ACA, HIPAA AND FEDERAL HEALTH BENEFIT MANDATES: PRACTICAL Q&A

The Affordable Care Act (ACA), the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other federal health benefit mandates (e.g., the Mental Health Parity Act, the Newborns and Mothers Health Protection Act, and the Women's Health and Cancer Rights Act) dramatically impact the administration of self-insured health plans. This monthly column provides practical answers to administration questions and current guidance on ACA, HIPAA and other federal benefit mandates.

Attorneys John R. Hickman, Ashley Gillihan, Carolyn Smith, Ken Johnson, Amy Heppner, and Laurie Kirkwood provide the answers in this column. Mr. Hickman is partner in charge of the Health Benefits Practice with Alston & Bird, LLP, an Atlanta, New York, Los Angeles, Charlotte, Dallas and Washington, D.C. law firm. Ashley, Carolyn, Ken, Amy, and Laurie are senior members in the Health Benefits Practice. Answers are provided as general guidance on the subjects covered in the question and are not provided as legal advice to the questioner's situation. Any legal issues should be reviewed by your legal counsel to apply the law to the particular facts of your situation. Readers are encouraged to send questions by E-MAIL to Mr. Hickman at john.hickman@alston.com.

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.

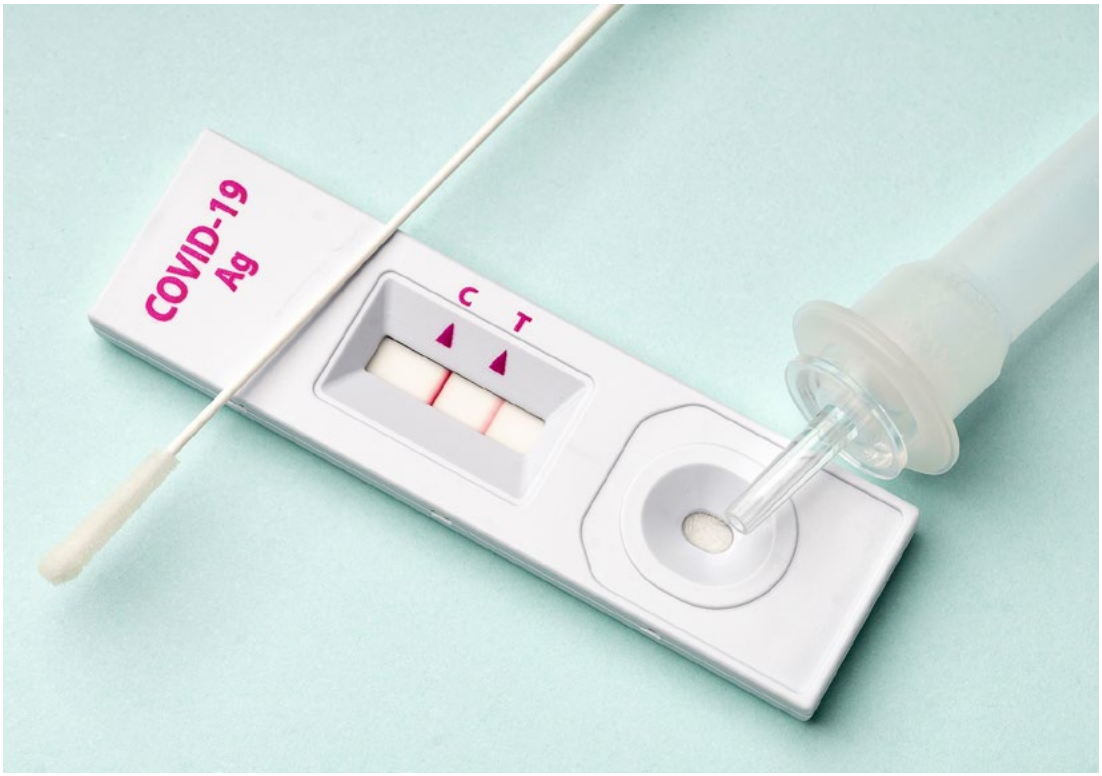
DIRECT COVERAGE SAFE HARBOR

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.

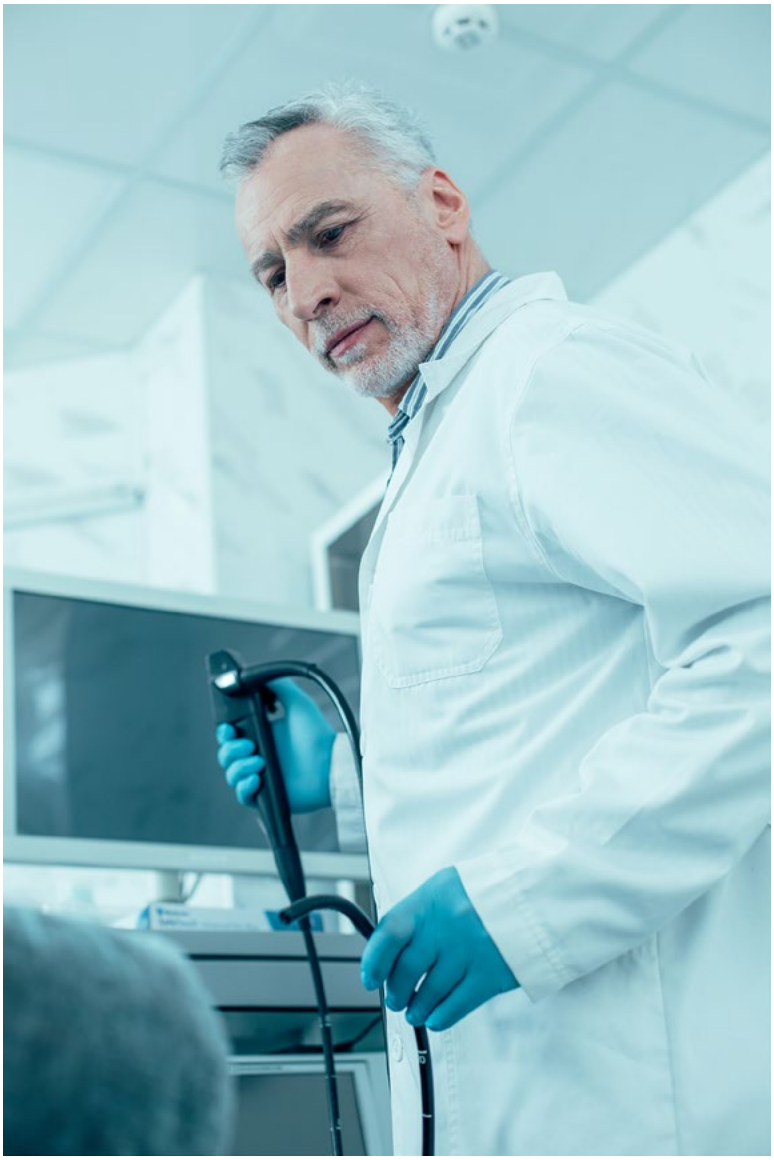
High deductible health plans (HDHP) are not addressed in either FAQs Part 51 or 52. However, as with the preexisting testing mandate, the relief provided in IRS Notice 2020-15 should apply.

That notice provides that, for the duration of the PHE, 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. ■