Westlaw Today
powered by Reuters

'Stark' differences: DOJ's renewed focus on stand-alone Stark Law violations

By Murad Hussain, Esq., Allison W. Shuren, Esq., and Loreli "Lori" Wright, Esq., Arnold & Porter*

MAY 29, 2024

The Department of Justice (DOJ) is breathing new life into False Claims Act (FCA) enforcement based on the Stark Law (Stark),[1] also known as the Physician Self-Referral Law. Over the past few months, DOJ has filed two FCA complaints-in-intervention focusing on Stark violations and announced at least two multimillion-dollar Stark-related settlements.

These developments come on the heels of similar DOJ activity throughout 2023, suggesting a likely uptick in Stark Law-based enforcement going forward.

Financial relationships that can trigger the Stark Law include ownership/investment interests and physician compensation arrangements, particularly where the compensation terms exceed fair market value (FMV) or vary with the volume or value of the referrals for "designated health services" (e.g., diagnostic and imaging services) generated by the compensated physician.

In theory, for cases involving certain federally reimbursed health care services, Stark-based False Claims Act claims require less proof than Anti-Kickback Statute-based FCA claims.

Additionally, the submission of claims that result from Stark violations can potentially qualify as false or fraudulent claims under the federal FCA, much as with FCA claims that result from violations of the criminal Anti-Kickback Statute (AKS), a criminal statute that also prohibits certain referral relationships among providers seeking payment from Medicare, Medicaid, and other federal insurance programs.

However, the AKS contains a heightened criminal *scienter* requirement,[2] while the Stark Law contains no *scienter* requirement at all. So, in theory, for cases involving certain federally reimbursed health care services, Stark-based FCA claims require less proof than AKS-based FCA claims.

Since early 2023, that theory has been borne out in a series of new FCA enforcement actions and resolutions involving large institutional health care providers and others, which we survey below. These new cases and settlement agreements (or at least DOJ's press releases announcing them) feature FCA theories that often focus on Stark violations standing alone, even when the underlying *qui tam* allegations also asserted AKS violations.

Several of these cases feature common themes: relators who are the defendant health care providers' own corporate executives or other employees, allegations of physician compensation that far exceeds FMV, and accusations that defendants furnished inaccurate information to the third-party valuation companies upon whom they relied when setting that compensation.

All of this suggests that Stark violations are an increasingly attractive target for the federal government's health care fraud and abuse enforcers.

United Neurology P.A.

On March 22, 2024, the U.S. Attorney's Office for the Southern District of Texas announced[3] that a Houston physician and his diagnostic facilities (operated under several business names, including United Neurology P.A.) agreed to pay US$1.8 million to settle FCA allegations regarding submissions of Medicare Part B claims for services that were supposedly medically unnecessary, as well as referred and billed in violation of the Stark Law.

In the original complaint, the relator alleged that the physician violated the FCA, Stark Law, *and* AKS by referring patients to an imaging center that he owned, but where he supposedly did not maintain a regular office. The relator also alleged that the doctor performed medically unnecessary diagnostic services in that imaging center, altered treatment records to obscure referral patterns, and used inadequately licensed personnel to perform imaging services.

According to the settlement agreement, the United States' intervention was limited to the Stark violation and medical necessity theories, and did not encompass the relator's AKS theories.

New York and Presbyterian Hospital

In February 2024, the U.S. Attorney's Office for the Eastern District of New York and the U.S. Department of Health and Human Services' Officer of Inspector General (HHS-OIG), together with

the state of New York through its Attorney General's Medicaid Fraud Control Unit, reached a settlement[4] with The New York and Presbyterian Hospital (NYPH) and its affiliated physician group, Park Slope Medicine, P.C. (Park Slope), under which NYPH and Park Slope agreed to pay US$17.3 million to avoid liability for certain conduct that may have violated the FCA, Stark Law, and the Civil Monetary Penalties Law.

The settlement arose from a self-disclosure that NYPH submitted to HHS-OIG in April 2016. NYPH self-reported that between April 2010 and October 2015, payments were made under a contract with an affiliated chemotherapy infusion clinic that linked the compensation paid to Park Slope doctors with the number of referrals the doctors made for chemotherapy, infusion, and other items and services received at the center.

The conduct covered by the settlement also involved instances in which Park Slope providers did not adequately supervise non-physician practitioners or other qualified assistants who provided services at the infusion center.

Cardiac Imaging Inc.

In October 2023, mobile cardiac PET scan provider Cardiac Imaging Inc. and Sam Kancherlapalli, Cardiac Imaging's former owner and CEO, settled False Claims Act *qui tam* allegations[5] that were filed against them by a former billing manager at Cardiac Imaging.

The suit alleged FCA liability based on violations of both AKS and the Stark Law. Cardiac Imaging and Kancherlapalli agreed to pay more than US$85 million and enter into a five-year Corporate Integrity Agreement with HHS-OIG.

Subsequently, in February 2024, the U.S. Attorney's Office in the Southern District of Texas announced[6] that it had filed a complaint partially intervening against Rick Nassenstein, Cardiac Imaging's former president, chief financial officer, and co-owner, who had not joined the settlement. Unlike the relator's original suit, however, the United States' complaint-in-intervention raised only Stark-based theories of FCA liability.

According to the allegations in the relator's original complaint and in DOJ's intervention complaint, Cardiac Imaging, Kancherlapalli, and Nassenstein supposedly violated the Stark Law through a scheme to pay fees exceeding FMV to referring cardiologists, who then sent patients to Cardiac Imaging for cardiac PET scans.

