AMERICAN HEALTH LAW ASSOCIATION

HEALTH LAW WEEKLY
June 17, 2022

Enforcement Trends for Genetic Testing and Potential Implications for Telehealth and Pharmacogenetic Companies

Luke Cass, Womble Bond Dickinson (US) LLP

Allison Pearl, Womble Bond Dickinson (US) LLP

The genetic testing industry has continued to grow in size and scope in recent years, but with this success comes increased regulatory scrutiny and potential liability, particularly during and after the COVID-19 pandemic. This article addresses the current civil and criminal enforcement climate, surveys the applicable statutes used by the Department of Justice (DOJ) and recent cases,[1] and concludes with helpful tips about how health care professionals and genetic testing labs can prepare for the increased scrutiny announced by the Attorney General for this area.

Background

Genetic and pharmacogenetic testing are new, potentially game-changing tools in preventive medicine. Cancer genomic (CGx) tests can assess whether a person's genetic makeup indicates a predisposition for certain kinds of illnesses, as well as how that person will respond to treatments. Pharmacogenetic (PGx) tests can ascertain a person's ability to metabolize certain medications, which correlates to how effectively that medication will perform for that person.

Another innovative feature of these tools is how easily accessible they are to consumers. Many genetic tests are available in take-home kits and panels that people can use and then send to a lab for testing and analysis. Telemedicine companies have paired with telemarketing companies and laboratories to create a robust industry for providing convenient genetic testing to consumers. The government has grown increasingly interested in this growing market because of the risk for fraud, kickbacks, and inflated pricing.

Furthermore, given the limited evidence supporting the reliability of genetic testing to date, Medicare has generally recognized that these tests are "medically necessary," and therefore reimbursable by Medicare, in a very limited range of circumstances. Nevertheless, Medicare has still paid billions for genetic tests over recent years. Between 2015 and 2018, Medicare payments for these tests more than doubled, to well over $1 billion in 2018. There is growing concern that the use of genetic tests may have less to do with clinical utility than with the financial incentives of the prescribers, doctors, and companies providing these tests, which has led to civil and criminal enforcement actions by the federal government.

Government Enforcement Actions

Criminal Enforcement

In September 2019, the government prosecuted 35 defendants associated with telemedicine companies and laboratories for allegedly fraudulently billing Medicare over $2.1 billion in genetic testing costs.[2] At the same time, the Centers for Medicare & Medicaid Services (CMS) and Center for Program Integrity took adverse administrative action against certain cancer genetic testing companies and medical professionals who submitted more than $1.7 billion in reimbursement claims to Medicare for genetic testing-related costs.[3] The investigation targeted an alleged scheme involving the payment of illegal kickbacks and bribes by CGx laboratories in exchange for the referral of Medicare beneficiaries by medical professionals working with fraudulent telemedicine companies, to receive expensive cancer genetic tests that were medically unnecessary. According to the government, the test results were often not even provided to the beneficiaries or were worthless to the patients' actual doctors. Some of the defendants also allegedly controlled a

telemarketing network that lured hundreds of thousands of elderly and/or disabled patients into a nationwide criminal scheme related to unneeded genetic testing. The defendants allegedly paid doctors to prescribe CGx testing, either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen.

Other prosecutions have followed in recent years. Most recently, in January 2022, an individual pleaded guilty in the Southern District of Florida to a $6.9 million conspiracy to defraud Medicare by paying kickbacks and bribes in exchange for doctors' orders for medically unnecessary lab tests that were then billed to Medicare.[4] The defendant allegedly exploited the uncertainty and anxiety of the pandemic by bundling COVID-19 testing with other forms of testing that patients did not need, including genetic testing and tests for rare respiratory pathogens.

Civil Enforcement

The government has also obtained sizable civil settlements under the False Claims Act (FCA) for prosecuting similar conduct. In October 2019, DOJ announced an FCA settlement with a laboratory and three of the company's principals.[5] The lab allegedly paid kickbacks to doctors and marketers for referrals and billed Medicare for medically unnecessary genetic testing. The defendants apparently disguised the physician kickbacks as payments for physician work on a clinical study. The government claimed, however, that the payments were used to leverage referrals from the physicians.

