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New Lawsuits Challenge DOL Fiduciary Rule

A new lawsuit has been filed challenging the Department of Labor's (DOL) interpretation of ERISA fiduciary

investment advice with respect to "cold calls" encouraging ERISA plan participants to roll their account balances into Individual Retirement Accounts (IRAs).

The suit was filed by the American Securities Association in the federal district court for the middle district of Florida. An earlier suit filed by the Federation of Americans for Consumer Choice in a Texas district court is challenging the validity of the DOL fiduciary rule, which took effect in February 2021 but did not start being enforced until February 1, 2022.

The issues in the two cases are different, but both are essentially an extension of a debate that has been ongoing since 2010 – when the DOL first tried to implement a new fiduciary rule.

The new rule retains the 5-part test for determining when someone is a fiduciary by virtue of providing investment advice with respect to ERISA plan assets for a fee, which has been in place since 1975. However, it interprets the test in ways that effectively expands the test's reach, especially with respect to rollovers from plans to IRAs.

The most recent lawsuit specifically targets sub-regulatory guidance the DOL issued in April 2021 in the form of "frequently asked questions" (FAQs). In particular, Q/A-7 stated that recommending an individual roll assets out of an ERISA plan can be the basis for fiduciary status even though no pre-existing investment advice relationship existed.

Read Rewards Policy Insider for updates on these cases and other issues relating to the new fiduciary rule.

Texas District Court Finds that Providers Can Bring Suit to Enforce COVID-19 Test Coverage Requirement

A District Court in Texas determined in late January that a provider of COVID-19 diagnostic testing can bring an action to enforce the COVID-19 testing reimbursement requirement under the FFCRA and the CARES Act. The case does not involve the Department of Labor's recent guidance relating to coverage of over-the-counter COVID-19 tests, but it does involve the same statutory provisions.

Background

The Families First Coronavirus Response Act ("FFCRA") and the Coronavirus Aid, Relief, and Economic Security ("CARES") Act require group health plans and health insurance issuers to cover COVID-19 diagnostic testing by qualified providers at no cost to their patients. The plan or insurer must generally

reimburse the provider based on their negotiated rate, or a cash price that the provider publishes on its website.

Case Overview

In *Diagnostic Affiliates of Northeast Houston, LLC v. United Healthcare Services*, Case No. 2:21-cv-00131, plaintiff Diagnostic Affiliates of Northeast Houston ("Diagnostic Affiliates") filed an action in the District Court for the Southern District of Texas against United Healthcare Services and its affiliates ("United") to recover payments for COVID-19 testing and related services. Diagnostic Affiliates had provided COVID-19 testing to individuals insured by United at its public cash price of $900 per test and claimed that United had then delayed, denied, or reduced payments of the claims. Diagnostic Affiliates alleged that these actions were in violation of the FFCRA and the CARES Act, while United argued that the suit should be dismissed because the FFCRA and the CARES Act did not provide a private right of action for providers to enforce their reimbursement claims.

The District Court agreed with Diagnostic Affiliates and denied the motion to dismiss, finding that there was an implied right of action under the statutes for a provider to enforce the right to reimbursement of COVID-19 testing against insurance plans and administrators. In addition to concluding that the mandatory reimbursement language in the laws supported finding a private right of action for claims for reimbursement, the court also reasoned that Congress wanted widespread COVID-19 testing, which could only be accomplished by private entities quickly incurring the cost of establishing testing sites across the country and procuring the supplies to administer tests.

Outlook

As a general matter, district court decisions have limited legal effect. However, providers and insurers alike should still monitor this case as it moves forward. Similar actions have been filed in Connecticut (*Murphy Med. Assocs., LLC et al. v. Cigna Health and Life Ins. Co. et al.*, Case No. 3:20-cv-01675-JBA; *Murphy Med. Assocs., LLC et al. v. Yale Univ. et al.,* Case No. 3:22-cv-00033) and New Jersey (*Genesis Lab. Mgmt. LLC v. United Health Grp. et al.*, Case No. 3:21-cv-12057-ZNQ-TJB), as well as a separate Diagnostic Affiliates' case brought against Cigna in Texas (*Diagnostic Affiliates of Northeast Houston, LLC v. Cigna Health and Life Ins. Co. et al.*, Case No. 2:22-cv-00007), and it is likely that this recent court order will spur even more reimbursement-related litigation.

