OIG Permits Drug Manufacturer to Sponsor Genetic Testing and Counseling



2/7/2025

On December 17, 2024, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued a favorable Advisory Opinion regarding a drug manufacturer's request to sponsor genetic testing, counseling, and education for patients with a rare genetic condition that affects the kidneys and potentially causes end-stage renal disease (the Arrangement). The drug manufacturer proposed the Arrangement to address limited insurance coverage for genetic testing needed to diagnose this condition, offering to cover the full cost of one genetic test, including necessary follow-up assays and counseling for eligible patients.

The OIG determined that the Arrangement implicates the Federal Anti-Kickback Statute and the civil monetary penalty provision prohibiting inducements to beneficiaries due to potential remuneration to providers that could induce drug prescriptions and remuneration to beneficiaries that could influence them to seek follow-up care from the healthcare professional who ordered the genetic testing and assay. However, the OIG concluded that the fraud and abuse risks associated with the Arrangement are low for the following reasons:

1. There are safeguards against overutilization as the tests are narrowly focused on rare conditions, often ruling out diagnoses rather than confirming them.

2. There is minimal influence on clinical decision-making as providers are not incentivized to prescribe or recommend the manufacturer's products.

3. There is a low risk of fraud given that fixed fees are paid for lab and counseling services, genetic counselors focus solely on

genetic tests and diseases and avoid treatment discussions, and data provided to the manufacturer does not identify patients or providers.

Accordingly, the OIG stated that it will not take action against the drug manufacturer for activities conducted as part of the Arrangement.

Click Here to read the entire February 2024 Healthcare Law Update now!

For more information, contact:
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com
Vanessa Coleman | 973.364.5208 | vcoleman@bracheichler.com

Authors

The following attorneys contributed to this insight.



Carol Grelecki

Member
Healthcare Law

973.403.3140 · 973.618.5540 Fax

cgrelecki@bracheichler.com



Edward J. Yun

Member
Healthcare Law

973.364.5229 · 973.618.5589 Fax

eyun@bracheichler.com



Vanessa Coleman

Associate
Healthcare Law

973.364.5208 · 973.618.5566 Fax

vcoleman@bracheichler.com