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HEALTH & WELFARE PLAN LUNCH GROUP

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LEGISLATIVE UPDATE

- General state of play
- March 11 gov't funding deadline
- Build Back Better
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  - Focus on mental health

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No Surprises Act Update

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CMS Enforcement Letters

- Detail how the states and CMS will work together in enforcing the No Surprises Act (NSA).
  - https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/CAA.
- Applies to insured plans.
- Result from a detailed survey CMS sent to the states and other communications between CMS and the states.
- CMS will enforce in many states in addition to state regulators.
  - States have ceded enforcement to CMS in some instances.
  - In some instances states will enforce.
  - Collaborative agreement between the states and CMS in other instances.

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CMS Enforcement Letters

- Determines:
  - Which NSA provisions will be enforced by CMS and which by the state
  - Whether a state has a "specified state law" for purposes of the NSA
    - If so, the federal NSA provisions regarding qualifying payment amount and the independent dispute resolution process do not apply to insured plans and state provisions will apply
    - Service by service approach. For example, if a state law does not cover emergency services at an independent free-standing emergency department, such services will come under federal NSA even if other services are under state law.
- Letters issued to all states except: Alaska, Arizona, Illinois, Nevada, New York, Ohio, and Tennessee.
- 16 states determined to have "specified state laws" for at least some services.

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Texas Medical Association v. U.S. Department of Health and Human Services

- February 23, 2022 decision by Texas federal district court.
- Sets aside the rebuttable presumption that, for independent dispute resolution (IDR) under the NSA, the qualifying payment amount (QPA) will be the amount paid to out of network providers for emergency services, air ambulance services, and out of network providers at in-network facilities.
  - QPA is generally the plan's median contacted rate with in-network providers for a service.
  - IDR is "baseball style" arbitration between a plan and an out of network provider over a disputed claim reimbursement.
- Rebuttable presumption was established in Part II of the Interim Final Regulations (IFR Part II).
- Healthcare provider groups generally are not in favor of the rebuttable presumption, whereas payers (plans an insurers) generally support the presumption. Congressional reaction to the rule has been mixed.

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Texas Medical Association v. U.S. Department of Health and Human Services

- Applies nationwide since Court vacated the specific provisions of the IFR Part II related to the rebuttable presumption.
- Did not vacate the other portions of IFR Part II so IDR will continue—just without the presumption.
- Court found IFR Part II invalid for lack of notice and comment that should be part of rulemaking.
- But further rulemaking likely cannot save the rebuttable presumption (at least in this Court's view) because the judge found the rebuttable presumption inconsistent with the provisions of the NSA.
- Presumably, DOJ will appeal to the Fifth Circuit.
- Other cases pending in other federal district courts.

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Texas Medical Association v. U.S. Department of Health and Human Services

- February 28, 2022 CMS issued a response.
- "The Departments are reviewing the court's decision and considering next steps… Specifically, the Departments will":
  - Effective immediately, withdraw guidance documents that are based on, or that refer to, the portions of the Rule that the court invalidated.
  - Provide training on the revised guidance for certified IDR entities and Disputing Parties. This training will be offered through webinars and roundtable discussions.
  - Open the IDR process for submissions through the IDR Portal. For disputes for which the open negotiation period has expired, the Departments will permit submission of a notice of initiation of the IDR process within 15 business days following the opening of the IDR Portal."
- Guidance is available here: https://www.cms.gov/files/document/memorandum-regarding-continuing-surprise-billing-protections-consumers.pdf

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Secretary of Labor v. Macy's Inc. et al.

DOL's Challenge to Macy's Wellness Program

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Secretary of Labor v. Macy's Inc. et al.

- Action brought by the Department of Labor against Macy's, Macy's group health plan and two ASOs for the group health plan in August 2017 in federal court in Ohio.
  - Pending over four years before motions to dismiss were decided.
- Decision on the motions to dismiss in November 2021 and DOL's motion for reconsideration on February 10, 2022.
- No findings of any liability at this point, simply letting limited claims go forward with some claims dismissed.
- Two claims—
  - Discriminatory wellness program under HIPAA/ERISA §702 (against Macy's alone),
  - Failure to follow out-of-network reimbursement methodology as stated under the plan document (against all defendants).

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Secretary of Labor v. Macy's Inc. et al.

- Failure to follow the plan document claims were dismissed because:
  - No harm to the ***plan*** as required under §502(a)(2) of ERISA.
  - DOL could not bring a claim under the "catch all" provisions of §502(a)(5) of ERISA because the real cause of action, if there was one, should be brought by participants and beneficiaries for benefits under §502(a)(1)(B) of ERISA.
- Discriminatory wellness program allegations all involved a smoking cessation program where DOL alleged there was a failure to provide a reasonable alternative standard. Different allegations for different time periods:
  - 2011 to 2012-- had to be tobacco free for six months even if you completed a smoking cessation course,
  - 2013 had to complete a smoking cessation course and did not have to be tobacco free-- ***but*** did not provide the "full reward" for completing the course (i.e. the affidavit itself stated the tobacco surcharge would "not be changed retroactively and no refunds or credits [would] be issued."),
  - 2014 forward—Only had to complete the course and 2013 language was deleted from the affidavit, but DOL still alleged "upon information and belief" that the full reward was not provided in all circumstances (i.e. refund of the tobacco surcharge on completion of the course).

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Secretary of Labor v. Macy's Inc. et al.

