

9:00-10:30am – *CLE Credit*

Criminal, Civil and Administrative Enforcement in Kickback Cases

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Arthur Di Dio, *Senior Trial Counsel, Civil Fraud Section, DOJ*

Ty Kelly, *Shareholder, Baker Donelson*

Speakers

- **Allan Medina**, Acting Senior Deputy Chief, DOJ Criminal Division, Fraud Section
- **Keshia Thompson**, Senior Counsel, HHS Office of Inspector General
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- **Ty Kelly**, Shareholder, Baker Donelson

- **Katherine Lauer**, Partner, Latham & Watkins LLP (Moderator)



OVERVIEW

- Criminal Enforcement of Kickbacks
- Administrative Enforcement of Kickbacks
- Civil FCA Enforcement of Kickbacks
- Case Law Developments Involving Kickbacks



Criminal Enforcement of Kickbacks

**Health Care Fraud and
Appalachian Regional Prescription Opioid (ARPO) Strike Force Map**



Anti-Kickback Statute Enforcement: Telemedicine

- Telemedicine companies solicit illegal kickbacks and bribes from DME suppliers and clinical laboratories in exchange for referrals
 - Operation Brace Yourself: alleged fraud totaling \$1.2 billion
 - Operation Double Helix: alleged \$2.1 billion in fraudulent Medicare billing for cancer genetic tests
 - 2020 Takedown: charges against more than 86 defendants in 19 judicial districts in connection with the submission of over \$4.5 billion in false and fraudulent claims
 - 2021 National Health Care Fraud Enforcement Action: over \$1.1 billion in allegedly false and fraudulent claims submitted by more than 43 criminal defendants in 11 judicial districts
- Kickback schemes evolve into COVID-19 related schemes during pandemic
 - 2021 National COVID-19 Health Care Fraud Enforcement Action: charges against 14 defendants in seven federal districts for over \$143 million in COVID-19 health care fraud and kickback schemes
 - 2022 National COVID-19 Health Care Fraud Enforcement Action: \$147 million in COVID-19 health care fraud and kickback schemes

Anti-Kickback Statute Enforcement: Sober Homes

- Sober Homes Initiative was announced in the 2020 National Health Care Fraud Takedown to prosecute defendants who exploit vulnerable patients seeking treatment for drug and/or alcohol addiction.
- First charges brought against more than a dozen criminal defendants in connection with more than \$845 million of allegedly false and fraudulent claims
- 2021-2022 convictions at trial
 - Addiction treatment facility owner convicted in \$58 million health care fraud scheme (April 2022)
 - Sober homes operators sentenced to 188 months and 97 months (March 2022, after December 2021 conviction)
 - Medical director convicted in \$110 million addiction rehabilitation fraud scheme (February 2022)

Anti-Kickback Statute Enforcement: Sober Homes and EKRA

- Eliminating Kickbacks in Recovery Act (“EKRA”), 18 U.S.C. § 220, enacted in October 2018
- Enacted as part of the SUPPORT Act of 2002 after HHS noted the increase in abusive patient brokering practices involving opioids and testing and treatment for opioid addiction
- Extends Anti-Kickback Statute prohibitions to commercial insurance
- Among other things, criminalizes payment of remuneration to “induce a referral of an individual to a . . . recovery home, clinical treatment facility, or laboratory”

Anti-Kickback Statute Enforcement: EKRA's Application to Payments to Marketers (S&G Labs)

- S&G Labs Haw., LLC v. Graves, 2021 WL 4847430 (D. Haw. Oct. 18, 2021)
 - Marketers' compensation included a base annual salary of \$50,000, plus a 35% "cut" of the monthly net profits generated by his client accounts
 - Laboratory terminated marketer because of EKRA concerns and marketer sued for breach of contract
 - Court held that EKRA did not apply because marketer only marketed to medical professionals and did not work directly with patients; therefore, there was no payment for the referral of an individual patient for laboratory services
 - Although the "commission-based compensation structure induced him to try to bring more business to S&G," it did not implicate EKRA because "the 'client accounts [Graves] serviced were not individuals whose samples were tested at S&G."

