

OIG Approves Pharmaceutical Manufacturer-Sponsored Genetic Testing and Counseling Arrangement

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The U.S. Department of Health and Human Services Office of Inspector General (OIG) published a favorable advisory opinion, [Advisory Opinion 22-06](#), approving an arrangement through which a biopharmaceutical company (the Requestor) provides free genetic testing and genetic counseling to patients who are diagnosed with, or suspected of having, a condition for which the manufacturer has approved medications. Released earlier this month, Advisory Opinion 22-06 is the first OIG advisory opinion to approve such an arrangement. However, according to OIG, had there been a closer nexus between the free services offered and sales of the company's products, the agency would likely have reached a different conclusion. The key factors leading to OIG's approval of the arrangement are set forth below.

The Proposed Arrangement

The Requestor manufactures two forms of a Food and Drug Administration–approved medication indicated for treating a rare disease that can occur spontaneously or as a hereditary condition and that can lead to heart failure and death. As part of the proposed arrangement, the Requestor offers a free genetic test to screen for specific gene mutations and free genetic counseling services to individuals who are 18 and older, reside in the U.S., and meet one of the following clinical criteria:

- the individual has a diagnosis for the disease at issue,
- the individual's physician suspects the individual has the disease based on clinical evidence but has not made a diagnosis, or
- the individual has not been diagnosed with the disease but has a family member with a confirmed diagnosis of the hereditary form of the disease.

Any physician can order genetic testing through the arrangement for any patient who meets the criteria, and, in doing so, the physician must attest both that the patient is eligible for the test and that the test is clinically appropriate. Those eligible to receive a genetic test also have the option of receiving genetic counseling, if requested by the ordering physician.

The genetic test provided through the arrangement detects specific mutations associated with the disorder but cannot diagnose the disease. Instead, the test provides certain other benefits, such as revealing whether a patient has the hereditary or spontaneously occurring form of the disease, which has implications for the pace of disease progression, and flagging gene mutations in patients who are related to someone who has the hereditary form of the disease, thereby increasing the likelihood of monitoring that patient for cardiac disease. The opinion states that only approximately 10% to 20% of patients with the relevant gene mutation will develop the disease treated by the manufacturer's medications. Moreover, the disease is rare and its symptoms are nonspecific. As a result, patients with the disease often do not receive a correct diagnosis for many years, which factored into OIG's analysis.

The opinion reflects several safeguards surrounding the Requestor's communications about the arrangement with prescribers, patients, and patient advocacy organizations.

With respect to prescribers, the opinion reflects that the Requestor's sales representatives distribute a limited number of specimen collection kits and materials about the arrangement to physicians, but these items are not distributed in a manner that takes into account physician usage of the arrangement or historic prescribing patterns. Further, the Requestor does not proactively provide information directly to patients or potential patients about the arrangement, although information may be provided through the Requestor's patient support program on a reactive basis to patients who have already received a prescription for the Requestor's product. Likewise, the Requestor provides information about the arrangement to patient advocacy groups who request information about patient support programs.

As part of the arrangement, the Requestor contracts with vendors to provide the genetic testing and genetic counseling described above. The relevant contracts specify that the vendors may not bill any third party for the services furnished pursuant to the arrangement, including any insurer or patient, and also prohibit the vendors from promoting the Requestor's products to patients, family members, providers, or payors.

The Agency's Analysis

According to OIG, the arrangement results in remuneration to both eligible patients and their physicians, thereby implicating the Anti-Kickback Statute (AKS) and the beneficiary inducement prohibition under the Civil Monetary Penalty Statute (CMP) — two laws aimed at curtailing fraud and abuse under Medicare, Medicaid, and other federal healthcare programs. With respect to patients, OIG noted that free genetic testing and counseling are "inherently valuable" and could induce patients to purchase the Requestor's products or influence the selection of a particular provider, practitioner, or supplier. With respect to physicians, OIG noted that the arrangement confers value that may induce prescriptions by creating an opportunity for physicians to bill for other services.

Nevertheless, OIG concluded that the arrangement posed a low risk of fraud and abuse under the AKS and the CMP, based primarily on the following factors:

- First, OIG concluded the arrangement is unlikely to lead to overuse or inappropriate use. This is principally because the results of the genetic test indicate only whether a patient carries one of the gene mutations, and presence of a gene mutation does not determine whether a patient has, or will develop, the disease and is not, standing alone, a medically appropriate basis to prescribe the manufacturer's medications. Further, OIG was persuaded by the manufacturer's certification that it

does not promote the use of the medications for patients who have not been diagnosed with the disease and that it does not have any financial interest in any other items or services used to treat or diagnose the disorder or related disease. OIG also highlighted the fact that the genetic testing covers only specific gene mutations, which have limited utility, and explained that if the free genetic testing covered a wider, unrelated range of genetic mutations, the arrangement could present a higher risk of overuse and inappropriate use.

- Second, OIG concluded the arrangement is unlikely to skew clinical decision making or raise concerns regarding patient safety or quality of care. OIG explained that the manufacturer does not require or otherwise incentivize providers who order the free testing to recommend, prescribe, or use the manufacturer's products. Moreover, use of the genetic testing may help improve patient safety and quality of care by helping patients get to a correct diagnosis and avoid inappropriate or harmful treatments.

- Third, OIG found that there are various safeguards in place to prevent use of the arrangement as a sales or marketing tool, including that the manufacturer's sales representatives do not distribute materials or specimen collection kits in a manner that takes into account a provider's historical prescribing of the Requestor's products or any other therapy used for the disease, and the manufacturer imposes caps on the number of kits a sales representative may distribute to any physician. OIG also found that there is a number of limitations on the exchange of data relating to the arrangement, and the terms of the manufacturer's contracts with the testing vendor and counseling vendor prohibit such entities from discussing treatment options with patients or their family or promoting the Requestor's products.

OIG's opinion comes amid the agency's increased interest in payment issues related to genetic testing, which it addressed in a report on the subject released in December. In that report, OIG noted that Medicare payments for genetic testing have quadrupled for calendar years 2016 through 2019, among other key statistics. OIG stated that while the reasons for the increase in genetic testing may be legitimate, the increase could also indicate areas of possible concern, such as excessive or fraudulent testing. The Department of Justice and certain state agencies have also increased their scrutiny in this area, as have various national news media.

In light of the scientific advances allowing for a focus on personalized medicine, along with increased government agency and media focus on genetic testing, the opinion provides an additional source of guidance for manufacturers that seek to raise access to tests through manufacturer-sponsored patient access and support programs.

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