- On the wellness program DOL alleged:
  - Violation of §702 of ERISA for a discriminatory wellness program.
    - Section 702 of ERISA incorporates the HIPAA nondiscrimination provisions into ERISA.
  - Breach of fiduciary duties under ERISA.
  - Self-dealing prohibited transaction under ERISA.
    - Alleged that the surcharge allowed Macy's to pay less in employer contributions.

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Secretary of Labor v. Macy's Inc. et al.

- In deciding the motion to dismiss the Court:
  - Let the allegations of a direct violation of ERISA §702 go forward for 2011-2013
    - For 2013 there was an issue on whether the "full reward" was required prior to the 2013 amendment to the wellness regulations but the Court let the claims for 2013 go forward.
    - The Court dismissed the §702 claim for 2014 forward, with leave to amend, because DOL's "upon information and belief" allegations were not sufficient.
  - The Court dismissed the fiduciary breach and prohibited transaction claims because the Court ruled Macy's was acting as a settlor and not a fiduciary in designing the wellness program with the allegedly deficient reasonable alternative standard.

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Secretary of Labor v. Macy's Inc. et al.

- DOL moved for reconsideration on the fiduciary breach claim alleging that even if Macy's was acting as settlor in designing the wellness program it breached its fiduciary duty in ***administering*** the plan under ERISA §404(a)(1)(D) because ERISA only requires adherence to plan documents "insofar as such documents and instruments are consistent with [ERISA's] provisions."
- On the decision for the motion for reconsideration the Court first chided DOL for not making this argument earlier.
- But the Court then concluded that requiring a fiduciary to administer plan documents insofar as the plan documents are consistent with ERISA ***does not*** mean that the inverse is true –(i.e. it is a fiduciary breach to administer a plan that is inconsistent with ERISA). It said DOL's argument relied on a logical fallacy called "denying the antecedent" or "the fallacy of the inverse."

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Secretary of Labor v. Macy's Inc. et al.

- Takeaways—
  - Examine wellness programs for compliance with ERISA/HIPAA (and the ADA and GINA),
    - Offer a compliant reasonable alternative standard providing the "full reward".
  - If DOL brings an action examine the defenses successfully raised by Macy's with regard to the fiduciary/settlor distinction as well as procedural arguments.
  - More to come: Macy's decision is just a decision on motions to dismiss. If not settled, it will proceed in district court and then likely go on to the 6th Circuit.
  - DOL is focusing on all aspects of Part 7 of ERISA affecting group health plans.
    - HIPAA nondiscrimination.
    - MHPAEA
    - ACA protections
    - Focus on Part 7 likely to be heightened with No Surprises Act protections.

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UPDATE ON COVERAGE OF OTC COVID-19 TESTS

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New: FAQs Part 52

- On February 4, 2022, the departments released FAQs Part 52 as a partial modification to and clarification of FAQs Part 51 on the COVID-19 test issue.

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Quick Review: Safe Harbors

Two safe harbors to control cost: direct coverage safe harbor and the monthly test limit safe harbor

- ***Direct Coverage Safe Harbor***: direct coverage of OTC COVID-19 tests "through both its pharmacy network and a direct-to-consumer shipping program, and otherwise limits reimbursement for OTC COVID-19 tests from non-preferred pharmacies or other retailers to no less than the actual price, or $12 per test (whichever is lower)."
- ***Monthly Limit Safe Harbor***: plans/issuers permitted to limit the number of OTC COVID-19 tests covered for each participant to no less than 8 tests per 30-day period (or per calendar month). Smaller number and/or shorter limit is not permitted

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NEW: Safe Harbors: Direct Coverage: Flexibility

- "Significant flexibility" in how plans provide access to OTC COVID-19 tests
  - direct-to-consumer shipping program that allows for orders to be placed online or by telephone,
  - the plan's pharmacy network
  - other non-pharmacy retailers, and
  - alternative OTC COVID-19 test distribution sites established by (or on behalf of) the plan or issuer.
- New guidance regarding the flexibility in creating direct-to-consumer shipping and direct coverage in-person programs is effective beginning February 4, 2022.

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Safe Harbors: Direct Coverage: Shipping Cost and Tax

- Plans must cover reasonable shipping costs related to covered OTC COVID-19 tests in a manner consistent with other items or products provided by the plan or issuer via mail order.
- For OTC COVID-19 tests purchased outside of the direct coverage program, the $12 maximum reimbursement limit includes shipping and sales tax costs.

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Safe Harbors: Direct Coverage: Adequate Access

- Adequate access does not mean all OTC COVID-19 tests that meet the statutory criteria under the FFCRA and CARES Act are available through the direct coverage program.
- A plan may cover tests from a limited number of manufacturers (e.g., those with whom the plan has a contractual relationship) if that would provide adequate access based on the facts and circumstances.
- Supply Shortages: If a plan is temporarily unable to provide adequate access through a direct coverage program due to supply shortage, but has otherwise established a compliant direct coverage program, such plan will not be out of compliance with the direct coverage safe harbor. The plan can still limit reimbursement of tests purchased outside of the direct coverage program to $12 per test.

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Combating Fraud and Abuse

- Plans may limit coverage of OTC COVID-19 tests purchased to tests purchased from "established retailers" that would typically be expected to sell OTC COVID-19 tests.
- Plans may exclude tests purchased from nontraditional sellers such as private individual, online auction, resale marketplaces, and resellers.