Anti-Kickback Statute Enforcement: EKRA's Application to Payments to Marketers (Schena)

- United States v. Schena, 2022 WL 1720083 (N.D. Cal. May 28, 2022)
 - Criminal prosecution of the president of a clinical laboratory who was alleged to have violated various federal laws, including EKRA for paying illegal kickbacks and bribes to individuals and marketing companies hired by the lab to generate physician referrals
 - Defendant moved to dismiss the EKRA counts, citing S&G Labs
 - Court expressly rejected S&G Labs, concluding that the plain meaning of “to induce a referral of an individual” includes situations where a marketer causes an individual to obtain a referral from a physician.
 - According to the Court, the conduct alleged by the government violated EKRA because “the marketers received a kickback to 'influence' the physician's referrals.”

Administrative Enforcement of Kickbacks

Administrative Liability for Kickback Conduct

- 42 U.S.C. § 1320a-7a(a)(7) - commits an act in § 1320a-7b(b)
- OIG may seek CMP or exclude individuals or entities who knowingly and willfully: (1) offer or pay remuneration, directly or indirectly, to induce referrals of Federal health care program business; or (2) solicit or receive remuneration, directly or indirectly, in return for referrals of FHCP business.

Administrative Liability for Kickback Conduct

- FCA cases CMP reference
- Affirmative cases –
OCIG Affirmative Litigation Branch
- Self-Disclosures to OIG's HCP Self-Disclosure Protocol

Affirmative Kickback Case Projects

- Urine drug specimen cup cases (13 CMPL settlements, \$2.1 million CMPs, 1 FCA settlement for \$1.4 million)
- Blood lab physician cases (17 settlements, \$2.3 million CMPs)

Recent Affirmative CMP Kickback Cases

- Raquel Paragas & DR Home Healthcare - \$112,000
- Dr. David Kaner & Kaner Medical Group - \$94,000
- Dr. Robert Megna & Ferris Family Medicine - \$195,000
- Christopher Vendrys, MD - \$264,000



Recent 42 U.S.C. 1320a-7(b)(7) Exclusions for Kickback Conduct

- Afrooz Javanford - 20 years
- Farah Kohan - 20 years
- Targol Boostani - 20 years
- Wilson Asfora, MD, Medical Designs, LLC & Sicage, LLC – 6 years
- Richard DeFoore – 3 years

What's New and Interesting?

[oig.hhs.gov](https://www.oig.hhs.gov) – Advisory Opinions, CIAs, regulations, and other information

November 2020

- Special Fraud Alert: Speaker Programs
- Final Rule: Revisions to Safe Harbors Under the AKS and CMP Rules Regarding Beneficiary Inducements

Civil FCA Enforcement of Kickbacks

Civil FCA Enforcement

- Give-Aways to Referral Sources
 - Via Intermediaries
 - Via Sham Agreements with the Referral Sources
 - Via Improper Compensation
 - Via Suspect Pricing
- Arranging For or Recommending
- Co-pay Assistance
- Hospital-Physician Arrangements



Give-Aways to Referral Sources – Via Intermediaries

- **True Health Diagnostics LLC and Boston Heart Diagnostics Corporation (E.D. Tex.)** – On January 31, 2022, DOJ filed its **complaint in intervention** against two laboratory CEOs, one hospital CEO, and other individuals and entities, alleging that the defendants conspired to pay physicians through suspect financial arrangements to induce referrals to the hospitals for laboratory testing performed by BHD or THD. The complaint alleges that the **hospitals paid part of their lab profits to recruiters**, who in turn kicked back those funds to the referring physicians. The recruiters set up **management service organizations (MSOs)** to make payments to referring physicians that were disguised as investment returns but were in fact in exchange for referrals. As alleged in the complaint, BHD and THD executives and their sales force leveraged the MSO kickbacks to doctors to increase referrals and, in turn, their bonuses and commissions. <https://www.justice.gov/opa/pr/justice-department-files-false-claims-act-complaint-against-two-laboratory-ceos-one-hospital>
- **17 Physicians and 2 Hospital CEOs (E.D. Tex.)** - On January 20, 2022 - March 22, 2022, seventeen Texas doctors and two hospital CEOs agreed to pay a total of \$2.8 million to **settle** allegations that they received thousands of dollars from eight MSOs in exchange for ordering laboratory tests from hospitals that were performed by BHD and THD. One hospital also allegedly paid kickbacks to the physicians in the form of volume-based commissions paid to independent contractor recruiters, who used MSOs to pay numerous doctors for their referrals. The MSO payments to the physicians were allegedly disguised as investment returns but in fact were based on, and offered in exchange for, the physicians' referrals. <https://www.justice.gov/usao-edtx/pr/seven-texas-doctors-and-hospital-ceo-agree-pay-over-11-million-settle-kickback> and <https://www.justice.gov/usao-edtx/pr/ten-texas-doctors-and-healthcare-executive-agree-pay-over-168-million-settle-kickback>



