



The Basics of the False Claims Act, STARK, and Anti-Kickback Statute and Recent Regulatory Developments

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Healthcare Fraud: A Top DOJ Priority

- Healthcare Fraud – particularly False Claims Act cases – have been a top priority of the Department of Justice for years.
- That is unlikely change anytime soon: the DOJ obtained more than \$3 billion in judgments and settlements from fraud claims between October 1, 2018 and September 30, 2019 – much of which came from healthcare fraud cases.
- Source: https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf

A Recent Example

- In September 2020, the DOJ charged 345 defendants (including over 100 licensed medical professionals) across 51 districts in a “National Health Care Fraud and Opioid Takedown.”
- The defendants were charged with submitting over \$6 billion in fraudulent claims, including \$4.5 billion connected to telemedicine.
- Source: <https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants>

Another Recent Development: The False Claims Act Working Group

- On Dec. 4, 2020, the Department of Health and Human Services announced the creation of a False Claims Act working group to enhance its participation with the DOJ and HHS Office of Inspector General to combat fraud.
- <https://www.hhs.gov/about/news/2020/12/04/hhs-announces-false-claims-act-working-group-enhance-efforts-combat-fraud-and-focus-resources-bad-actors.html#.X8xll8DVOas.linkedin>

FCA, STARK, and Anti-Kickback Basics

- The False Claims Act (FCA): Prohibits submitting false or fraudulent claims to the federal government for reimbursement.
- Interesting fact: It was enacted in 1863 in response to defense contractor fraud during the Civil War.
- The statute broadly applies to any claims submitted regardless of industry, and is commonly used to combat Medicare and Medicaid fraud.

False Claims Act (con't)

- For example, a provider who submits a claim for Medicare reimbursement for an “upcoded” procedure (i.e., coded as a more expensive procedure) has violated the FCA.
- Violations can result in both criminal and civil liability, including treble damages.

False Claims Act (con't)

- Private citizens (known as relators) are incentivized to pursue whistleblower FCA suits through qui tam actions.
- The majority of federal FCA suits are brought through this process.
- If the government prevails in the action, the relator receives a portion of the recovery.

STARK Law

- STARK is an anti-referral law. It generally prohibits a physician from referring patients for “Designated Health Services” to an entity if the physician or an immediate family member has a financial relationship with that entity.
- In March 2020, CMS issued blanket waivers that temporarily waived sanctions for certain financial arrangements for CMS-designated “Covid-19 Purposes.”

Anti-Kickback Statute

- The federal Anti-Kickback Statute generally prohibits a healthcare professional from providing something of value to another person in exchange for that person referring a patient whose care will be paid for by a federal program (e.g., Medicare)
- Violations of this statute subject the violator to criminal liability and often run afoul of the FCA as well.

Current DOJ Priorities

- Source: DOJ Remarks (Jody Hunt, Assistant Attorney General), 2020 Qui Tam Conference)
- Coding fraud within Managed Care Programs (e.g., Medicare Advantage)
- Nursing home fraud: Using the FCA and other statutes to address substandard care in nursing homes as part of the National Nursing Home Initiative

Current DOJ Priorities (con't)

- Electronic Health Record fraud: Using electronic health record systems to influence physician behavior.
- *See, e.g.*, the Practice Fusion case in which a company used its EHR system to influence opioid prescriptions, receiving kickbacks from an opioid company as a result.
- <https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0>

Current DOJ Priorities (con't)

- Telemedicine fraud: increased use of telemedicine services has resulted in an increased focus on this area.
- See, e.g., Operation Rubber Stamp, which recently resulted in charges in the Southern District of Georgia. Telemedicine executives allegedly paid doctors and nurse practitioners to order unnecessary equipment, medications, or testing, with little or no patient interaction. Equipment companies, labs, and pharmacies purchased those orders in exchange for illegal kickbacks and submitted false claims to Medicare.
- <https://www.justice.gov/usao-sdga/pr/operation-rubber-stamp-major-health-care-fraud-investigation-results-significant-new>

Current DOJ Priorities (con't)

- During the Covid-19 pandemic, CMS permitted Medicare reimbursement for telemedicine services that would previously have been available only to persons living in certain designated rural areas.
- These relaxed rules carry some risk of liability: For example, reimbursement for an “E-Visit” or “Virtual Check-in” requires a prior established relationship between doctor and patient.
- For example, a provider who seeks reimbursement for an E-Visit provided to a new patient would probably violate the FCA.

STARK Blanket Waivers

- In March 2020, CMS issued blanket waivers that temporarily waive sanctions for financial arrangements for “Covid-19 Purposes.”
- Covid-19 Purposes are broadly defined: “Diagnosis or medically necessary treatment of Covid-19 for any patient or individual,” or “securing the services of physicians and other healthcare practitioners and professionals, to furnish medically necessary services in response to the Covid-19 outbreak in the United States.”

STARK Blanket Waivers (con't)

- Both CMS and the OIG have indicated they will exercise some enforcement discretion with respect to these waivers:
- CMS: “The Secretary will work with the Department of Justice to address False Claims Act relator suits where parties using the blanket waivers have a good faith belief that their remuneration or referrals are covered by a blanket waiver.”
- These blanket waivers pose some risk of liability for less-than-vigilant providers who fail meet the Covid-19 Purposes requirement.

Cooperation Credit: Sometimes It Makes Sense if We All Just Get Along

- Cooperation credit refers to a DOJ policy intended to facilitate cooperation and incentivize reporting misconduct.
- Generally, the credit results in a reduction of damages and penalties.
- It is a useful means to minimize liability, particularly if the misconduct was committed by a few bad actors.

Cooperation Credit (con't)

- Cooperation credit may be granted for disclosing previously undisclosed conduct or undertaking remedial measures.
- It is possible to earn credit for disclosures made after an investigation is ongoing, provided the disclosed conduct is outside the scope of the investigation.
- Source (DOJ Manual): <https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112>