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HSA/HDHP Issues

- When notifying participants of OTC coverage, plans should consider a notice to individuals not to use a health debit card or otherwise seek reimbursement from a health FSA or HRA for the cost (or the portion of the cost) of OTC COVID-19 tests paid or reimbursed by the plan.
- Health FSA or HRA administrators will also want to be prepared to assist individuals with correction procedures should they mistakenly receive reimbursement from a health FSA or HRA for OTC COVID-19 test costs covered by a plan.
- Expenses incurred for OTC COVID-19 tests already paid or reimbursed by a plan are not HSA-qualified medical expenses, and an individual that mistakenly takes a distribution to pay for such test that has been paid for or reimbursed by the plan must either (1) include the distribution in gross income; or (2) if and as permitted under Q&A 37 and 76 of IRS Notice 2004-50, repay the distribution to the HSA.

Correction

- High deductible health plans (HDHP) are not addressed in either FAQs Part 51 or 52. However, as with the preexisting testing mandate, the relief provided in IRS Notice 2020-15 should apply. That notice provides that, *until further guidance*, HDHPs may provide coverage for COVID-19 testing and treatment before the deductible is met.

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Enforcement

- The Departments note that they may request information from plans and issuers, such as the number and location of in-person options, to ensure that covered individuals have adequate access to OTC COVID-19 tests

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Additional Items of Note

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Blue Cross Blue Shield Antitrust Settlement Update

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Background

- $2.67 billion settlement available from class action antitrust litigation *In re: Blue Cross Blue Shield Antitrust Litigation MDL 2406*, N.D. Ala. Master File No. 2:13-cv-20000-RDP. https://www.bcbssettlement.com
- Monetary Damages are available to individuals and companies that purchased or received health insurance provided or administered by Blue Cross Blue Shield Association and settling affiliates (collectively "BCBS") during the following periods:
  - Fully insured policy period 2/7/08-10/16/20.
  - Self-funded 9/1/15-10/16/20.
- Notice to class members provided on 5/31/21 and deadline to file claim 11/05/21.

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What is New?

- The Court has re-opened the opt-out period for self-funded accounts.
- Self-funded accounts that previously filed a claim have until **May 2, 2022 to opt out** from the settlement damages class.
- The updated notice clarifies that an opt out from the damages class also takes the account out of the injunctive relief class for "Second Blue Bids."
  - The "Second Blue Bid" portion of the settlement was designed to enable large, geographically dispersed, self-funded national employers (5,000 or more employees) to have the opportunity to receive a second bid from a settling individual BCBS plan in addition to the employer's local settling individual BCBS plan.
  - A Second Blue Bid is unavailable to employers headquartered in areas where there are already two licensed settling individual BCBS plans.
- Updated notice is available at https://www.bcbssettlement.com/admin/services/connectedapps.cms.extensions/1.0.0.0/asset?id=74891eaa-4806-4718-ad9e-078d084313a7&languageId=1033&inline=true

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Who is Affected?

- A "self-funded entity account" that purchased or was enrolled in a Blue Cross and/or Blue Shield administrative services plan at any point in time between 9/01/2015 and 10/16/2020.
- "Self-funded entity accounts" encompass any account, employer, health benefit plan, ERISA plan, non-ERISA plan, or group that purchased, were covered by, participated in, or were enrolled in a self-funded health benefit plan.
  - ***Not included***: sponsors, administrators, fiduciaries, or members of a self-funded account.
- A "self-funded health benefit plan" is any commercial health benefit product other than commercial health insurance, including administrative services only contracts or accounts, administrative services contracts or accounts, and jointly administered administrative services contracts or accounts.

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What are the Options?

- Stay in the settlement class (no opt out).
- Opt out: elect to exclude the account from the settlement damages class (account will not receive a distribution from the settlement fund or individualized injunctive relief, including the right to request a Second Blue Bid).
- Withdraw a previous opt out and remain in the damages class.

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What is at stake?

- If the account opts out, it will keep its right to sue BCBS and its settling affiliates for monetary damages and individualized injunctive relief related to the claims in this case.
- The ability to sue depends on the individual facts and circumstances surrounding the account's claim, *e.g.* venue, applicable statute of limitations, amount of fees at issue, etc.
- Injunctive relief may include the right to pursue in litigation more than one BCBS bid based upon the account's individual facts and circumstances.
- Note that accounts that may opt out are still part of a "relief class" and the court approved settlement agreement precludes claims for *indivisible* injunctive relief to the extent claims for those remedies are released for the BCBS settling plans.

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What is at stake?

- Given structure of settlement relief, there are potential prohibited transaction and fiduciary issues for ERISA covered plans due to the DOL's perceived presence of ERISA plan assets.
- The DOL views a group health plan's cause of action against the BCBS settling defendants as an ERISA plan asset based on its Statement of Interest brief filed with the court on 10/19/2021.
- Other examples of potential plan assets identified by the DOL are the employee portion of prior premiums or contributions paid as well as trust assets if the plan is funded.

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Potential Prohibited Transaction Issues

- Prohibited transaction provisions in ERISA Section 406(a) apply to "parties in interest" which includes the plan's current service providers.
- For self-funded plans currently using BCBS defendants as third-party administrators, the DOL's view is that agreeing to the settlement is an exchange of a plan asset for consideration from a party-in-interest.
- In order to avoid a prohibited transaction, the DOL says that the requirements in PTE 2003-39 are pertinent such as the condition that the authorizing fiduciary acting on behalf of the plan has acknowledged in writing that it is a fiduciary with respect to the settlement of the litigation on behalf of the plan.