Give-Aways to Referral Sources – Via Intermediaries

- **Reliance Medical Systems, LLC (C.D. Cal.)** – On May 5, 2022, Reliance Medical Systems, LLC, and its owners Bret Berry and Adam Pike, agreed in principle to pay the United States \$1,000,000 to **settle** allegations that the defendants funneled kickbacks to spine surgeons through intermediary distributorships, Apex and Kronos (“**physician-owned distributorships**” or “**PODs**”), that they co-owned with surgeons who implanted RMS spinal devices. <https://www.law360.com/articles/1490669>
- **Spinefrontier (D. Mass.)** – On March 5, 2020, DOJ filed its **complaint in intervention** against Spinefrontier and related entities and executives alleging that the defendants **created a sham consulting company**, Impartial Medical Experts, LLC, to funnel kickbacks in the form of **consulting fees** to spine surgeons who implanted Spinefrontier devices. The complaint alleges that the defendants paid “consulting” spine surgeons \$500 for a cervical procedure, and \$1,000 for a lumbar procedure — but only if the surgeon used SpineFrontier devices. The consulting spine surgeons allegedly often performed little or no work beyond implanting the devices and the defendants did not systematically collect or use feedback from the consultants and paid them even when they had provided no feedback at all.
<https://www.justice.gov/opa/pr/doj-files-suit-against-spine-device-manufacturer-and-executives-alleging-kickbacks-surgeons>



Give-Aways to Referral Sources – Via Intermediaries

- **Wilson Asfora, M.D. (D.S.D.)** – On May 3, 2022, Dr. Asfora, a neurosurgeon, and two **medical device distributorships (i.e., PODs)** that he owns, Medical Designs LLC and Sicage LLC, agreed to pay \$4.4 million to **settle** allegations that the defendants violated the AKS and caused the submission of false claims. The United States alleged that the defendants knowingly engaged in three kickback schemes to allow Asfora to profit from his use of over a dozen devices in his medical procedures. First, Medical Designs and Sicage paid Asfora **profit distributions** in exchange for Asfora using their devices in his spine surgeries. Second, Medical Designs acted as a distributor, reselling other manufacturers' spinal devices and **splitting the profits** with Asfora when he used those devices in surgeries. Third, Asfora received kickbacks from Medtronic USA Inc. in exchange for using its SynchroMed II infusion pumps. At Asfora's request, Medtronic allegedly paid the kickbacks to Asfora through a restaurant he owned, in the form of **lavish meals and alcohol** for Asfora and his friends, colleagues, and business partners. <https://www.justice.gov/usao-sd/pr/neurosurgeon-and-two-affiliated-companies-agree-pay-44-million-settle-healthcare-fraud>
- **Sanford (D.S.D.)** – On October 28, 2019, Sanford Health, Sanford Medical Center, and Sanford Clinic (collectively, Sanford), of Sioux Falls, South Dakota, agreed to pay \$20.25 million to **settle** allegations that they knowingly submitted false claims to federal healthcare programs resulting from **violations of the AKS and medically unnecessary spinal surgeries** performed by Dr. Asfora. The United States alleged that Sanford knew that one of its neurosurgeons was receiving kickbacks from his use of implantable devices distributed by his **PODs**. Sanford allegedly received warnings from Asfora's colleagues about the kickbacks and was aware of the heightened compliance risks associated with PODs. In addition, Asfora's colleagues repeatedly warned Sanford that Asfora was performing medically unnecessary procedures involving the devices in which he had a substantial financial interest. The United States alleged that, despite these repeated warnings, Sanford continued to allow him to profit from the devices he used in surgeries performed at Sanford, and to submit claims to federal healthcare programs for these surgeries, including procedures that were medically unnecessary. <https://www.justice.gov/opa/pr/sanford-health-entities-pay-2025-million-settle-false-claims-act-allegations-regarding>
- **Medtronic (D.S.D.)** – On October 29, 2020, Medtronic USA Inc. agreed to pay \$8.1 million to **settle** allegations that it violated the AKS and caused the submission of false claims by paying kickbacks, in the form of **funding social events at Asfora's restaurant**, so that he would use Medtronic's infusion pumps. <https://www.justice.gov/opa/pr/medtronic-pay-over-92-million-settle-allegations-improper-payments-south-dakota-neurosurgeon>