Industry players should take note that, wherever there is a remuneration arrangement between a laboratory and a referral source, regulators and relators are likely to take interest. Pertinently, in the above case, the DOJ held individuals to account, not just the companies.

Settlements in this area have not been limited to kickback arrangements. Whether or not the conduct runs afoul of the Anti-Kickback Statute, the government has shown an inclination to hold providers liable for prescribing or performing genetic tests it finds are medically unnecessary. That creates a substantial risk, given the still-limited set of circumstances where genetic testing has been deemed "medically necessary" by CMS, its contractors, and the medical community as a whole.

Upcoding, or the inflation of costs to garner larger reimbursement payments from Medicare, has also been a liability risk for Medicare participants. In July 2019, a genetics company announced that it had agreed to settle a non-intervened FCA suit, where the relator in the case alleged that the company upcoded its billings, causing Medicare to vastly overpay in reimbursing for certain genetic testing.[6] Given that coding conventions for genetic testing are still being developed and modified within the Medicare program, labs must ensure that their practices comply with the most up-to-date coding standards.

Common Pitfall Areas

Liability, civil or criminal, for medically unnecessary genetic testing and related kickback schemes are obviously the biggest risks for industry players, but they are not the only ones. Below are some of the other most common enforcement areas.

The False Claims Act & Stark Law

The FCA[7] was enacted in 1863 by a Congress concerned that suppliers of goods to the Union Army during the Civil War were defrauding the Army. The FCA is designed to discourage contractor fraud against the federal government. Generally, Sections 3729(a)(1)(A) and (B) of the FCA set forth liability for any person who knowingly submits a false claim to the government or causes another to submit a false claim to the government, or knowingly makes a false record or statement in order to get a false claim paid by the government. Section 3729(a)(1)(C) creates additional liability for those who conspire to violate the FCA. The FCA currently provides for a civil penalty between $12,537 and $25,076 for each false claim, plus treble the amount of the government's damages.

The FCA also allows private citizens to file suits on behalf of the government (called "qui tam" suits) against those who have defrauded the government. Private citizens who successfully bring qui tam actions may receive a portion of the government's recovery. Numerous DOJ investigations and lawsuits arise from such qui tam actions. DOJ obtained more than $5.6 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending September 30, 2021.[8]

To violate the FCA a person must have submitted, or caused the submission of, the false claim (or made a false statement or record) with knowledge of the underlying falsity. In Section 3729(b)(1), knowledge of false information is defined as being: (1) actual knowledge, (2) deliberate ignorance of the truth or falsity of the information, or (3) reckless disregard of the truth or falsity of the information. Falsity alone, however, is not sufficient for FCA liability. Under the FCA, the requisite intent is the knowing *presentation* of what is known to be false, as opposed to innocent mistake or mere negligence. To be clear, the phrase "known to be false" does not mean "scientifically untrue," it means a lie. Courts have held that the FCA is concerned with ferreting out "wrongdoing, not scientific errors," so a genuine mistake is not sufficient.

Another way FCA liability can occur is under an implied false certification theory. To establish liability under the false certification theory of the FCA, a plaintiff must show that: (1) a government contract or program required compliance with certain conditions as a prerequisite to a government benefit, payment, or program; (2) the defendant failed to comply with those conditions; and (3) the defendant falsely certified that it had complied with the conditions in order to induce the government benefit. Under the theory of implied certification, FCA liability may arise even absent an affirmative or express false statement, where submission of such documents represents an implied certification by a contractor of its continuing adherence to all material portions of the contract.

The physician self-referral law, or Stark Law,[9] prohibits a referral by a physician of a Medicare or Medicaid patient to an entity providing designated health services (DHS) if the physician (or his/her immediate family member) has a financial relationship with that entity. Penalties for violations of the Stark Laws can include denial of payment for the DHS provided, refunds for amounts wrongfully collected, civil penalties of up to $27,750 for each service that a person "knows or should know" was provided in violation of the law, plus three times the amount of improper payment the entity received from the Medicare program, exclusion from the Medicare program and/or state health care programs including Medicaid, and civil penalties for attempting to circumvent the law of up to $185,009 for each circumvention scheme.