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Potential Fiduciary Issues

- Important fiduciary issues for all ERISA plans, including fully insured plans and plans that no longer contract with BCBS, have still not been resolved:
  - Are the settlement damages allocated to employer groups ERISA plan assets?
  - If plan assets what are the permissible uses? (some employees may receive individual allocations)
  - What is the time frame to use the allocations if plan assets?
  - Do plan sponsors need to notify employees of the settlement?
  - Does a plan fiduciary have to decide formally whether it is reasonable in light of the plan's likelihood of full recovery for the plan to accept the settlement or opt out?

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Potential TCPA Issues for Health and Wellness Programs

- *Fiorarancio v. Wellcare Health Plans*, Inc.,
  - Health plan allegedly violated the TCPA by contacting the plaintiff's cell phone twenty times over an eleven-month period, leaving eighteen voicemails and sending two text messages.
  - While merely a preliminary motion to dismiss, case serves as a clear warning concerning TCPA compliance issues.
- TCPA may apply to certain communications with health, wellness, and disease management participants
- TCPA generally applies to text and telephonic communications unless specifically authorized
- Evaluate administrator practices and compliance responsibilities

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National and Public Health Emergency Extensions and Impact on Health Benefits

- National Emergency versus Public Health Emergency
  - Public Health Emergency extension on January 16th Until April 16, 2022 (unless ended sooner)
  - National Health Emergency Extended on Feb 18, 2022 Until March 1, 2023 (unless ended sooner)
- Impact on Coverage Mandates
- Impact on Outbreak Period Obligations
  - COBRA Elections and Premiums
  - HIPAA Special enrollment
  - Claims filing and appeals

Thanks!

- Questions?

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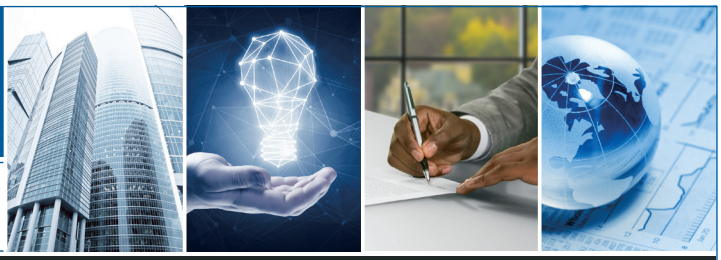

Employee Benefits & Executive Compensation ADVISORY ■

FEBRUARY 14, 2022

Testing for COVID and Your Kits for Free: Expanded Coverage of OTC COVID-19 Test Kits and Developments in Preventive Care

On January 10, 2022, the U.S. Departments of Labor (DOL), Health and Human Services (HHS), and Treasury issued FAQs Part 51, which expands coverage of COVID-19 diagnostics tests by plans and issuers to include over-the-counter (OTC) COVID-19 at-home tests without a prescription. Two preventive care items are also included in FAQs Part 51. On February 3, 2022, the Centers for Medicare and Medicaid Services announced that Original Medicare and Medicare Advantage will provide coverage for up to eight OTC COVID-19 tests for beneficiaries at no cost starting in early spring. On February 4, 2022, the departments released FAQs Part 52 as a partial modification to and clarification of FAQs Part 51 on the COVID-19 test issue.

Key Provisions

- Required coverage of OTC COVID-19 tests by group health plans. For tests purchased on or after January 15, 2022, group health plans must extend coverage to OTC COVID-19 tests that a participant purchases without an order or clinical assessment from a health care provider and without imposing any cost-sharing, prior authorization, or other medical management requirements. Consistent with prior guidance from the departments, coverage of OTC tests for public health surveillance or employment purposes is not required. Under a safe harbor established in the FAQs, plans may limit reimbursement for tests purchased out of network to $12 by providing "direct coverage" through preferred pharmacies and retailers **and** offering a direct-to-consumer shipping option. There is significant flexibility to providing direct coverage through various mechanisms (e.g., coupons, drive-through distribution sites, existing online platforms for retailers), and there is enforcement relief in times of test supply shortages. Through a second safe harbor, plans are allowed to set limits on the number and frequency of OTC COVID-19 tests purchased. The OTC test coverage requirement applies to grandfathered plans but does not apply to retiree-only plans (i.e., plans with less than two participants who are active employees) or excepted benefit plans (e.g., vision only, dental only, FSA).
- Preventive care requirements for colonoscopies. For plan or policy years beginning on or after May 31, 2022, colonoscopies conducted as a follow-up to a positive non-invasive stool-based screening test or direct visualization screening test for colorectal cancer for individuals ages 45–75 are required preventive services under the ACA.
- Preventive care requirements relating to contraceptive services. In response to complaints and public reports of potential violations of the contraceptive coverage requirements, the FAQs make it clear that, under the ACA preventive care requirements, nonexempt plans must provide coverage for all FDA-approved, cleared, or granted contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual without cost-sharing, whether or not specifically identified in the current FDA Birth Control Guide.