Give-Aways to Referral Sources – Via Sham Agreements

- **Paksn Inc. (C.D. Cal.)** – On June 14, 2021, DOJ filed its **complaint in intervention** against Paksn Inc., one of its owners, Prema Thekkek, and seven of their skilled nursing facilities owned alleging that the defendants paid kickbacks to referring physicians pursuant to **sham medical directorship agreements** that purported to provide compensation for administrative services. The complaint alleges that the defendants hired physicians who promised in advance to refer a large number of patients to the SNFs, paid physicians in proportion to the number of expected referrals, and terminated physicians who did not refer enough patients. <https://www.justice.gov/opa/pr/united-states-files-suit-against-california-skilled-nursing-chain-and-its-owner-allegedly>
- **Village Home Care, LLC (M.D. Fla.)** - On January 15, 2021, DOJ filed its **complaint in intervention** against Village Home Care, LLC, a home healthcare provider in Ocala, Florida, and Joy Rodak, VHC’s owner and operator, alleging that defendants entered into **sham financial arrangements, including medical directorship and sublease agreements**, with V. Reddy, M.D., and K. Reddy, M.D., in exchange for their referrals. [U.S. ex rel. Jacobs and Raney v. Village Home Care, LLC, et al., Case No. 8:14-cv-1557-CEH-JSS \(M.D. Fla.\)](#).
- **Vishnu Reddy, M.D.** – On October 21, 2021, Dr. V. Reddy paid the United States \$100,000 to **settle** allegations that he entered into a sham Medical Director agreement with VHC pursuant to which Dr. Reddy accepted remuneration in exchange for patient referrals in violation of the AKS and Stark Law.
- **Kuchakulla Reddy, M.D.** – On October 21, 2021, Dr. K. Reddy paid the United States \$62,000 to settle allegations that he entered into a sham sublease with VHC pursuant to which Dr. Reddy accepted remuneration in exchange for patient referrals in violation of the AKS and Stark Law.

Give-Aways to Referral Sources – Via Improper Compensation

- **Oaktree Medical Center, P.C. (D.S.C.)** – On September 2, 2021, the U.S. District Court for the District of South Carolina entered **default judgments** for the United States totaling \$136,025,077 against South Carolina pain management clinics, drug testing labs, and a substance abuse center, after the defendants failed to defend against the United States’ allegations. The complaint, which was filed on May 31, 2019, alleged that the defendant entities, all of which were owned or operated by chiropractor Daniel McCollum, provided illegal financial incentives to providers to induce their referrals of urine drug tests in violation of the AKS and Stark Law. The illegal financial incentives included **compensating employed pain physicians based on the value of their UDTs to McCollum’s labs** by sharing revenues from non-federal health program referrals with physicians in exchange for their federal health care program referrals.
<https://www.justice.gov/opa/pr/united-states-obtains-140-million-false-claims-act-judgments-against-south-carolina-pain>

