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Decoding DOJ's Crackdown on Genetic Testing: High-Profile Indictments and Practical Takeaways for the Cancer and Pharma Genomics Industries

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In the advent of DNA testing, companies such as Ancestry.com and 23andMe have made it easy and convenient to submit DNA samples for testing from your own home. This type of genetic—also known as genomic—testing has been applied to a variety of uses, including paternity determinations and the discovery of genetic ancestors and relatives. It is no overstatement to note that genetic testing has also revolutionized the health care industry, making it possible to asses a person's risk of developing certain genetic diseases and response to certain types of treatments. For example, cancer genomic (CGx) testing uses DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain types of cancers in the future. In addition, pharmacogenetic (PGx) testing has been used to detect specific genetic variations in genes that impact the metabolism of certain medications and, thus, help determine the effectiveness of such medications if used by a particular patient.

Nonetheless, such uses have also attracted the attention of federal prosecutors, who have begun cracking down on allegedly fraudulent schemes to market, prescribe, and obtain Medicare reimbursements for CGx and PGx tests, particularly in the absence of sufficient indicators of medical necessity.

Given the government's hawk-eyed view of the genetic testing industry, this article provides an overview of the government's recent indictments involving genetic testing, the government's main theories and concerns in those cases, as well as some practical take-aways to consider.

Recent Indictments and Collateral Consequences

Over the last six months, the U.S. Department of Justice (DOJ) has announced a string of charges—spanning multiple federal districts—against dozens of doctors, genetic laboratory owners, and marketers allegedly involved in conspiracies to commit—and the substantive commission of—health care fraud violations, including the payment and receipt of unlawful kickbacks.

In a particularly large takedown in September of 2019, DOJ announced charges in five federal districts, against 35 defendants, for their alleged participation in health care fraud and kickback schemes, through which $2.1 billion was billed to Medicare for CGx testing.[1]

In relevant part, CGx labs were accused of paying kickbacks and bribes to medical professionals who, in turn, prescribed CGx testing to Medicare beneficiaries—testing, which the government alleges was medically unnecessary and ineligible for Medicare reimbursement. The government alleges the defendants often used telemedicine companies, through which doctors who did not actually treat—or in some cases, even speak with—beneficiaries, nevertheless issued prescriptions.

These charges were part of a concerted initiative and partnership among the Federal Bureau of Investigation, the Drug Enforcement Administration, the U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG), the Medicare Fraud Strike Force and Health Care Fraud Unit of the DOJ's Criminal Division Fraud Section, and U.S. Attorney's Offices in Florida, Georgia, Louisiana, Texas, and New Jersey.

In January of this year, guilty pleas were entered in similar, but smaller, takedowns in the Eastern District of Texas and Pittsburgh. In Pennsylvania, the defendant admitted to participating in conspiracies and violations of the Anti-Kickback Statute for conduct that involved billing Medicare for CGx and PGx testing within a coverage area offering the highest reimbursement rates in the United States. As part of the plea agreement, the defendant agreed to make restitution to CMS in an amount just over $77 million.[2] And in a case investigated by HHS-OIG and the U.S. Department of Homeland Security, 12 individuals were indicted in Texas for conspiracy to commit illegal renumerations in violation of the Anti-Kickback Statute. One individual has already pled guilty to conspiracy to defraud the United States for conduct involving the payment and receipt of more than $28 million in illegal kickback payments in exchange for the referral and arrangement of PGx testing.[3]

Potential sentences for each charge range from five to ten years in prison, fines of $250,000, or both. In addition, the Centers for Medicare & Medicaid Services (CMS) also took adverse administrative action against the CGx testing companies and medical professionals allegedly involved in the multi-jurisdictional scheme, the consequences of which can range from the implementation of corporate integrity agreements to exclusion from federal health care programs. Importantly, CMS has been aggressive in its efforts to use claims review and beneficiary education to identify fraud in areas, like genetic testing, which it deems high risk.

Main Theories

The government's primary theories in these cases include (i) the use of illicit marketing arrangements; (ii) the lack of medical necessity; and (iii) the improper use of telemedicine as a means to order genetic testing.