DOL Supplements Guidance on Covering Over-the-Counter COVID-19 Tests

The Department of Labor on February 4 issued additional guidance to supplement and clarify its previous guidance implementing the requirement for group health plans to cover over-the-counter (OTC) COVID-19 tests for at home use without a prescription. Among other things, the "Supplemental FAQs" provide significant new detail on the "direct coverage" safe

harbor that plan sponsors must use in order to be able to limit reimbursements for tests obtained from non-preferred providers to no more than $12 per test.

"Direct Coverage" Safe Harbor

The key requirements of the "direct coverage" safe harbor are as follows:

- The plan must provide direct coverage through both its pharmacy network and a direct-to-consumer shipping program;
- Participants who obtain OTC COVID-19 tests through the plan's pharmacy network and designated direct-to-consumer shipping program do not incur any upfront out-of-pocket costs; and
- The plan takes reasonable steps to ensure participants have "adequate access" to OTC COVID-19 tests through an "adequate number" of in-person and online retail locations.

According to the Supplemental FAQs, whether a plan provides "adequate access" through its direct coverage program will be a facts and circumstances determination. However, the Supplemental FAQs also states that "adequate access" generally requires that "OTC COVID-19 tests are made available through at least one direct-to-consumer shipping mechanism and at least one in-person mechanism."

Additionally, the Supplemental FAQs clarify that "adequate access" does not require a plan's direct coverage program to include all otherwise available OTC COVID-19 tests. A plan could limit its direct coverage program to tests from a limited number of manufacturers, such as those the plan has a contractual relationship with. However, a plan still must cover all OTC COVID-19 tests that meet the statutory requirements.

The Supplemental FAQs also clarify that a plan's direct coverage program will be able to take advantage of the safe harbor even if it is temporarily unable to meet the "adequate access" standard due to a supply shortage.

There are a number of mechanisms for providing direct coverage. These include:

- A direct-to-consumer shipping program that accepts orders online or by telephone;
- The plan's pharmacy network;
- Other non-pharmacy retailers, including giving coupons to participants to obtain free tests from certain retailers; and
- OTC COVID-19 test distribution sites that the plan establishes for participants.

The Supplemental FAQs clarify that a direct-to-consumer shipping mechanism is any program the provides direct coverage of OTC COVID-19 tests to participants, and that does not require them to go to an in-person location to obtain them. Such programs can be provided by a pharmacy or other retailer, directly by the plan, or by any other entity on the plan's behalf.

If a plan uses a third-party, it does not have to be an exclusive arrangement with the plan. For example, a plan could contract with a retailer that maintains an online ordering platform that is available to the public at large.

The Supplemental FAQs also provide that plans "must cover reasonable shipping costs … in a manner consistent with other items or products provided

by the plan or issuer via mail order." This issue was not addressed in the initial FAQs.

Regarding in-person mechanisms, the Supplemental FAQs provide that participants must have access through an "adequate number" of locations "which could include pharmacies and other retailers, or independent distribution sites set up by, or on behalf of, a plan or issuer." Relevant facts and circumstances to consider for purposes of determining compliance with this "adequate number" standard include:

- Locality of the plan's participants;
- Current utilization of the plan's pharmacy network if coverage is available through such network; and
- How the plan notifies participants of the retail locations, distribution sites, or other mechanisms, and which tests are available under the direct coverage program.

On audit, the Supplemental FAQs state the Departments might ask plans to provide information about the number and location of in-person options, among other things, in order to determine if the safe harbor requirements are being met.

Whatever mechanisms a plan uses, the Supplemental FAQs make clear that plans have to make sure that participants have the information they need to access OTC COVID-19 tests. If different mechanisms are used, the information must include which tests are available under each mechanism.

Other Guidance

According to the Supplemental FAQs, plans can limit coverage to OTC COVID-19 tests purchased from "established retailers that would typically be expected to sell OTC COVID-19 tests." In other words, plans do not have to reimburse participants for tests purchased from individuals (either in-person or online), or from sellers using online auctions or resale marketplaces. However, if plans are going to implement such limits, they must clearly communicate to participants about the types of retailers that they can use if they expect to be reimbursed by the plan.

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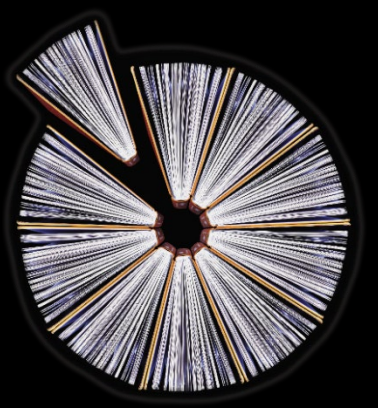

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