

Genetic Testing: The New Wild West for Health Care Fraud

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In September 2019, the Department of Justice (DOJ) charged 35 individuals, across various jurisdictions, with crimes arising from allegations that they were involved in various genetic testing fraud schemes that cost taxpayers over \$2.1 billion. News Release, Dep't of Justice, *Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over \$2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged* (Sept. 27, 2019), <http://tiny.cc/ue38hz>. The government alleged that the individuals had engaged in “audacious schemes” to target seniors and the disabled through the ordering of cancer genetic screening (CGx) laboratory tests. *Id.* CGx tests are performed to screen patients for genetic variations that may show that a patient is predisposed to developing certain cancers. DOJ alleged that physicians were bribed to order these very expensive DNA tests and that in a number of cases the physicians did not even treat the patients or only saw them via a cursory telemedicine consultation.

Recent Genetic Testing Indictments Continue a Pattern of Government Scrutiny

While these are some of the first criminal charges filed in the genetic testing arena, they are unlikely to be the last. And this is not DOJ's first regulatory foray into the industry. The government has obtained often sizable recoveries via civil settlements under the False Claims Act. As genetic testing continues to grow, allegations of fraud will grow as well. The federal government has launched over 300 investigations into alleged fraud in the genetic testing industry, many of which are almost certainly ongoing.

Several years ago, the toxicology industry became inundated with fraudulent schemes. Genetic testing, which is similarly lucrative and prone to abuse, is particularly fertile ground for fraud. If nothing else, the history of health care fraud suggests that when a new high-reimbursement service or product arises, that which is old is new again. Substantially similar fraud schemes that were previously employed in one corner of the industry are exported to the new service or product. Genetic testing is but a new chapter in the iterative saga of healthcare fraud.

An Introduction to Genetic Testing

Genetic testing has promising medical uses. However, while its prospects are broad, with potential applications across the medical spectrum, its potential remains largely unrealized at this juncture. Cancer screenings are one common application, but others abound, both legitimate and illegitimate.

Pharmacogenetic/pharmacogenomic (PGx) tests are a major growth area in the genetic testing industry where concerns over fraudulent conduct have arisen. PGx tests, when used legitimately, are aimed at identifying genetic variations that may show that a patient has a genetic predisposition to an unusual reaction to a specific medication (*e.g.*, the patient may metabolize a medication at an abnormally low

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or high rate). PGx tests may, therefore, prove valuable if a patient has shown an otherwise unexplained reaction to a certain medication.

Yet, the scientific evidence supporting PGx tests (and genetic testing generally) in the overwhelming majority of cases remains remarkably slim. DNA testing shows some parallel to the stem cell therapy hype that arose decades ago, where a cutting-edge health care service was marketed as a veritable cure-all of widespread application. History has, of course, shown otherwise, with the efficacy of stem cell therapy limited to a quite narrow range of uses.

PGx testing is growing robustly among practitioners in the pain and addiction management sectors, the notion, at least nominally, being that individuals on opioids and other drugs should have their genes tested to determine if they are prone to metabolizing the drugs in unusual ways. The science supporting that rationale remains limited at best. And practices in pain and addiction management have gone under the regulatory microscope before for engaging in questionable practices involving urine drug testing and other arrangements. PGx is likely to garner similar prosecutorial attention.

Given the limited evidence supporting genetic testing to date, Medicare has generally recognized that PGx and other genetic tests are medically necessary in only a very narrow set of cases. Medicare administrative contractors have issued numerous local coverage determinations (LCDs) making that clear. Even where no LCD is at issue, to be reimbursable, a test must still be reasonable and medically necessary, and, thus, the absence of an LCD addressing a particular test does not mean that the test meets the medical necessity standard.

Further, the Medicare Claims Processing Manual explains that screening tests (genetic or otherwise) are generally not covered by Medicare. Medicare Claims Processing Manual, ch. 16, § 120.1. A practitioner who routinely performs genetic tests on patients, regardless of each patient's clinical history and presentation, would almost certainly run afoul of Medicare's requirements and raise the ire of regulators. Meanwhile, laboratories that encourage physicians to order medically questionable tests may also find themselves facing substantial liability. See *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 166 (D.D.C. 2017) ("Laboratories have a legal duty to ensure that they do not submit claims for medically unnecessary tests.").

Despite the limited medical evidence, Medicare has paid billions for genetic tests. Between 2015 and 2018, Medicare payments for these tests more than doubled, to well over \$1 billion in 2018. The use of genetic tests, in many cases, may have less to do with clinical utility and more to do with financial incentives. Of course, Medicare largely operates on a chase-and-pay basis, paying for services with little or no prepayment scrutiny, only seeking to claw back improper payments after subsequent review. Medicare has thus remained among the softest targets for those engaged in health care fraud.

DOJ's Indictments Parallel Civil False Claims Act Enforcement Actions

Given the sums of money at issue, the genetic testing industry has attracted many enterprising individuals, including those willing to flout legal requirements. While the schemes were particularly boldfaced in the indictments discussed above, more nuanced but similarly troubling schemes have drawn regulatory interest. Recent False Claims Act settlements are instructive.

