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The Latest on Pharmaceutical Company-Sponsored Diagnostic Testing Programs

Jesse A. Witten and Kennedy Ferry*

In this article, the authors examine an advisory opinion issued by the Office of Inspector General of the U.S. Department of Health and Human Services that approved a pharmaceutical manufacturer's program to sponsor genetic testing and counseling.

Pharmaceutical company sponsorship of diagnostic testing remains an area with a gaping divide between the views of regulators and industry, with regulators focused on potential fraud and abuse concerns while industry emphasizes the obvious benefits to patients of early and accurate diagnosis. The most recent regulatory development occurred on December 17, 2024, when the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) issued Advisory Opinion No. 24-12 (AO 24-12),[1] which approved a pharmaceutical manufacturer's program to sponsor genetic testing and counseling. This is the OIG's second favorable opinion regarding free genetic testing and counseling offered by a pharmaceutical company. Previously, the OIG issued Advisory Opinion No. 22-06, approving a biopharmaceutical company's proposed arrangement to provide free genetic testing and counseling to patients.

Background

In AO 24-12, the requestor was a pharmaceutical company that manufactures a drug to treat a subtype (Subtype 1) of an "ultra-rare genetic condition," which can lead to recurrent kidney stones and chronic kidney disease. The requestor's drug is the second drug of its kind approved to treat Subtype 1. Not all patients diagnosed with Subtype 1 are prescribed the requestor's drug.

Under the arrangement approved by the OIG, the requestor provides general disease-state awareness education, free genetic

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testing, and free genetic counseling. The requestor pays for genetic testing for eligible patients whose health care provider attests that the patient meets certain clinical or family medical history criteria. The eligible patient's provider would choose to order one of three commercially available genetic testing panels under the arrangement. The first testing panel is a 45-gene panel that tests for several genetic disorders associated with kidney stone diseases, most of which are rare or ultra-rare diseases. In most cases, this testing panel would be used to rule out conditions, rather than to diagnose a specific condition. The second testing panel tests for the three subtypes of the condition. The third testing panel tests for a specific variant or mutation that has been seen in a direct relative of the eligible patient.

If the genetic test is inconclusive, the requestor also pays for a Condition Urine Metabolic Assay. Finally, the requestor pays for optional genetic counseling, which is provided in 15-minute increments before receiving the test and after receiving the results. Genetic counselors are prohibited from discussing the requestor's drug or any other potential treatment with patients or health care providers.

The requestor has written agreements with a lab and its subsidiary, under which the lab or subsidiary has agreed to furnish the genetic testing, genetic counseling, and certain administrative services related to the arrangement. The requestor pays fixed fees that are set in advance and consistent with fair market value for the services provided by the lab and its subsidiary. The provider ordering the test must acknowledge on the order form that the provider agrees not to bill for any genetic testing or counseling services provided under the arrangement.

The requestor does not receive identifiable patient data, nor does it receive information identifying health care professionals who order tests under the arrangement from the lab or its subsidiary. Neither patients nor payors are billed for the genetic testing or counseling, and participation in the arrangement is not conditioned on the use of the requestor's drug or any other product manufactured by the requestor.

The OIG's Analysis

The OIG concluded that the requestor's arrangement implicates the Anti-Kickback Statute (AKS) because it results in remuneration

to patients and health care professionals that may induce the purchase or prescription of the requestor's drug. According to the OIG, the arrangement also implicates the beneficiary inducement provision of the Civil Money Penalties Law because the provision of a free genetic test, possible free Assay, and free genetic counseling services could influence a beneficiary to seek follow-up care from the health care provider who ordered the test.

Nonetheless, the OIG issued a favorable advisory opinion, finding that the risk of fraud and abuse is sufficiently low for the following three reasons.

Low Risk of Overutilization or Inappropriate Utilization

The OIG viewed the safeguards related to how a patient obtains free genetic testing as sufficient. Patients are only eligible for free testing if they meet certain "narrow eligibility criteria," consisting of clinical and family history criteria. Additionally, neither the patient nor any payor can be billed for any component of the genetic test or counseling. Finally, the condition is ultra-rare, and in most cases, the sponsored testing will rule out conditions, rather than result in a diagnosis of the condition that the requestor's drug treats.

