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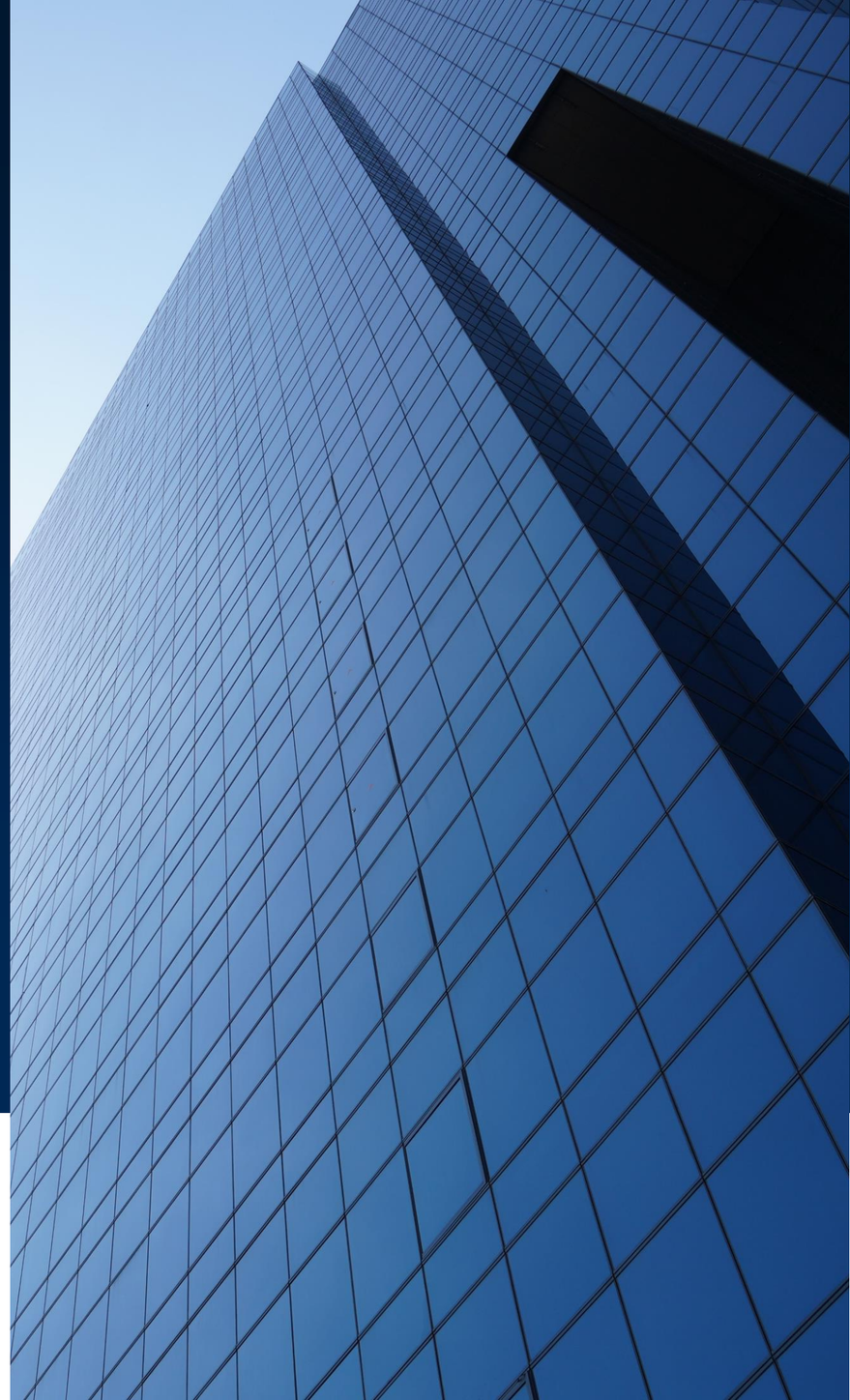
What We Know and Don’t Know About the COVID-19 OTC Test Kit Requirement