Criminal Statutes Applicable to Health Care Fraud

The government can charge health care fraud criminally as a substantive charge, scheme, conspiracy, or all three.

Proof of a violation of health care fraud under 18 U.S.C. § 1347 requires a showing that the defendant knowingly and willfully executed a scheme to defraud a government health care program. In criminal cases, willfulness generally means that an act was undertaken with a "bad purpose," that is, with knowledge that the act is unlawful. Aiding and abetting requires proof that the defendant "consciously shared the principal's knowledge of the underlying criminal act and intended to help the principal" accomplish it. In the case of health care fraud, proof of guilt either as a principal or as an aider or abettor requires proof of specific intent, which may be established by circumstantial evidence.

To prove conspiracy to commit health care fraud under 18 U.S.C. § 1349, the government must prove beyond a reasonable doubt: (1) that an agreement existed to commit the underlying substantive offense; (2) that the defendant knew of the agreement; and (3) that the defendant voluntarily joined it with the intent to commit the underlying offense. Guilty knowledge and intent may be proven solely by circumstantial evidence.

The government could also charge another conspiracy statute, 18 U.S.C. § 371, in these circumstances. This statute provides that "[i]f two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both." To establish a conspiracy under this law, the government must prove beyond a reasonable doubt that: (1) a conspiracy existed; (2) the defendant knew of and voluntarily participated in the conspiracy; and (3) there was an overt act in furtherance of the conspiracy. The government must prove both intent to agree and intent to commit the substantive offense. But a formal agreement is not required. Rather, the agreement may be shown by a concert of action, with all the parties working together, with a single design for the accomplishment of a common purpose.

As mentioned above, the federal Anti-Kickback Statute[10] (AKS) is a criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of business reimbursable by federal health care programs. Examples of prohibited kickbacks include receiving financial incentives for referrals, free or very low rent for office space, or excessive compensation for medical directorships. Other kickbacks include waving copayments, either routinely or on a selective basis. Possible penalties for violating the AKS include fines of up to approximately $25,000, up to five years in jail, and exclusion from participating in Medicare and Medicaid.

The Travel Act[11] makes it a federal crime to use facilities of interstate commerce to promote, manage, establish, or carry on specific, statutorily defined "unlawful activity," which includes state bribery offenses. The broad definition of interstate commerce under the Travel Act makes it an attractive charge to federal prosecutors because of its relatively low threshold for federal jurisdiction. All that's needed to implicate DOJ enforcement authority is an interstate call, use of a cell phone, any use of the United States mails, the deposit of a check or wire transfer into a bank account, a credit card charge, or traveling from one state to another. In the health care context, this means that DOJ prosecutors can charge defendants with bribery under state law if a facility of interstate commerce, like the mails or a cell phone, were used to carry on the crime.

This scenario is precisely what Dallas federal prosecutors capitalized on in a massive, multi-defendant conspiracy case involving approximately $40 million in bribes and kickbacks.[12] The medical center in the case was a physician-owned out-of-network hospital that set its prices for services and was generally reimbursed at substantially higher rates than in-network providers. The government alleged that hospital employees used shell companies to funnel bribes and kickbacks to surgeons in exchange for patient referrals. According to the indictment, two surgeons received $4,595,000 and $3,400,000, respectively, in bribes and kickbacks in exchange for referring their patients to the hospital. As part of the conspiracy, certain defendants paid bribes and kickbacks of $500 per month to approximately 40 primary care physicians and practices to refer patients to the hospital or surgeons associated with the hospital. In addition to paying surgeons and primary care physicians, certain co-conspirators also paid a host of other related actors in the industry, including workers' compensation preauthorization specialists, lawyers, businesses, and chiropractors.