Low Risk of Skewing Clinical Decision-Making and Low Risk of Patient Safety/Quality Concerns

The OIG noted that the genetic tests offered under the arrangement are commercially available, and the arrangement does not incentivize providers to recommend or prescribe products manufactured by the requestor. "Importantly," the requestor cannot engage in targeted marketing based on the arrangement because it does not receive any identifiable patient data or information identifying prescribers who order the tests.

Low Risk of Fraud and Abuse Based on Remuneration Provided to the Lab and Subsidiary

Although the lab and subsidiary that provide the genetic testing and counseling could be referral sources for the requestor's drug, the OIG identified certain safeguards that limit the risk of fraud and abuse. Specifically, the requestor pays fixed fees for the services

provided by the lab and subsidiary, the genetic counselors do not provide information about potential treatments, and neither the lab nor the subsidiary provide the requestor with data that would allow the requestor to identify prescribers or eligible patients.

Recent Enforcement Actions

Despite its approval of the arrangements in AO 22-06 and AO 24-12, the OIG cautioned in both opinions that it "would likely reach a different conclusion" for "this type of arrangement" if the facts were different or if there were "a more direct nexus" between the free genetic test and counseling services and the purchase of the drug manufactured by the requestor. In other words, the favorable opinions were based on the specific facts presented, and free genetic testing programs with other terms and conditions may well continue to face scrutiny. The threat of scrutiny and enforcement is evidenced by recent False Claims Act settlements.

In December 2023, Ultragenyx Pharmaceutical Inc. agreed to pay $6 million to resolve allegations that it paid illegal remuneration in the form of free genetic testing and counseling in exchange for referrals and to induce the purchase of a drug it manufactures to treat a rare inherited disorder. According to the settlement agreement,[2] Ultragenyx paid a lab to conduct genetic tests at no cost to patients or health care providers, and it separately paid the lab to provide Ultragenyx with test results, which it used to find potential patients for its drug and follow up with their health care providers to market the drug.

In November 2024, QOL Medical LLC and its chief executive officer agreed to pay $47 million to resolve allegations that it offered illegal kickbacks, in the form of free Carbon-13 breath tests, to induce claims for its drug that treats a rare genetic condition causing chronic gastrointestinal symptoms. According to the settlement agreement,[3] among other things, QOL provided free Carbon-13 breath tests to health care providers and asked the providers to give the kits to patients with common gastrointestinal symptoms. QOL allegedly paid a lab to analyze and report the results, including names of health care providers who ordered the test, to QOL. QOL used the results to make sales calls for the drug to health care providers whose patients tested positive on the breath test.

Both the Ultragenyx and QOL cases were triggered by the filing of qui tam lawsuits by whistleblowers.

In Summary

- The OIG concluded that the requestor's arrangement implicates the AKS because it results in remuneration to patients and health care professionals that may induce the purchase or prescription of the requestor's drug.
- Nonetheless, the OIG issued a favorable advisory opinion, finding that the risk of fraud and abuse is sufficiently low for three reasons:
    1. Low risk of overutilization or inappropriate utilization,
    2. Low risk of skewing clinical decision-making and low risk of patient safety/quality concerns, and
    3. Low risk of fraud and abuse based on remuneration provided to the lab and subsidiary.
- The OIG has issued two favorable advisory opinions to such arrangements, but both opinions warn that the OIG would "likely" have issued a negative opinion if there had been a "more direct nexus" between the free testing and the purchase of the drug. In the absence of a regulatory safe harbor, it appears that the OIG will provide regulatory guidance only on a case-by-case basis.

Conclusion

The provision of free genetic and diagnostic testing by pharmaceutical companies is an emerging area of regulatory uncertainty. The OIG has issued two favorable advisory opinions to such arrangements, but both opinions warn that the OIG would "likely" have issued a negative opinion if there had been a "more direct nexus" between the free testing and the purchase of the drug. In the absence of a regulatory safe harbor, it appears that the OIG will provide regulatory guidance only on a case-by-case basis.

Notes

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1. https://oig.hhs.gov/documents/advisory-opinions/10117/AO-24-12.pdf.

2. https://www.justice.gov/archives/opa/media/1330036/dl?inline.
3. https://www.justice.gov/usao-ma/media/1376406/dl.