Give-Aways to Referral Sources – Via Suspect Pricing

- **Professional Compounding Centers of America (W.D. Tex.)** – On November 1, 2021, DOJ filed its **complaint in intervention** alleging that the defendant, a supplier of chemical ingredients used in drug compounding, violated the AKS and caused the submission of false claims to TRICARE **by inflating its average wholesale prices and using the resulting AWP spreads**, in some instances thousands of percent over actual selling prices, to induce the purchase of its ingredients. The complaint alleges that inflating AWPs enabled PCCA to charge higher prices than its competitors and earn greater profits, and to overcome member pharmacy complaints over PCCA's higher prices by emphasizing the greater reimbursement potential of its ingredients, due to its falsely inflated AWPs. PCCA's member pharmacies then submitted hundreds of thousands of compound prescription claims to TRICARE for highly inflated reimbursement amounts based on PCCA's AWPs. In other words, PCCA knowingly used its inflated AWP pricing as an illegal kickback to induce the purchase of its products.
<https://www.justice.gov/opa/pr/justice-department-files-complaint-against-professional-compounding-centers-america-inc>



Give-Aways to Referral Sources – Via Suspect Pricing

- Taro Pharmaceuticals USA, Sandoz Inc., and Apotex Corporation (E.D. Pa.) - On September 20, 2021, three generic pharmaceutical companies agreed to pay to the United States \$447.2 million to **settle** allegations that they violated the AKS and caused the submission of false claims by **conspiring to fix the price of generic drugs**, resulting in higher drug prices for federal health care programs and beneficiaries. The United States alleged that through a **horizontal price fixing scheme**, the companies caused increases in their revenues and profits and thereby provided each other with something of value as an incentive for the scheme. The United States further alleged that the purpose of the market allocation scheme was arranging for the customers (wholesalers, pharmacies, etc.) to purchase from certain companies but not others. Finally, a portion of their drug purchases were reimbursed or purchased by federal healthcare programs.
<https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability>

Arranging For or Recommending

- **athenahealth** (D. Mass) – On January 28, 2021, athenahealth, Inc., a developer of electronic health records (EHR) services, agreed to pay \$18.25 million to **settle** allegations that it paid illegal kickbacks to generate sales of its EHR product, athenaClinicals, and caused the submission of false claims. In a **complaint filed in conjunction with today’s settlement**, the United States alleged that Athena violated the AKS and FCA in through three marketing programs. First, Athena funded all-expense-paid sporting, entertainment, and recreational events (including the Masters Tournament and Kentucky Derby) for its customers and prospective customers. Second, Athena paid kickbacks to customers through its “Lead Generation” program designed to identify new prospective customers. Under this program, Athena paid up to \$3,000 per physician that signed up for Athena services, regardless of how much time (if any) the client spent speaking or meeting with the lead. Third, Athena entered into deals with competing companies that had discontinued their health information technology products. Pursuant to these “**Conversion Deals,**” the companies agreed to refer their clients to Athena, and Athena paid competitors based on the value and volume of practices that were successfully converted into Athena customers.
<https://www.justice.gov/usao-ma/pr/athenahealth-agrees-pay-1825-million-resolve-allegations-it-paid-illegal-kickbacks>

Co-pay Assistance Program Cases

- **Teva Pharmaceuticals (D. Mass.)** – On August 18, 2020, DOJ filed its **complaint in intervention** alleging that the Teva conspired with a specialty pharmacy, Advanced Care Scripts, Inc., and two purportedly independent foundations, Chronic Disease Fund and The Assistance Fund, to violate the FCA and AKS by using the foundations as conduits to **subsidize Medicare co-pays for Copaxone**, a drug used to treat Multiple Sclerosis, all while steadily raising Copaxone’s price.
<https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-drug-maker-teva-pharmaceuticals>
- **Collier Anesthesia Pain and Tampa Pain Relief Center (M.D. Fla.)** – On February 1, 2022, Collier Anesthesia Pain, LLC, a Ft. Myers pain management clinic, and Tampa Pain Relief Center, Inc., agreed to pay \$1,665,000 to **settle** allegations that they violated the AKS and caused the submission of false claims by causing affiliated surgery centers to **waive copayments** for surgical facility fees in order to induce patients to receive injection procedures.
<https://www.justice.gov/usao-mdfl/pr/pain-clinic-pays-more-16-million-settle-false-claims-act-and-kickback-allegations>