Coverage for OTC COVID-19 Tests

Background

FAQs Part 51 provides the guidance promised by President Biden on December 2, 2021 for implementing coverage of OTC COVID-19 diagnostic tests as required by the Families First Coronavirus Response Act (FFCRA), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, and the Affordable Care Act (ACA). FAQs Part 52 is a response to questions raised by stakeholders regarding FAQs Part 51. Beginning March 18, 2020, the FFCRA has generally required group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) to cover certain items and services related to COVID-19 tests without cost-sharing, prior authorization, or other medical management. The CARES Act expanded the scope of covered items and services.

The coverage mandate applies for the duration of the public health emergency (PHE) relating to the COVID-19 pandemic, which has been renewed effective January 16, 2022. The coverage mandate does not apply to retiree-only plans or to excepted benefit plans. Under previously issued FAQs, plans are required to cover testing for asymptomatic individuals, but not for public health surveillance or employment purposes.

The departments clarified in FAQs Part 43 that the testing mandate applied to OTC COVID-19 tests intended for at-home testing if the test was ordered by an attending health care provider. FAQs Part 51 Q1 expands the coverage of at-home OTC COVID-19 tests to include those tests purchased for personal use, *without* a prescription, and that can be used and processed without the involvement of a laboratory or other health care provider. FAQs Part 52 Q4 clarifies that at-home specimen collection COVID-19 test kits that can be purchased over the counter but that require the specimen to be processed in a laboratory are *not* covered by the new mandate in Part 51; however, these types of tests must still be covered in accordance with the FFCRA if ordered by an attending health care provider. FAQs Part 51 reiterates that plans are not required to cover tests for public health surveillance or employment purposes. **In all cases, including under the safe harbors, required tests must be covered without imposing any cost-sharing requirements, prior authorization, or other medical management requirements.**

FAQs Part 51 provides two safe harbors that plans may use to satisfy the coverage mandate for obtaining OTC COVID-19 tests without a prescription: (1) a "direct coverage" safe harbor that allows plans to limit the dollar amount of reimbursements for OTC COVID-19 tests purchased from a nonpreferred seller to no more than $12 per test, so long as participants can obtain tests with no upfront out-of-pocket expenditure directly from a participating pharmacy or retailer *and* through a direct-to-consumer shipping program; and (2) a cap of eight tests per covered person, per 30-day period (or calendar month).

Initially, FAQs Part 51 left many unanswered questions about satisfying these safe harbors, and the departments responded with much-needed clarification in FAQs Part 52.

Direct coverage safe harbor

Plans cannot limit coverage of OTC COVID-19 tests to only those tests purchased through preferred pharmacies and retailers. However, FAQs Part 51 Q2 permits plans that satisfy a "direct coverage" safe harbor to limit reimbursement for tests from nonpreferred pharmacies and retailers to $12 per test (or actual price if lower). For tests that come more than one to a package, each test in the package can be treated as a single test for purposes of the $12 calculation. Plans may provide more generous reimbursement above the $12 limit (up to actual cost) if they choose to do so. The safe harbor is designed to encourage direct coverage of OTC tests without requiring an up-front payment by the plan participant, who must then seek reimbursement post-purchase, thus helping to remove potential financial barriers for participants.

To qualify for the "direct coverage" safe harbor and limit exposure to the cost of tests purchased from nonpreferred sources, Q2 of Part 51, as modified by Q1 of Part 52 (effective February 4, 2022), provides:

- A plan or issuer generally must make OTC COVID-19 tests available "through both its pharmacy network and a direct-to-consumer shipping program." However, Q1 of Part 52 provides some additional, albeit likely limited, leeway. The direct-to-consumer shipping program may be provided through in-network pharmacies and retailers, or through an entity designated by the plan. FAQs Part 52 Q1 allows for numerous options for direct coverage mechanisms:
  - Direct-to-consumer shipping mechanism. Any program that allows a participant to obtain an OTC COVID-19 test with no up-front cost and does not require them to pick up the test at an in-person location will meet the departments' safe harbor requirement for a "direct-to-consumer shipping program." A direct-to-consumer shipping mechanism can also include online or telephone ordering and may be provided through a pharmacy or other retailer, the plan directly, or any other entity on behalf of the plan. The program does not have to provide exclusive access through one entity, as long as it allows a participant to place an order for OTC COVID-19 tests to be shipped to them directly. For example, if a plan has opted to provide direct in-person coverage of OTC COVID-19 tests through specified retailers, and those retailers maintain online platforms where individuals can also order tests to be delivered to them, the departments will consider the plan to have provided a direct-to-consumer shipping mechanism.
  - In-person mechanisms. In-person mechanisms can include nonpharmacy retailers, distribution of coupons for OTC COVID-19 tests from certain retailers without cost-sharing, and alternative distribution sites established by, or on behalf of, the plan, such as a stand-alone drive-through or walk-up distribution site. Such sites can operate independently of a pharmacy or other retailer.
- "Direct coverage" means that the participant "is not required to seek reimbursement post-purchase; instead, the plan or issuer must make the systems and technology changes necessary to process the plan's or issuer's payment to the preferred pharmacy or retailer directly (including via a direct-to-consumer shipping program) with no upfront out-of-pocket expenditure by the participant." Q1 of Part 52 reiterates the "no upfront out-of-pocket expenditure" requirement of Part 51. Q2 of Part 52 adds that "plans and issuers must cover reasonable shipping costs [for the direct-to-consumer shipping mechanism] in a manner consistent with other items or products provided by the plan or issuer via mail order." For purposes of reimbursing a participant for a test purchased by a nonpreferred seller, sales tax and reasonable shipping cost related to the test are included in the total price and would need be to be covered, up to $12 per test. This means that if an OTC COVID-19 test purchased from a nonpreferred seller costs $10, and shipping plus tax totals $12 or more, the plan would be responsible for covering $12, and not $10.
- Individuals must have "adequate access" to OTC COVID-19 tests through an "adequate number" of retail locations (in-person and online). Adequate access is an "all relevant facts and circumstances" analysis, and Part 51 Q2 gives two examples: (1) the locality of participants or coverage; and (2) current utilization of the plan's pharmacy network by its participants. Part 52 provides that providing adequate access "will depend on the facts and circumstances, but will generally require that OTC COVID-19 tests are made available through at least one direct-to-consumer shipping mechanism and at least one in-person mechanism." Part 52 Q1, footnote 14, provides that there may be "some limited circumstances in which a direct coverage program could provide adequate access, and therefore satisfy the requirements of the safe harbor, without establishing both a direct-to-consumer shipping mechanism and an in-person mechanism." The footnote provides an example of a small employer plan with a population that lives and works in a localized area. For such a plan, it could be possible that no direct-to-consumer shipping program is needed so long as distribution at a nearby location provides adequate access to OTC COVID-19 tests. While there might be other limited circumstances beyond the example, the departments clearly contemplate both a direct-to-consumer shipping mechanism and an in-person mechanism in most instances.