In October 2019, DOJ announced a False Claims Act settlement with pharmacogenetic lab UTC Laboratories Inc. and three of its principals. News Release, Dep't of Justice, *Genetic Testing Company and Three Principals Agree to Pay \$42.6 Million to Resolve Kickback and Medical Necessity Claims* (Oct. 9, 2019), <http://tiny.cc/lg38hz>. The lab agreed to pay \$41.6 million, with the three individuals agreeing to

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pay another \$1 million. *Id.* The case resolved allegations, brought to light via multiple qui tam complaints, that the lab paid kickbacks to doctors as well as marketers and relatedly billed for medically unnecessary tests. The physician kickbacks were allegedly “thinly-disguised” as seemingly legitimate payments for physician work on a UTC-led clinical study. *Id.* In fact, the government claimed, the payments were used to leverage referrals from the physicians. The clinical study “work” was purportedly no more than smoke and mirrors. *Id.*

The UTC case is more indicative of the sort of kickback arrangements most common in the diagnostic testing industry as a whole, where the kickback is, at least to some degree, concealed as a seemingly legitimate payment. In fact, the purported kickback in the UTC case is quite similar to that alleged by DOJ in another multimillion-dollar genetic testing fraud settlement involving Primex Clinical Laboratories, LLC, and the owner of a related company, where Primex was accused of concealing kickbacks as payments to doctors for providing clinical data to the lab. News Release, Dep’t of Justice, Laboratory and Owner of Lab Management Services Company to Pay \$3.77 Million to Resolve Kickback and Medical Necessity Claims (Jan. 25, 2018), <http://tiny.cc/2g38hz>. Whenever there is a remuneration arrangement between a laboratory and a referral source, regulators and relators are likely to take note.

Pertinently, in both UTC and Primex, DOJ held individuals to account. Despite robust revenue, oftentimes labs may be thinly capitalized. This is often strategic, as the companies move funds to individuals, trusts, or shell companies to hide assets. Individual accountability can mitigate those concerns. If DOJ, consistent with the Yates Memorandum, continues to hold individuals accountable, the government may be able to avoid what often occurred during the (still ongoing) toxicology lab crackdown: Labs billed the government for billions, moved assets out of their corporate coffers, sought bankruptcy protection once regulators took notice, and largely avoided substantial civil liability. Memorandum from Sally Q. Yates, Deputy Attorney Gen., U.S. Dep’t of Justice, to All Component Heads and United States Attorneys (Sept. 9, 2015), <http://tiny.cc/ltsajz>.

While DOJ has shown a preeminent focus on holding companies and individuals accountable for kickback schemes, settlements in this area have not been limited to kickback arrangements. In UTC, the government pursued both kickback and medical necessity claims. Meanwhile, in an earlier January 2019 FCA settlement, another genetic lab, GenomeDx Biosciences, agreed to pay \$1.99 million to resolve allegations that it billed Medicare for medically unnecessary genetic tests. News Release, Dep’t of Justice, Genetic Testing Company Agrees to Pay \$1.99 Million to Resolve Allegations of False Claims to Medicare for Medically Unnecessary Tests (Feb. 11, 2019), <http://tiny.cc/kh38hz>. Thus, whether the test runs afoul of the Anti-Kickback Statute (AKS) or not, the government has evinced an inclination to hold providers liable for simply referring or performing tests it finds are medically unnecessary. That is a rather substantial concern given the still-limited set of circumstances where genetic testing has been deemed necessary by CMS, its contractors, and the medical community as a whole.

The industry has faced allegations of upcoding as well. In July 2019, Myriad Genetics announced that it had agreed to settle a non-intervened FCA suit involving some of its genetic tests. *Myriad Genetics Settles Improper Medicare Billing Complaint for \$9.1M*, 360DX (July 19, 2019), <http://tiny.cc/xh38hz>. The relator alleged that Myriad had upcoded its billings, causing Medicare to vastly overpay for the tests. Given that genetic coding conventions are still being developed and modified, labs must ensure that their practices comply with operative CPT and HCPCS coding standards.

Common Diagnostic Fraud Schemes

Genetic testing schemes are likely to fall into a few basic fact patterns:

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Remuneration to Physicians: As the UTC and Primex cases show, remuneration to physicians for referrals may be disguised as superficially legitimate payments (e.g., “consultation fees”), services, or other forms of remuneration. In some cases, a physician (or his or her practice) may have an equity (or other financial interest) in the genetic testing lab, which may give rise to violations of the Anti-Kickback Statute and/or Stark Law.

DOJ has shown a long-standing inclination to prosecute violations of the AKS and Stark Law. Illegal remuneration has a tendency to poison the otherwise sound medical decision making of physicians and create a less-than-level competitive playing field in the health care market. What is more, the law is such that a referral resulting from a violation of the AKS is, by definition, a “false claim” under the FCA, making these cases particularly easy to prove for DOJ and relators. *See, e.g.*, 42 U.S.C. § 1320-7b(g).

While the schemes allegedly at issue in UTC and Primex are emblematic of some of the disguised kickback arrangements common in the diagnostics industry, there are a number of other financial arrangements that may also arise.