January 2022



Presented By:
Regulatory and Legislative Strategy Group

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Presentation Agenda

1. Background and FAQ Part 51
2. Additional Considerations and Unanswered Questions
3. Industry Implementation
4. Q&A

Background

FFCRA AND CARES ACT

Section 6001 of the FFCRA

- Requires group health plans and health insurance issuers to provide coverage without cost-sharing, prior authorization or other medical management requirements for the following:
  - In vitro diagnostic products authorized by the FDA for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19
  - Items and services furnished to individuals during health care provider office visits (including in-person and telehealth), urgent care and ER visits that result in an order or administration of an in vitro diagnostic product described above, but only to extent the items/services relate to the evaluation of the individual for purposes of determining the need for the product

Section 3201 of the CARES Act

- Amendments included broader range of diagnostic items and services plans and issuers must cover without cost-sharing, prior authorization or medical management
- Plans and issuers providing coverage are required to reimburse any provider of COVID-19 diagnostic testing the amount equal to the negotiated rate or cash price of service if no negotiated rate exists

Background

AGENCY GUIDANCE UNDER THE FFCRA AND CARES ACT

FAQ Part 43

- Plans and issuers must cover COVID-19 tests intended for at-home testing under section 6001 of the FFCRA
  - Applies only when test is ordered by attending health care provider after determining test is medically appropriate for individual
  - Coverage must be provided without cost-sharing, prior authorization or other medical management requirements
  - Coverage of COVID-19 testing for surveillance or employment purposes not required under section 6001 of the FFCRA

FAQ Part 44

- Plans and issuers may distinguish between COVID-19 testing for individualized diagnosis and testing for general workplace health and safety
  - To the extent they are not inconsistent with the FFCRA's prohibition on medical management, plans and issuers may employ programs designed to detect and address fraud and abuse

Background

TIMING AND APPLICABILITY

Public Health Emergency

- Determined by Secretary of HHS pursuant to section 319 of the Public Health Service Act (PHS Act)
- January 31, 2020 - Declared a public health emergency exists due to COVID-19
- Lasts until Secretary declares emergency no longer exists or after expiration of 90-day period. Secretary may extend emergency for subsequent 90-day periods for as long as the emergency exists
- Renewed January 14, 2022

Note: The public health emergency is separate from the National Emergency which applies for purposes of defining the Outbreak Period extensions

Plans subject to section 6001 of the FFCRA

- Group health plans and health insurance issuers offering group or individual health insurance coverage, including:
  - Grandfathered and non-grandfathered health plans
  - Fully and self-insured group health plans
  - Private employment-based group health plans (ERISA plans)
  - Non-federal government plans (e.g., state and local government plans) and church plans

FAQ Part 51

Released January 10, 2022

FAQ Part 51

KEY TAKEAWAYS

- Group health plans must cover over-the-counter (OTC) COVID-19 tests under section 6001 of the FFCRA, *with or without* an order or individualized clinical assessment by an attending health care provider

- January 15, 2022 – The date plans and issuers must begin providing coverage for OTC COVID-19 tests available without an order or individual assessment. Coverage must be provided during public health emergency

- FAQ Part 51 does not modify prior agency guidance with respect to coverage of COVID-19 testing for employment or public health screening purposes

FAQ Part 51

COVERAGE OF OTC COVID-19 TESTING

- Coverage applies even without order of individualized clinical assessment issued by health care provider to tests that do not require a health care provider’s order under applicable Food and Drug Administration (FDA)
- Applies to OTC COVID-19 tests authorized for use by the FDA
- OTC COVID-19 tests must be covered without imposing any cost-sharing, prior authorization or other medical management requirements
- Plans and issuers may require a participant who purchases an OTC COVID-19 to submit a claim for reimbursement in accordance with reasonable internal claims procedure
- Plans and issuers are not required to provide coverage by directly reimbursing sellers of OTC COVID-19 tests

