands or retailers where a test must be purchased in order to be covered, this information should be clearly communicated to participants.