Medical Service Organizations: Both legal and medical practitioners should keep a particular eye out for arrangements involving Medical Service Organizations (MSOs) or similar arrangements that may be used to try to launder kickbacks through an intermediary between the lab and the referring physician. MSOs are quickly spreading throughout the diagnostic industry, and their legitimacy, in many cases, is dubious at best.

An MSO is a company nominally created to provide management and other administrative services to a laboratory (or other health care entity) for a fee. MSOs that involve physicians as investors or managers may be used by genetic testing labs for illegal purposes such as smokescreens for arrangements that run afoul of the AKS or Stark Law. In such cases, the MSO physician may refer patients to the lab, with the lab paying the MSO a “management fee,” although the MSO performs little to no legitimate managerial services for the lab. The physician is then paid a part (or all) of the so-called management fee through his or her financial interest in, or nominal role at, the MSO. The idea is that by adding an additional link in the remuneration chain (which makes the referral payment from the lab to the physician less direct) and disguising the referral fee as a “management fee,” regulators may be none the wiser. That simple contrivance is unlikely to fool investigators and prosecutors.

Pass-Through Billing: Another common scheme that seeks to launder illegal remuneration involves pass-through billing. Under a pass-through billing arrangement, a physician purchases a test from the lab and is then entitled to bill payers for the test. Pass-through billing is illegal in many states, but it remains legal in others. Regardless of state law, these arrangements may implicate federal fraud and abuse laws. If the test is sold at less than fair market value and in such a way as to allow the referring physician to unduly profit from the referral, then the arrangement may run afoul of the AKS or Stark Law. Pass-through billing arrangements are both remarkably common and, given that the question turns largely on a matter of arithmetic (is the physician impermissibly making a profit on the pass-through billing arrangement?), difficult to defend.

Payments to Marketers: The federal government has made clear that paying commissions to independent contractors (often referred to as “1099 salespeople”) for referrals runs afoul of the Anti-Kickback Statute. In the UTC case, the lab purportedly paid independent marketers for referrals on a commission basis. The facts of UTC are far from unusual. It is common practice in the genetic testing industry, and diagnostic industry as a whole, for labs to pay independent marketers on a per referral basis. In such cases, both the marketer and the lab may face liability. OIG has scrutinized these arrangements since the 1990s, and the

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government's interest has not waned. *See, e.g.*, Office of the Inspector Gen., Advisory Op. No. 99-3 (Mar. 16, 1999). In fact, in September 2019, DOJ settled an FCA case involving allegations that a pharmacy paid 1099 salespeople commissions based on referrals, obtaining a settlement not just from the pharmacy and two of its executives, but from its private equity backer as well, emphasizing DOJ's keen interest in holding all relevant actors liable for these schemes. News Release, Dep't of Justice, Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay \$21.36 Million to Resolve False Claims Act Allegations (Sept. 18, 2019), <http://tiny.cc/2h38hz>.

Waiving Copays and Other Forms of Remunerations to Patients: Genetic testing services can cost upwards of \$5,000 per test, and thus patient copays tend to be substantial. In order to avoid scaring off patients via "sticker shock," labs may waive or substantially reduce copays or similar patient payment obligations. If such financial assistance is provided systematically or otherwise without legitimate consideration of a patient's financial condition, then regulators may find that the arrangement violates the Anti-Kickback Statute. Copay waivers have been on the government's radar since at least 1994, and scrutiny of these arrangements has grown substantially over time, particularly in recent years. *See* Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994). As health care costs, and attendant copays, continue to rise, the temptation to waive patient copays has risen as well.

Policies that Lead to Medically Unnecessary Tests: Practices, particularly those with a financial interest in a genetic testing lab, may institute policies that coerce their practitioners to order genetic tests when they are unnecessary. These policies may be issued under the guise of the standard of care, claiming that the practice is providing cutting-edge "personalized" or "precision" medicine services to its patients. In some cases, the purported rationale may be based on practicing "defensive medicine."

Even where a test is necessary to identify a specific genetic variation, an entity may have a policy that pushes physicians to order additional, unnecessary tests to identify other genes. Whenever a physician or practice has a blanket policy (*e.g.*, a standing order) to order a specific test or battery of tests, the legitimacy of those tests may be questioned. In the most egregious cases, a standing order may result in patients providing a genetic sample before they are even seen by their physician (*e.g.*, during intake by a medical assistant).

Upcoding: Upcoding may occur where a provider bills payors for a more expensive test (or panel of tests) than that which was actually performed. Given that genetic testing is relatively new, Medicare and other insurance auditors may find it difficult to adequately crack down on such practices. Auditors may not be readily familiar with the relevant coding standards, which may change over time. In fact, in the Myriad Genetics case, Myriad was accused of flouting coding conventions, which were in a state of substantial flux.

Fraud bonanzas of the past teach us that once the federal government and relators take notice of rapid growth and widespread noncompliance in a specific part of the health care sector, they will seek to hold bad actors accountable. The genetic testing industry, still in its relative infancy, is proving to be no different.