FAQ Part 51

DIRECT COVERAGE PROGRAM

- Plans and issuers may provide coverage by reimbursing sellers of OTC COVID-19 tests directly – known as “direct coverage”
  - Use of this method is “strongly encouraged” by the DOL, HHS and Treasury

- Direct coverage allows participants, beneficiaries or enrollees to obtain OTC COVID-19 tests without providing upfront payment and seeking reimbursement

- Plans and issuers using direct coverage may not limit coverage to tests provided through preferred pharmacies or other retailers unless safe harbor is satisfied

Direct Coverage Safe Harbor

FAQ PART 51

- Applies to direct coverage program that meets the statutory requirements of section 6001(a)(1) of the FFCRA through both its pharmacy network and a direct-to-consumer shipping program
  - Applies only to OTC COVID-19 tests administered *without* a health provider's prescription or involvement

- Plans and issuers offering the direct coverage program may limit reimbursement for OTC COVID-19 tests from *non-preferred* pharmacies or other retailers to no less than the actual price of the test, or $12 per test (whichever amount is lower)

- Must make systems and technology changes necessary to process payments to the preferred pharmacy or retailer directly (including the direct-to-consumer shipping program)
  - May not require upfront out-of-pocket expenditures

- Must take reasonable steps to ensure participants have adequate access to OTC COVID-19 tests through adequate number of retail locations (including both in-person and online)

Limited Test Quantity Safe Harbor

FAQ PART 51

- Plans and issuers may limit the number of OTC COVID-19 tests covered for each participant, beneficiary or enrollee to no less than eight tests per 30-day period (or per calendar month)
  - Limit applies on a per-participant/beneficiary/enrollee basis
  - Plans and issuers may set more generous limits

- Applies to OTC COVID-19 tests available *without* a health provider's prescription or involvement

- Safe harbor satisfied only if coverage is provided without cost-sharing, medical management or prior authorization

Fraud and Abuse

FAQ PART 51

- Plans and issuers may take reasonable action to prevent, detect and address fraud and abuse when providing coverage of OTC COVID-19 tests

- Programs that require individuals to “submit multiple documents or involve numerous steps that unduly delay a participant’s, beneficiary’s or enrollee’s access to, or reimbursement for, OTC COVID-19 tests are not reasonable.”

- Examples of permissible activities:
  - Reasonable steps to ensure test was purchased for the covered individual’s own use (or use by another covered family member) if steps do not create significant barriers for obtaining the tests
  - Requiring reasonable documentation of proof of purchase with a claim for reimbursement for the cost of the OTC COVID-19 test

Additional Considerations & Unanswered Questions

FAQs

Are employers required to notify their employees with respect to coverage of OTC COVID-19 tests?

FAQ Part 51 does not describe any specific requirement under section 6001 of the FFCRA.

Optional notice under FAQ Part 51:

- Plans and issuers may provide education and information resources if the resources “make clear that the plan or issuer provides coverage for, including reimbursement of, all OTC COVID-19 tests that meet the statutory criteria under section 6001(a)(1) of the FFCRA (subject to the safe harbors in Q2 and Q3), and such information is consistent with the test’s emergency use authorization (EUA).”

Examples:

- Quality information for specific OTC COVID-19 tests (including shelf life and expiration dates)
- How to obtain tests from plan/issuer or designated sellers
- How to submit claims for reimbursement (including electronic and paper filing options)

FAQs

Are plans required to furnish a summary of material modifications (SMM) with respect to plan changes for coverage of OTC COVID-19 tests?

Possibly.

Examples that may trigger requirement to provide SMM:

- If plan has general exclusion for OTC medicines and supplies without a health care provider's order that must now cover OTC COVID-19 tests without a health care provider's order
- If plan sponsor imposes a limit on number of tests purchased by covered individuals during a specified amount of time
- If a plan using a direct coverage arrangement places a cap on maximum reimbursement amount

FAQs

Can plan sponsor of a self-insured group health plan increase employee contribution levels midyear in response to coverage of OTC COVID-19 tests?