- Part 52 Q1 clarifies that adequate access does *not* require a plan to make all eligible OTC COVID-19 tests available to its participants through its direct coverage program. Subject to an all relevant facts and circumstances analysis, a plan could limit the direct coverage program to designated manufacturers, such as those with whom the plan has a contractual relationship or from whom the plan has been able to obtain OTC COVID-19 tests directly. However, the safe harbor still requires the plan to reimburse, up to $12, any OTC COVID-19 test eligible under the FFCRA purchased from a nonparticipating provider.
- Key information needed to access OTC COVID-19 testing must be effectively communicated to participants, such as dates of availability of the direct coverage program, participating retailers or other locations, distribution sites, or other mechanisms for distributing tests, as well as which tests are available under the direct coverage program. Part 52 Q1 emphasizes that such notices should be very clear to explain which tests are available under the direct coverage program, and if the plan offers different mechanisms for obtaining tests under its direct coverage program, which tests are available under each mechanism. For example, if tests from Manufacturer X are available for direct coverage, but only from Provider A, then precise and accurate information must be communicated to participants. We recommend that plans have a process for keeping this information current, such as through a website.

Meeting the requirements of the direct coverage safe harbor under FAQs Part 51 has been burdensome for plans, and FAQs Part 52 Q1 has provided much-needed modification and guidance. In FAQs Part 52 Q2, the departments address the OTC COVID-19 testing supply shortage and provide some enforcement relief. Because of widespread shortages of OTC COVID-19 tests at the time FAQs Part 51 was issued, many plans were unable to meet the safe harbor even when making good-faith, diligent efforts to do so, putting into doubt whether the $12 cap for reimbursements for tests purchased from nonpreferred sellers could be applied.

While plans are still responsible for taking "reasonable steps" for ensuring accessibility of direct coverage options for obtaining OTC COVID-19 tests, and while plans should still avoid delays that are "significantly longer than the amount of time it takes to receive other items under the plan's or issuer's direct-to-consumer shipping program," FAQs Part 51 Q2 states that a plan will not fail to satisfy the direct coverage safe harbor if it has established a direct coverage program that otherwise meets the requirements (as revised by Q1 of FAQs Part 52) but is temporarily unable to provide adequate access due to a supply shortage. In that circumstance, a plan that otherwise complies with the safe harbor may continue to limit reimbursement to $12 per test (or the full cost of the test, whichever is lower) for OTC COVID-19 tests purchased from a nonpreferred provider.

Can an employer purchase OTC COVID-19 tests in massive quantities and provide them to plan participants in lieu of using a third party for the direct coverage program? FAQs Part 52 Q1 confirms that the direct coverage mechanisms can be flexible and include distribution directly by the plan or by an entity on behalf of the plan. Presumably, this is broad enough to include the employer. However, an employer designated by the plan to step in to take on the role of the direct-to-consumer shipping program or set up an in-person distribution site will face a number of logistical and compliance issues (e.g., HIPAA compliance).

For fully insured plans, states will not be considered to have failed to substantially enforce Section 6001 of the FFCRA if a state follows this safe harbor.

Monthly test limit safe harbor

FAQs Part 51 Q3 provides that plans can limit the number of OTC COVID-19 tests purchased to no more than eight tests per covered person per 30-day period (or per calendar month). FAQs Part 52 clarifies that a 30-day period can be a rolling 30-day period. This safe harbor is designed, in part, to discourage behaviors that could lead to future

shortages, such as stockpiling. The limit does not apply to COVID-19 tests purchased with a prescription or other health care provider involvement. Plans cannot set a lower limit, even if proportional with the safe harbor.

For example, a limit of four tests per 15-day period is not allowable under the safe harbor, even if the monthly outcome is the same. If several OTC COVID-19 tests come in one package, each test can be counted individually for purposes of enforcing the eight-test limit. Presumably, this means that only a pro-rata portion would need to be reimbursed for packages that exceed this limit. For example, if a package of 10 OTC COVID-19 tests costs $100, it is reasonable to assume that only $80 would be eligible for reimbursement in a given month (or 30-day period) for one covered person.

