

## Client Alert

### **Agencies Issue FAQs Regarding Coverage of Over the Counter COVID-19 Diagnostic Tests**

On December 2, 2021, President Biden announced that federal agencies would soon issue guidance regarding the availability of coverage/reimbursement from group health plans and health insurance carriers for individuals who purchase over the counter, at-home COVID-19 diagnostic tests (“OTC COVID-19 tests”). Accordingly, on January 10, 2021, the agencies released “[FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act \(FFCRA\) and Coronavirus Aid, Relief, and Economic Security Act \(CARES Act\) Implementation](#)” which, among other things, requires group health plans and health insurance carriers to reimburse participants, beneficiaries, or enrollees (“Individuals”) for no less than eight (8) OTC COVID-19 tests per calendar month beginning on January 15, 2022 (i.e., for tests purchased on or after January 15, 2022).

#### **Background**

During the COVID-19 public health emergency, the FFCRA requires group health plans (self-funded, fully-insured, grandfathered, and non-grandfathered plans, but not excepted benefits such as dental or vision) and health insurance issuers (“Plans and Carriers”) to cover testing or certain other items or services intended to diagnose COVID-19 without cost sharing (deductibles, copays, or coinsurance), prior authorization, or other medical management requirements. It also permits the agencies to implement the FFCRA through sub-regulatory guidance, program instruction, or otherwise. The CARES Act expanded the FFCRA to, among other things, include a broader range of reimbursable COVID-19 diagnostic items and services that must be covered without cost-sharing, prior authorization, or medical management during the public health emergency.

In 2020, the agencies implemented several FAQs intended to serve as statements of policy to implement the above-referenced requirements under the FFCRA and CARES Act. Since that time, the FDA has authorized at-home OTC COVID-19 diagnostic tests that individuals can self-administer and self-read to diagnose COVID-19. Accordingly, per the agencies, the FAQs issued on January 10, 2022 are intended to address both the FDA’s approval of at-home OTC COVID-19 tests and the President’s request for additional guidance on group health plan coverage for these tests to address the ongoing COVID-19 public health emergency.

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### **FAQ Guidance**

Pursuant to the FAQs, Plans and Carriers must cover OTC COVID-19 tests that meet the criteria specified under the FFCRA even if they are not ordered by a health care professional, and must cover such tests without imposing cost-sharing, prior authorization, or medical management requirements. This is so even if there is no order from a health professional for an Individual.

Coverage by the plan may be accomplished by directly reimbursing Individuals for their purchase upon submission of a claim by the Individual, or by reimbursing the entity who sold the OTC COVID-19 test directly, though the agencies strongly encourage plans to adopt the latter approach.

Note, however, there is no requirement for Plans or Carriers to provide coverage of OTC COVID-19 tests that are intended for employment testing, such as weekly testing an unvaccinated Individual is required to undergo pursuant to the OSHA Emergency Temporary Standard (“ETS”) or an employer’s own mandated testing program.

Plans and Carriers are required to reimburse OTC COVID-19 tests purchased from any retailer or pharmacy if the test meets the FFCRA statutory criteria, but if the test is administered without a health care provider’s assessment or order for testing and purchased from out-of-network pharmacies or retailers, then the Plan or Carrier may limit reimbursement to the lower of the actual price or \$12 per test if the Plan or Carrier arranges for direct coverage (meaning the Individual who purchases the OTC COVID-19 test is not required to seek reimbursement post-purchase or make any up-front out-of-pocket expenditures) of OTC COVID-19 tests that meet the FFCRA criteria through both its pharmacy network and a direct-to-consumer shipping program. Per the agencies, the direct-to-consumer shipping program may be provided through one or more in-network provider(s) or another entity designated by the Plan or Carrier.

In order to limit reimbursements for tests purchased from non-preferred providers, Plans and Carriers must ensure there are an adequate number of retail locations (in-person and online) with access to OTC COVID-19 tests and communicate necessary information about the direct coverage program, including when it is available and which retail pharmacies are available.

Per the agencies, whether access is adequate is determined based on all relevant facts and circumstances, including where Individuals are located and current utilization of the Plans’ or Carrier’s pharmacy network by Individuals. Further, if there are significant delays for individuals to receive the OTC COVID-19 tests, such as through the shipping program, the Plan or Carrier must allow Individuals to purchase (and be reimbursed for) their OTC COVID-19 tests from any retailer.

The agencies also recognize the important need for adequate testing to be available to health care providers who are diagnosing and treating COVID-19, and that everyone has reasonable access to OTC COVID-19 tests. Thus, to prevent stockpiling and provide adequate safeguards, the agencies permit Plans and Carriers to limit OTC COVID-19 tests purchased by Individuals without a health care provider's involvement or assessment, the agency provides a safe harbor from agency enforcement action for Plans or Carriers that limit the number of OTC COVID-19 tests eligible for reimbursement per Individual to no less than eight (8) tests per 30-day period or per calendar month. Plans and Carriers are not permitted to limit Individuals to a smaller number of tests over a short period of time (such as limiting Individuals to four (4) tests per 15-day period). Plans can choose to be more generous by reimbursing a larger number of OTC COVID-19 tests (i.e., more than 8) per calendar month if they prefer.

### **Testing for Employment Purposes**

Plans and Carriers are permitted to address suspected fraud and abuse, such as taking reasonable steps to ensure OTC COVID-19 tests are purchased for an Individual's (or their covered family member's) own personal use as long as the steps do not create significant access barriers. This may include requiring attestations that the OTC COVID-19 test was purchased by the Individual for personal, non-employment related use, will not be reimbursed by another source, and will not be made available for resale as long as the attestation process is reasonable and does not result in undue delay of reimbursement. Plans and Carriers may also require reasonable documentation as proof of purchase, such as the UPC code from the OTC COVID-19 test, when claims are submitted.

Finally, Plans and Carriers may assist Individuals by providing education and information resources to support Individuals seeking OTC COVID-19 testing as long as the materials clearly indicate the Plan or Carrier is required to cover all OTC COVID-19 tests that meet FFCRA criteria (subject to the safe harbors referenced previously). The FAQs provide some examples of potential education and information resources Plans and Carriers may use.

### **What Does This Mean for Employers?**

Employers are encouraged to work with their carriers or third-party administrators and stop-loss carriers to ensure these new requirements are implemented and to determine whether the plan will implement any of the permitted safe harbors so that this can be effectively communicated to employees and their family members.

The agencies clarified that they will not take enforcement action against Plans or Carriers for modifying health insurance coverage mid-year to meet these requirements or for failing to meet the 60-day advance notice requirements (for changes made to information required to be included in SBCs) if notice of these changes is provided as soon as reasonably practicable.



Finally, employers should clearly articulate to employees that the employer’s testing policy adopted pursuant to the OSHA ETS, if any, is not subject to this requirement and, employees are expected to pay out of pocket for weekly COVID-19 tests without seeking reimbursement from the employer’s group health plan if the employer does not pay for the applicable testing. Further, pursuant to the OSHA ETS, while the employer may allow an OTC COVID-19 test to be used for purposes of applicable employment testing, the test may not be both self-administered and self-read unless observed by the employer or an authorized telehealth proctor.

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