It's unclear.

General Rule:

- Do plan documents give plan sponsor power to amend the plan?
- Cost changes may allow participants to make midyear election changes
- Does Section 125 cafeteria plan document recognize cost change as a permissible event?
- Is the cost change "significant" and will changes occur automatically?
- Does the medical plan permit participants to terminate coverage midyear?

COBRA rates generally must remain consistent for determination period
Applicable large employers (ALEs) will need to consider the impact increasing costs have on the affordability of coverage for purposes of the employer shared responsibility provisions

Whether a plan sponsor can increase employee contributions midyear with the stated reason solely to cover the cost of COVID-19 tests remains unanswered and could be subject to increased legal scrutiny. Employers and plan sponsors considering these changes are directed to consult with legal counsel.

FAQs

How quickly must the plan reimburse a claim for an OTC COVID-19 test? Is there a deadline to submit reimbursements?

Specific timeframe not stated.

CMS encourages health plans to provide prompt reimbursement for claims for at-home tests

FAQ Part 51:
Reimbursement should be in accordance with the plan or issuer's reasonable internal claims procedures, consistent with applicable federal and state law
Plan sponsors should review internal claims procedures for applicable time period

FAQs

Can plans and issuers using a direct coverage program limit reimbursement amounts for OTC COVID-19 tests purchased from preferred pharmacies or retailers?

The reimbursement limit described in FAQ Part 51 of $12 or the actual price of the test (whichever is lower) applies to tests obtained *at non-preferred pharmacies or other retailers* only when the plan offers a direct coverage option

Reimbursement amounts through preferred pharmacies or retailers or through a direct-to-consumer shipping program will likely depend on the plan's *negotiated fee schedule* with preferred network provider

This amount will not necessarily be capped at $12 per test

FAQs

Must direct coverage program include both preferred pharmacies and direct-to-consumer shipping programs to satisfy FAQ Part 51 Q2 safe harbor?

It is not entirely clear.

FAQ Part 51:
"through both its pharmacy network ***and*** a direct-to-consumer shipping program…"
"systems and technology changes necessary to process the plan's or issuer's payment to the preferred pharmacy or retailer directly (including the direct-to-consumer shipping program)…"

Statements could be interpreted to mean the plan needs to offer direct coverage either through its pharmacy network or a direct-to-consumer shipping program, but not both, in order to take advantage of the safe harbor

Employers should discuss issue with legal counsel if PBM is not implementing a direct-to-consumer shipping program

FAQs

Are the costs of at-home COVID-19 tests reimbursable under a health FSA or HSA?

Yes.

The cost of home COVID-19 tests is an eligible medical expense that can be paid or reimbursed by health FSAs, HSAs or HRAs. - IRS News Release IR-2021-181

IRS news release does not specify whether at-home COVID-19 tests purchased for diagnostic purposes or employment purposes are reimbursable. Consultation with your legal counsel is advised because of the ambiguity.

Industry Implementation

Administration of Coverage

WILL TESTS BE COVERED UNDER PRESCRIPTION DRUG BENEFIT, MEDICAL BENEFIT OR BOTH?

  - Do either/both vendors offer a direct access network and home delivery option?
  - Do vendors satisfy the safe harbors provided in FAQ Part 51?

- Are carriers adopting both a direct coverage option and claim submission option?

- Purchases made at pharmacy counter versus retail checkout

- How are carriers and employers generally handling communication and education?

Cost Implications – Pharmacy vs. Medical

- Will there be implementation or per claim fees?
- Are vendors incorporating a cap on reimbursement amounts?
- Negotiated rates with direct coverage providers
- Risk of “double dipping”

Question & Answer

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