Hospital-Physician Arrangements

- **Flower Mound Hospital (N.D. Tex.)** – Flower Mound Hospital, a partially physician-owned hospital, agreed to pay \$18.2 million to **settle** allegations that it violated the AKS and Stark Law and caused the submission of false claims by **repurchasing shares from physician-owners aged 63 or older and then reselling those shares to younger physicians**. The United States alleged that FMH took into account the volume or value of physicians' referrals when it (1) selected the physicians to whom the shares would be resold and (2) determined the number of shares each physician would receive.
<https://www.justice.gov/opa/pr/flower-mound-hospital-pay-182-million-settle-federal-and-state-false-claims-act-allegations>

CASE LAW DEVELOPMENTS ON KICKBACKS

FAIR MARKET VALUE PAYMENTS

U.S. v. Medtronic, 2022 WL 541604 (C.D. Cal., Feb. 23, 2022)

- Medtronic manufactured medical device called the Pipeline, surgically inserted at site of a brain aneurism to treat that brain aneurism.
- Relator alleged that Medtronic compensated doctors to induce them to order a greater number of Pipeline devices for their patients.
- Relator alleged, among other things, that Medtronic used a proctoring program where it regularly overpaid doctors to teach other doctors about Pipeline; Medtronic acquired at an inflated rate companies in which doctors with a high volume of Pipeline usage held ownership interests such that result was that doctors received a substantial windfall which significantly exceeded the FMV of their ownership interest.

FAIR MARKET VALUE PAYMENTS CONTINUED

U.S. v. Medtronic, 2022 WL 541604 (C.D. Cal., Feb. 23, 2022)

- Court found that it was plausible that the amount paid for the proctoring services was more than FMV and was → a kickback.
- Court also found that AKS Personal Services Safe Harbor does not defeat claims because the safe harbor requires that “the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service.”

“Moreover, even some FMV payments will qualify as illegal kickbacks, such as when the payor has considered the volume of reimbursable business between the parties, in providing compensation and otherwise intends for the compensation to function as an inducement for more business.”
- Court cites *U.S. v. Vibrant*, 2020 WL 4818706 (N.D. Cal 2020) (noting that remuneration may violate AKS regardless of whether the payment is fair market value for services rendered) and 70 Fed. Reg. 4858 (Jan. 31, 2005).

INDIRECT REFERRALS

Stop Illinois Health Care Fraud LLC v. Sayeed, 2020 WL 6896265 (7th Cir. Nov. 24, 2020)

- Defendant owned Management Principals, Inc. (MPI), which arranged medical referrals to other entities and advertised itself as a one stop shop. HCI was a senior program that surveyed seniors' needs and referred to home health, including to MPI on a rotating basis.
- HCI and MPI entered into a management services agreement, which HCI's attorney drafted.
- Purpose of agreement was for HCI to give MPI access to its files so it could perform data mining. MPI wanted access to raw data to assist it in becoming an Accountable Care Organization, which required enrolling 5,000 Medicare patients.

Are MPI's payments under the agreement intended to secure access to the client information so it could solicit a prohibited referral under the AKS?

INDIRECT REFERRALS

CONTINUED

Stop Illinois Health Care Fraud LLC v. Sayeed, 2020 WL 6896265 (7th Cir. Nov. 24, 2020)

- Bench trial held on 2/22/2021; court found that Defendants violated the Anti-Kickback Statute, False Claims Act, and Illinois False Claims Act, and no affirmative defense applied.
- HCI gave MPI access to its files that contained client contact information. MPI used that contact information to solicit those clients for Medicare services → same outcome as if HCI had directly referred patients to MPI.

Giving MPI access to client contact information that was used to solicit clients → Referral

Fees paid → Remuneration

Inducement was knowing and willful → AKS Violation

VOLUME-BASED REFERRALS

U.S. v. Mallory, 988 F.3d 730 (4th Cir. 2021)

- Two labs that provided blood testing for cardiovascular disease and diabetes entered into exclusive contracts with Blue Wave, a consulting company, to market and sell blood tests.
- In addition to a base fee, the labs paid Blue Wave a percentage of their revenue based on the number of blood tests that physicians ordered. Further, Blue Wave used independent contractors to market to physicians, who were also paid based on the number of blood tests ordered.
- To boot, physicians were paid for blood tests ordered under “shipping and handling” and “draw” fees.