Because the safe harbor provides that the eight-test limit can be per 30-day period or per calendar month, plans should determine which unit of time to use and clearly communicate that to plan participants. Plans can have a higher limit but may wish to consider potential availability issues. FAQs Part 52 footnote 16 clarifies that a plan does not fail to meet this safe harbor due to a supply shortage of OTC COVID-19 tests. If a participant is unable to obtain eight tests in a 30-day period (or calendar month) due to a shortage, the plan will not be out of compliance.

Plan enforcement efforts to prevent fraud and abuse

FAQs Part 51 Q4 provides that plans can take reasonable steps to ensure that OTC COVID-19 test kits purchased without a prescription or health care provider involvement are being purchased for the permitted purpose of *personal use*, so long as they are not burdensome nor create significant barriers for participants. FAQs Part 52 Q2 also allows plans to protect against fraud and abuse for OTC COVID-19 tests purchased from a private individual, online auction, resale marketplaces, and resellers. Examples provided in FAQs Part 51 Q4 and FAQs Part 52 Q3 include:

- Requiring an attestation that the test is for a personal use, not employment purposes, will not be and has not been reimbursed by another source (such as a spouse's plan or health FSA), and will not be used for resale.
- Requiring documentation in the form of the UPC code of the test or a receipt from the seller with the purchase price and date of purchase.
- Limiting coverage to tests purchased from established retailers that would typically be expected to sell OTC COVID-19 tests.

The ability to exclude reimbursements for tests purchased from nontraditional sellers is significant for plans as a fraud and abuse deterrent. Should a plan implement such a policy, participants must be provided with accurate information about the retailers from which purchased tests are generally covered by the plan and general information about the types of resellers for which reimbursement will be declined.

There is flexibility in drafting the attestation form that FAQs Part 51 Q4 suggests because there is no model attestation form or claim form from the departments. We recommend using language that can be easily understood by the average participant. The differences between personal use and employment use for purposes of coverage should be clearly explained to avoid misunderstandings that could lead to delays in processing reimbursements. If the plan has a fraud and abuse rescission clause, this could be included in the attestation as both a reminder and acknowledgement of the consequences of serious fraud and abuse.

Plan communications on OTC COVID-19 coverage

Plan sponsors must provide notice of the coverage changes as soon as reasonably practicable. The notice would include:

- A statement of which plans must cover the OTC COVID-19 tests, taking care to exclude retiree plans and plans offering excepted benefits if OTC testing coverage is not extended.

- An explanation of the types of OTC tests covered. For example, clarify that only OTC tests that can be used and processed at home without the involvement of a laboratory or other health care provider are covered without a prescription and that other types of COVID-19 tests, including specimen-collection tests that must be processed in a lab, are not covered without a prescription.
- If using the direct coverage safe harbor, a detailed explanation about which tests are available under the direct coverage program, and if different mechanisms apply for obtaining tests from specific manufacturers, explain which tests are available under each mechanism. Also provide instructions for the process (e.g., take your insurance ID card to the pharmacy counter), locations, relevant contact information, dates of availability, and any other information necessary to ensure easy access and a seamless process for direct coverage.
- If using the monthly limit safe harbor, a clear explanation of the per-person limit, the time frame (i.e., fixed 30-day period, rolling 30-day period, or calendar month), and how multitest packs are counted and reimbursed.
- Information for participants on how to submit a claim for reimbursement (e.g., online, mail, fax), whether the claim should be submitted to the medical plan or the pharmacy benefit manager, and a description of the required documentation needed for substantiation.
- If the plan chooses to limit reimbursements for tests purchased from nonpreferred sellers to established retailers that would typically be expected to sell OTC COVID-19 tests, a clear explanation of the types of sellers that may be excluded (e.g., private individual, online auction, resale marketplaces, and resellers).

We also recommend including a reference to any applicable appeal procedures for denied claims. If a self-funded plan has a carve-out vendor or PBM for pharmacy, the communication should clarify whether the coverage is being provided through the pharmacy vendor, the group health plan, or both. Offering through both may present coordination challenges in limiting the tests to eight per month or 30-day period.

Although not required, education and consumer support can also be provided to participants. Any communication or resource must be clear that the plan covers OTC COVID-19 tests and be consistent with the emergency use authorization (EUA), including practical information to help consumers understand how OTC COVID-19 tests performed and read at home are different from tests performed by a doctor or processed in a laboratory. Consumer education materials should also offer guidance for assessing quality information for specific OTC COVID-19 testing products, such as shelf life and expiration dates, as well as reliability information about OTC COVID-19 test results, such as the expected rate of false positives and false negatives based on the test's labeling. Resources for where to find active FDA recalls of OTC COVID-19 tests would also need to be included in these communications. Plans and plan sponsors are not required to provide educational materials or consumer support, but if they choose to, these guidelines should be reviewed and followed.

Plan amendments

Nonenforcement policies provided in FAQs Part 42 Q9 apply here for purposes of communicating plan changes. As under that guidance, the departments will not take enforcement action against any plan that makes modifications consistent with the latest FAQs to provide greater coverage related to the diagnosis and treatment of COVID-19 without providing at least 60 days' notice. Plans must provide notice of the changes as soon as reasonably practicable. HHS will not take enforcement action against any health insurance issuer that changes the benefits or cost-sharing structure of its plans mid-year to provide increased coverage for services related to the diagnosis and treatment of COVID-19.