The bribes and kickbacks resulted in bills over half of a billion dollars, including more than $10 million billed to the Department of Defense health care program TRICARE, more than $25 million to the Department of Labor's Federal Employees' Compensation Act (FECA) health care program, and more than $60 million to the federal employees' and retirees' health care program. The hospital itself had collected more than $200 million in allegedly tainted and unlawful claims. Ten defendants pleaded guilty, and seven were convicted at trial. The hospital's managing partner was found guilty on six counts of commercial bribery

in violation of the Travel Act, as was one doctor. But four defendants were acquitted of Travel Act charges.

In June 2018, the U.S. Attorney in New Jersey charged executives of a New Jersey-based laboratory for a conspiracy in which millions of dollars in bribes were paid to physicians for blood sample referrals worth more than $100 million to the company.[13] Each defendant had previously pleaded guilty to an information charging one count of conspiracy to violate the AKS and the Travel Act and one count of money laundering. The investigation resulted in the convictions of 53 defendants—38 of them of doctors—in connection with the bribery scheme, which its organizers admitted involved millions of dollars in bribes and resulted in more than $100 million in payments to the lab from Medicare and various private insurance companies.

Health care companies should also be aware of mail and wire fraud. To prove mail or wire fraud under 18 U.S.C. §§ 1341, 1343 the government must show three elements: (1) a scheme to defraud based on material false pretenses or representations; (2) the defendant's knowing and willing participation in the scheme with the intent to defraud; and (3) the use of interstate mail or wire communications in furtherance of that scheme.

Aggravated identity theft,[14] or using or transferring the names, birth dates, and Social Security numbers of real people during and in relation to the health care fraud, is also an option for prosecutors. This statute applies to a variety of crimes where someone wrongfully obtains another person's means of identification, not only those iterations that relate to conventional theft. Pursuant to 18 U.S.C. § 1028A(a)(1), a person is guilty of aggravated identity theft if, in relation to any crime listed in Section 1028A(c), the person "knowingly transfers, possesses, or uses, without lawful authority, a means of identification of another person . . . ." The statute defines the term "means of identification" as "any name or number that may be used, alone or in conjunction with any other information, to identify a specific individual, including any name, social security number, [or] date of birth."[15] Under this statute, the government is required to prove beyond a reasonable doubt that the defendant knew that the means of identification that the defendant used belonged to another person. The "knowing" requirement applies "to two elements: the 'means of identification' and 'of another person.'" The statute imposes a two-year mandatory sentence of imprisonment consecutive to any other sentence.

Compliance & Advice of Counsel

This past March, the Attorney General announced a Director for COVID-19 Fraud Enforcement, who will lead the charge on pandemic fraud, and a budget increase to hire 120 attorneys and 900 FBI agents.[16] In this enforcement climate, compliance programs and legal advice are vital protections for genetic testing labs and health care professionals working in these heavily regulated areas. Companies and individuals should prioritize enlisting the support of experienced legal counsel in order to navigate these risks.

Having a corporate compliance program is a good first step. In doing so, companies should ask three questions: (1) Is your compliance program well designed? (2) Is it applied in good faith? And (3) Does it actually work in practice? These questions come from DOJ guidance and are important starting points for companies and labs.

Caution should also extend to any assertions to regulators as well. For example, the Medicare Enrollment Application (Form CMS-855B) contains a number of landmines for applicants seeking to enroll in the Medicare program. It requires that the applicant disclose all owners and any individuals or businesses with managing control over the provider, including any individual or entity with 5% or more ownership, managing control, or a partnership interest of any size. Part of the reasoning behind this disclosure is that CMS can deny enrollment to a company if the company or any of its owners was criminally convicted or experienced any adverse disciplinary action from Medicare or Medicaid within the last ten years. Clinical Laboratory Improvement Amendments (CLIA) certifications for laboratories participating in Medicare programs deserve similar cautious treatment. Material falsifications on these forms can lead to criminal penalties under 18 U.S.C. § 1001.