VOLUME-BASED REFERRALS

CONTINUED

U.S. v. Mallory, 988 F.3d 730 (4th Cir. 2021)

- Government maintained that AKS prohibited labs from paying Blue Wave for inducing others to arrange the tests and that AKS prohibited Blue Wave from paying its salespeople for recommending purchase of the tests.
- Jury convicted and the Fourth Circuit affirmed.
 - Attorneys from lab warned Defendants that paying commissions to independent contractors *might* violate the AKS and the jury could have reasonably concluded that Defendants should have given more consideration to the many subsequent warnings about the commissions.

** Increased settlements for paying independent contract marketers based on volume.

** Look for more criminal AKS cases here as willfulness is easier to prove with *Mallory* out there – it is more important than ever to carefully structure arrangements to comply with the AKS's safe harbors where applicable.

THE TWO SIDES OF EKRA

S&G Labs Haw., LLC v. Graves,

2021 WL 4847430 (D. Haw. Oct. 18, 2021)

- EKRA does not apply to situations where a marketer obtains a referral of patients by securing them indirectly from physicians, rather than working with individual patients directly.

U.S. v. Schena, 2022 WL 1720083

(N.D. Cal. May 28, 2022)

- There is no requirement of "directness" in the text of EKRA; it applies to situations where someone "pays or offers any remuneration," to "induce" an individual into using laboratory or clinical services. 18 U.S.C. § 220(a).
- No requirement of direct interaction between the marketer and the individual.

CAUSATION UNDER AKS

U.S. ex rel. Fitzer v. Allergan, Inc. et al, 2022 WL 846211 (D.M.D. Mar. 22, 2022)

- Companies selling LAP-BAND devices had a physician locator tool on their website that allowed patients to find local surgeons that could perform the surgery implanting the LAP-BAND device
- Relator alleged that companies provided surgeons with free advertising to induce surgeons to recommend the LAP-BAND medical device instead of alternative operations and required surgeons to meet a LAP-BAND surgery quota to stay on their website
- Notably, the complaint
 - Relied on physicians' use of a Medicare code that did not exclusively relate to LAP-BAND devices
 - Even if the Medicare claims data had exclusively related to LAP-BAND surgeries, did not allege that those claims were linked to any particular patient who was exposed to an illegal recommendation or referral
 - Did not allege when relevant procedures took place or when claims were submitted
 - Left open the possibility that physicians did not even know they were on the website

WHAT STANDARD OF CAUSATION APPLIES?

Not but for, not proximate cause – but “middle of the road”

“A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient...A link is required, but it is less than’ showing that the bribe succeeded in producing the prescription....In other words, Relators need only show that the [defendants’] referral...actually sat in the causal chain.”

- Given the deficiencies in the complaint, the court held that the complaint failed to allege the requisite casual link between the alleged AKS violation and the allegedly false claims.
- The court noted that this approach has been adopted by several courts, citing opinions from the Third Circuit, Southern District of New York, and District of Massachusetts.

AKS IN EHR CASES

“EHR technology plays an important role in the provision of medical care, and it is critical that the selection of an EHR platform be made without the influence of improper financial inducements.”

– Acting Assistant Attorney General Brian Boynton for DOJ’s Civil Division

Athenahealth Agrees to Pay \$18.25 Million to Resolve Allegations that It Paid Illegal Kickbacks

BOSTON – athenahealth, Inc. (Athena), a Watertown-based developer of electronic health records (EHR) services, has agreed to pay \$18.25 million to resolve allegations that it violated the False Claims Act (FCA) by paying illegal kickbacks to generate sales of its EHR product, athenaClinicals.

Electronic Health Records Vendor to Pay \$145 Million to Resolve Criminal and Civil Investigations

Practice Fusion Inc. Admits to Kickback Scheme Aimed at Increasing Opioid Prescriptions

Practice Fusion Inc. (Practice Fusion), a San Francisco-based health information technology developer, will pay \$145 million to resolve criminal and civil investigations relating to its electronic health records (EHR) software, the Department of Justice announced today.

Questions / Discussion