HRA/HSA/HDHP issues

As indicated in IRS News Release IR 2021-181, OTC COVID-19 tests are already eligible medical expenses for purposes of reimbursement under health flexible spending arrangements (health FSAs) and health reimbursement arrangements (HRAs). FAQs Part 52 Q5 provides some helpful guidance. When notifying participants of OTC coverage, plans should consider a notice to individuals not to use a health debit card or otherwise seek reimbursement from a health FSA or HRA for the cost (or the portion of the cost) of OTC COVID-19 tests paid or reimbursed by the plan. The health FSA or HRA administrator will also want to be prepared to assist individuals with correction procedures should they mistakenly receive reimbursement from a health FSA or HRA for OTC COVID-19 test costs covered by a plan.

Likewise, FAQs Part 52 Q5 explains that expenses incurred for OTC COVID-19 tests already paid or reimbursed by a plan are not HSA-qualified medical expenses, and an individual that mistakenly takes a distribution to pay for such test that has been paid for or reimbursed by the plan must either (1) include the distribution in gross income; or (2) if and as permitted under Q&A 37 and 76 of IRS Notice 2004-50, repay the distribution to the HSA.

High deductible health plans (HDHP) are not addressed in either FAQs Part 51 or 52. However, as with the preexisting testing mandate, the relief provided in IRS Notice 2020-15 should apply. That notice provides that, until further guidance is issued, HDHPs may provide coverage for COVID-19 testing and treatment before the deductible is met. The IRS may provide additional guidance on issues for HSAs and other account-based arrangements regarding the OTC testing coverage mandate.

Enforcement

FAQs Part 52 Q1 states that the departments may request information from plans and issuers to ensure that participants, beneficiaries, and enrollees have adequate access to OTC COVID-19 tests, such as the number and location of in-person options. In April 2020, the departments stated in FAQs Part 42 that "Our approach to implementation is and will continue to be marked by an emphasis on assisting (rather than imposing penalties on) group health plans, health insurance issuers and others that are working *diligently and in good faith* to understand and come into compliance with the new law." It is hoped that the departments will be lenient as plans work in good faith to put systems in place to come into compliance with the testing requirements in FAQs Part 51, as modified and clarified by Part 52.

That said, FFCRA Section 6001(b) provides that the testing provisions (which now include the OTC requirement) "shall be applied by" HHS, DOL, and Treasury "as if included in the provisions of" the Public Health Service Act (PHSA), the Employee Retirement and Income Security Act (ERISA), and Chapter 100 of the Internal Revenue Code (IRC) that contain the ACA requirements. ERISA comes with DOL enforcement, and a violation of Chapter 100 of the IRC carries with it the $100 per person per day penalty under Code Section 4980D pursuant to Code Section 9834. This $100 per day penalty would be in addition to paying the full amount for the test (i.e., excess over $12 if a direct coverage violation is found).

Effective date

The requirement to cover OTC COVID-19 tests as set forth in FAQs Part 51 is effective for tests purchased on or after January 15, 2022 until the end of the COVID-19 PHE. Plans may provide coverage for OTC COVID-19 tests purchased without an order or individualized clinical assessment before January 15, 2022. The modifications provided in FAQs Part 52 Q1 are effective as of February 4, 2022.

Preventive Care Requirements Under the ACA

The ACA requires non-grandfathered group health plans, other than retiree plans or plans providing only excepted benefits, to cover certain preventive care items and services without cost-sharing. In Q8 and Q9, FAQs Part 51 addresses two issues under the ACA preventive care requirements: colonoscopies and contraceptive coverage requirements. The preventive care requirements do not apply to retiree-only plans or excepted benefit plans.

Colonoscopies

For individuals 50–75 years old, non-grandfathered group health plans and health insurance issuers have had to cover, without any cost-sharing requirement, colonoscopies scheduled and performed as a screening procedure pursuant to the U.S. Preventive Services Task Force (USPSTF) recommendation. Any items and services that are an integral part of performing the colonoscopy likewise must be covered without cost-sharing.

On May 18, 2021, the USPSTF updated its recommendation for colorectal cancer screening by extending it to adults aged 45 to 49 years. In addition, the updated recommendation includes a follow-on colonoscopy conducted after a positive noninvasive stool-based screening test or direct visualization screening test for colorectal cancer for individuals ages 45–75. As stated in USPSTF recommendation, the follow-up colonoscopy is an integral part of the preventive screening without which the screening would not be complete.

FAQs Part 51 provides that the USPSTF recommendation is considered to have been issued as of May 31, 2021. Thus, in accordance with the ACA, non-grandfathered plans must provide coverage without cost-sharing consistent with the May 18, 2021 recommendation effective for plan or policy years beginning on or after May 31, 2022.

Contraceptive coverage

Under the ACA preventive care requirements, nonexempt plans are required to cover all FDA-approved, cleared, or granted contraceptive products that are determined by an individual's medical provider to be medically appropriate for such individual without cost-sharing, whether or not specifically identified in the current FDA Birth Control Guide. Reports and complaints over the years indicate that participants are being denied contraceptive coverage in violation of some of these safeguards. The departments are actively investigating these complaints and reports and may take enforcement or other corrective actions.

The departments are also assessing what types of changes to existing guidance or regulations may need to be made to better ensure individuals receive the coverage they are entitled to under the law and will issue additional guidance. Plans and issuers should revisit their mechanisms and processes used to review these claims and requests.

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