The second option is to seek the advice of legal counsel when structuring any and all arrangements. Besides providing guidance and identifying and remedying risky conduct, lawyers can also provide their clients with an "advice of counsel" defense should they later be subject to an enforcement action. In some circumstances, proof that a defendant's acts or omissions occurred in good faith reliance on the mistaken advice of counsel can be used as a defense to liability. However, asserting this defense means precisely following the advice given and then waiving attorney-client privilege over communications with lawyers. Because analyzing an advice of counsel defense requires an evaluation of the client's reasonable reliance on that advice, such a waiver or privilege may extend not only to the advice relied upon, but also to the information provided to counsel in order to receive the advice, and any related advice the defendant received from other counsel.

Conclusion

DOJ's Criminal Division has 80 prosecutors focused solely on prosecuting complex health care fraud matters in 15 Health Care Fraud and Appalachian Regional Prescription Opioid Strike Forces across the country, including the District of Columbia. As the Attorney General stated, the Department is "using big data—our own, and the data of other departments and agencies—to identify payment anomalies that are indicative of fraud."[17] For genetic testing labs and health care professionals in this enforcement climate, a commitment to compliance and seeking legal advice are necessities, not investments.

About the Authors

Luke Cass and **Allison Pearl** are attorneys with Womble Bond Dickinson (US) LLP and members of the firm's White-Collar Defense, Investigations, and Regulatory Enforcement group.

---

[1] In all discussed cases, we omit the names of defendants and note that charges are merely accusations, all defendants are presumed innocent unless and until proven guilty.

[2] Dep't of Justice, News Release, *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), https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against.

[3] *Id.*

[4] Dep't of Justice, News Release, *Lab Owner Pleads Guilty to $6.9 Million Genetic Testing & COVID-19 Testing Fraud Scheme* (Jan. 13, 2022), https://www.justice.gov/opa/pr/lab-owner-pleads-guilty-69-million-genetic-testing-covid-19-testing-fraud-scheme.

[5] Dep't of Justice, News Release, *Genetic Testing Company and Three Principals Agree to Pay $42.6 Million to Resolve Kickback and Medical Necessity Claims* (Oct. 9, 2019), https://www.justice.gov/opa/pr/genetic-testing-company-and-three-principals-agree-pay-426-million-resolve-kickback-and.

[6] *See Myriad Genetics Settles Improper Medicare Billing Complaint for $9.1M*, genomeweb (July 19, 2019), https://www.genomeweb.com/reimbursement/myriad-genetics-settles-improper-medicare-billing-complaint-91m#.YqeLaXbMJPZ.

[7] 31 U.S.C. §§ 3729-3733.

[8] Dep't of Justice, News Release, *Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021* (Feb. 1, 2022), https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year.

[9] 42 U.S.C. § 1395nn.

[10] 42 U.S.C. § 1320a-7b.

[11] 18 U.S.C. § 1952(a)(3).

[12] U.S. Attorney's Office Northern District of Texas, News Release, *Executives, Surgeons, Physicians, and Others Affiliated with Forest Park Medical Center (FPMC) in Dallas Indicted in Massive Conspiracy* (Dec. 1, 2016), https://www.justice.gov/usao-ndtx/pr/executives-surgeons-physicians-and-others-affiliated-forest-park-medical-center-fpmc.

[13] U.S. Attorney's Office for the District of New Jersey, News Release, *President Of New Jersey Clinical Laboratory And His Brother, A Senior Employee, Sentenced To Prison In $100m+ Test Referral/Bribery Scheme* (June 13, 2018), https://www.justice.gov/usao-nj/pr/president-new-jersey-clinical-laboratory-and-his-brother-senior-employee-sentenced-prison.

[14] 18 U.S.C. § 1028A.

[15] *See* 18 U.S.C. § 1028(d)(7)(A).

[16] Dep't of Justice, News Release, *Justice Department Announces Director for COVID-19 Fraud Enforcement* (Mar. 10, 2022), https://www.justice.gov/opa/pr/justice-department-announces-director-covid-19-fraud-enforcement.

[17] Dep't of Justice, Remarks as Delivered, *Attorney General Merrick B. Garland Delivers Remarks to the ABA Institute on White Collar Crime* (Mar. 3, 2022), https://www.justice.gov/opa/speech/attorney-general-merrick-b-garland-delivers-remarks-aba-institute-white-collar-crime.