Illicit Marketing Arrangements

Under the Anti-Kickback Statute, it is illegal to solicit or receive any kickback, bribe, or rebate—in cash or in kind—in return for referring an individual for services for which reimbursement may be made by a federal health care program.[4]

In the genetic testing realm, activities flagged by federal enforcers as indicative, or falling squarely within the bucket, of illegal renumerations include:

- Soliciting the submission of genetic cancer tests via telemarketing efforts and live marketing at purported "health fairs";
- The use of physician recruiters;
- Efforts to broker the sale of physicians' orders;
- Offering gift cards to acquire DNA samples and Medicare information from patients;
- Arrangements in which medical professionals enter into agreements with clinical labs where payments are based on the percentage of Medicare reimbursements received in connection with such tests; and
- The billing of sham invoices for services when payment is pre-determined based on a percentage of the Medicare reimbursement.

DOJ has also taken issue with marketing efforts that target the elderly, disabled, or other vulnerable Medicare recipients.

Lack of Medical Necessity

While much of the medical community agrees that genetic testing can be incredibly beneficial and is the wave of the future in medicine, lack of medical necessity is one of the primary theories brought forth by the government in prosecuting these cases. The theory hinges upon the government's allegation that the defendants improperly induced beneficiaries—particularly those who were elderly or disabled—to agree to genetic testing by using aggressive marketing tactics when the tests were not necessary for the diagnosis or treatment of a specific medical problem. The government specifically has argued that because these tests were not used to diagnose cancer and were not used in the treatment of the beneficiaries' cancer, the tests were not medically necessary as required for reimbursement. In support of this argument, the government relies on 42 U.S.C. § 1395y(a)(1)(A), which states that Medicare does not cover diagnostic testing that is "not reasonable and necessary for *the diagnosis or treatment of illness* or injury or to improve the functioning of a malformed body member," and 42 C.F.R. § 411.15(a)(1), which provides that, unless an exception applies, there is no coverage for "[e]xaminations performed for a purpose *other than treatment or diagnosis of a specific illness*, symptoms, complaint or injury."

Use of Telemedicine

The government further takes issue that, in many of these alleged schemes, genetic tests were ordered by telemedicine physicians. In particular, the government is focused on and argues that these telemedicine physicians had little or no interaction with the beneficiaries and, thus, the tests were not ordered by treating physicians as required by Medicare.[5]

Additionally, in some of the alleged schemes, beneficiaries were provided the telemedicine visits free of charge, which the government perceives as suspect and argues was a form of improper inducement to get beneficiaries to agree to the genetic tests.

Lastly, CMS has been cautious in its approach to telemedicine. While the agency appears to continue expanding access to telemedicine for its beneficiaries, the government argues that the telemedicine visits in which the genetic tests were ordered did not qualify for reimbursement under Medicare's requirements. As such, the government takes the position that, since the

underlying visits were not reimbursable, neither were the genetic tests ordered during those visits. Notably, this argument appears to entirely disregard whether the beneficiaries would have otherwise qualified for reimbursable genetic testing, as it focuses solely on whether the underlying visits were reimbursable.

Practical Compliance Strategies

Individuals and entities in the genetic testing space should take care to avoid any appearance of involvement in illegal health care fraud and kickback schemes. Best practices include:

- Careful review of all arrangements with marketing companies and marketers;
- Ensuring that no payments for any services are tied, directly or indirectly, to the value or volume of referrals;
- Ensuring that all office visits for ordering of tests are properly reimbursable;
- Documenting medical necessity for each and every test;
- Documenting that patients are receiving the results of such tests; and
- Being mindful of Medicare's Anti-Solicitation Rule, which prevents providers from directly contacting beneficiaries via phone without written consent.

While genetic testing is an invaluable tool for patients and health care providers in the prevention, early detection, and treatment of cancer and other genetically predictable diseases, individuals and entities alike must be mindful of potentially fraudulent activity, lest increased scrutiny from federal enforcers chill development in an innovative and life-saving industry.

About the Authors

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[1] DOJ, Press Release, Sept. 27, 2019, https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against.
[2] DOJ, Press Release, Jan. 10, 2020, https://www.justice.gov/usao-wdpa/pr/pittsburgh-area-lab-owner-pleads-guilty-multiple-kickback-conspiracies-connection.
[3] DOJ, Press Release, Jan. 14, 2020, https://www.justice.gov/usao-edtx/pr/twelve-indicted-kickback-conspiracy-former-ceo-pleads-guilty.
[4] 42 U.S.C. § 1320a-7b(b).
[5] *See* 42 C.F.R. § 410.32(a) ("All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem."); Chapter 15 of the Medicare Benefit Policy Manual, Section 80.1 ("Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42

C.F.R. 410.32(a), or by a qualified nonphysician practitioner, as described in 42 C.F.R. 410.32(a)(3).").