Cardiologists were allegedly paid around $500 per hour, a rate reflective of the value of their time as if they were fully occupied with supervising Cardiac Imaging's scans, even though the cardiologists were caring for other patients in their offices (or were not even onsite).

The intervention complaint against Nassenstein alleges that, although Cardiac Imaging had retained an outside valuation firm to support the rates that it paid, the firm's valuation opinion relied on inaccurate information from Cardiac Imaging about the extent of the physicians' services. The complaint also alleges that Cardiac Imaging compensated the cardiologists for additional services that were not actually provided.

Steward Health Care System

In December 2023, DOJ and the U.S. Attorney's Office for the District of Massachusetts filed a Stark Law-based FCA complaint-in-intervention[7] against Steward St. Elizabeth's Medical Center of Boston, Inc. (SEMC), Steward Medical Group, Inc., and Steward Health Care System, LLC (collectively, Steward). The lawsuit was originally filed in 2018 by SEMC's chief financial officer.

The government alleges that SEMC paid its chief of cardiac surgery over US$4.8 million in improper incentive-based compensation, based on a formula that relied in part on the number of cases that he referred to Steward affiliates, and that this compensation also exceeded FMV.

Notably, although the government noticed its intent to intervene in a count of the relator's *qui tam* complaint that included both Stark and AKS violations, the United States' complaint-in-intervention ultimately focused exclusively on Stark-based theories of FCA liability, without alleging any AKS violations.

Community Health Network

In a December 2023 settlement, Community Health Network (Community) agreed to pay[8] US$345 million and enter into a five-year Corporate Integrity Agreement to resolve allegations stemming from a *qui tam* suit originally filed by Community's former chief financial and chief operating officer.

The U.S. Attorney's Office for the Southern District of Indiana later intervened in the suit and eventually settled the allegations that Community paid above-FMV compensation to its employed cardiologists, cardiothoracic surgeons, vascular surgeons, neurosurgeons, and breast surgeons; that it awarded bonuses to employed physicians based on the number of their referrals; and that it submitted claims to Medicare for services resulting from these supposedly unlawful referrals.

As with the Cardiac Imaging case discussed above, Community had also retained an outside valuation firm to review physician compensation, but allegedly provided false information to the firm. The claims against Community in the United States' complaint-in-intervention rested solely on Stark-based theories of FCA liability.

Covenant Healthcare System

In March 2023, regional hospital system Covenant Healthcare System (Covenant) and two of its physicians agreed to pay[9] over US$69 million to settle a 2012 *qui tam* suit brought by a former Covenant executive (who was also one of its employed physicians).

Stark-based claims in the suit included an array of alleged financial relationships between Covenant and various physicians (including medical directorship arrangements, employment relationships, office space rental, and equipment lease arrangements) that did not qualify for any Stark Law exceptions.

The settlement was finalized in 2021, but documents remained under seal until 2023, while the U.S. Attorney's Office for the Eastern District of Michigan continued to investigate into the two physicians.

The settlement agreement is not public, but relator's claims as settled against Covenant included FCA theories of liability based on both the AKS and Stark Law, featuring allegations that Covenant compensated its physicians well above FMV and paid them for services that were not actually provided. And DOJ's press release identifies several Stark-only settlement theories.

In this era of renewed Stark-based FCA enforcement, institutional health care providers and physicians alike should carefully evaluate their financial arrangements to ensure compliance with these complex self-referral prohibitions, and providers should consider consulting counsel with extensive Stark Law experience.

Notes:

[1] 42 U.S.C. § 1395nn.

[2] https://bit.ly/4alAcFN

[3] https://bit.ly/44KNQRF

[4] https://bit.ly/3V0Fn9F

[5] https://bit.ly/3WJjjSf

[6] https://bit.ly/4alAJaL

[7] https://bit.ly/3K4qQ6E

[8] https://bit.ly/4bCJC0H

[9] https://bit.ly/3UHEcuu

About the authors

Murad Hussain (L) is a partner in **Arnold & Porter**'s white-collar defense and investigations practice in Washington, D.C. He represents clients in all stages of criminal health care fraud prosecutions, False Claims Act litigation, Centers for Medicare & Medicaid Services administrative proceedings, and related internal and government investigations. He also serves as an adjunct professor of trial practice at the Georgetown University Law Center. He can be reached at Murad.Hussain@arnoldporter.com. **Allison W. Shuren** (C), also a Washington-based partner, co-chairs the firm's life sciences and health care regulatory practice. She advises health care and life science clients on regulatory, compliance and enforcement matters. Her clients include global manufacturers of medical devices, pharmaceuticals, biologics and diagnostics as well as emerging companies, developers of virtual and digital health technology, private equity funds, and a broad range of health care service providers. She can be reached at allison.shuren@arnoldporter.com. **Loreli "Lori" Wright** (R), a senior associate in the firm's life sciences and health care regulatory practice, counsels clients on a broad range of regulatory and transactional matters, including licensure and certification of health care facilities, corporate practice restrictions, Medicare and Medicaid program participation requirements, telehealth and telemedicine, and health care fraud, abuse and self-referral laws. She is based in Denver and can be reached at loreli.wright@arnoldporter.com. This article was originally published April 5, 2024, on the firm's website. Republished with permission.

This article was published on Westlaw Today on May 29, 2024.