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The Evolving Kickback from a Prosecutor's Perspective

Health Care Compliance Institute Webinar, April 1, 2020

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Overview of Presentation

- The Anti-Kickback Statute
- Exposure for AKS Violations
- Government Players in AKS Enforcement
- Recent Trends in Enforcement
- Practice Pointers for AKS Compliance

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The Anti-Kickback Statute (AKS)

42 U.S.C. §1320a-7b(b)

(1) Whoever **knowingly and willfully** solicits or receives any **remuneration** (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever **knowingly and willfully** offers or pays any **remuneration** (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

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The Anti-Kickback Statute (AKS)

42 U.S.C. §1320a-7b(b)



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The Anti-Kickback Statute (AKS)

The English Version



Breaking It Down

Offering or asking for something of value in exchange for referring any service or good that is paid for by Federal Health Programs is BAD – actually criminal conduct.

BUT: it has to be on purpose, knowing that what you are doing is wrong.

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The Anti-Kickback Statute (AKS)

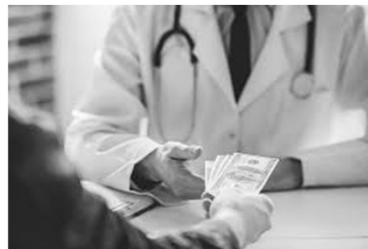
The English Version

Offering or Soliciting Remuneration

Not just money, but that is most obvious.

Things of value such as:

- office space on the cheap (FMV)
- paying for staff in office
- discounts on products (not under safe harbor)
- services such as practice development
- event sponsorships
- travel



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The Anti-Kickback Statute (AKS)

The English Version

In return for:

- Referring for services
- Ordering equipment
- Using devices
- Plan of care



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The Anti-Kickback Statute (AKS)

The English Version

Paid for by Federal Healthcare Program



Don't forget DOL, VHA, and Federal employees workers' compensation, among others

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The Stakes

Violations punishable by up to 10 years in prison.



Criminal Penalty of up to \$100,000 per violation

False Claims Act Liability of Three Times the Amount of All Claims Submitted that Were Caused by the Kickback plus penalties of \$11,000 to \$22,000 per claim



Exclusion from Government Payor Programs



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The Players



- Office of Counsel to the Inspector General, Department of Health and Human Services
 - Industry Guidance Branch – Advisory Opinions and other guidance documents
 - Administrative and Civil Remedies Branch – FCA, Self-Disclosures, Exclusion, CMPL
 - Administrative Litigation Branch- Affirmative Exclusions and CMPL
- Office of the Inspector General Department of Health and Human Services
 - Investigations, Agents
 - Exclusions Branch
- United States Department of Justice
 - The United States Attorney's Office
 - Criminal Division at the Department of Justice
 - Civil Division at the Department of Justice (Civil Frauds)
 - The Federal Bureau of Investigation
- State Medicaid Fraud Control Units
- Defense Criminal Investigative Services (DCIS)

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Recent Cases – Covidien, March 11, 2019

Covidien to Pay Over \$17 Million to The United States for Allegedly Providing Illegal Remuneration in the Form of Practice and Market Development Support to Physicians

Covidien LP has agreed to pay \$17,477,947 to resolve allegations that it violated the False Claims Act by providing free or discounted practice development and market development support to physicians located in California and Florida to induce purchases of Covidien's vein ablation products, the Department of Justice announced today.

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Recent Cases -- Covidien

Products

- ClosureFast™ radiofrequency ablation catheters that treat venous reflux disease

Marketing and practice development services as remuneration

- Customized marketing plans
- Scheduling and conducting lunch and learn meetings and dinners with other physicians to drive referrals
- Providing substantial assistance in planning, promoting and conducting vein screening events to cultivate new patients for those practices

Investigation prompted by two whistleblower suits

- *United States ex rel. Hayes, et al. v. Covidien, Inc., et al.*, Case No. C 14-1511-EDL (N.D. Cal.), and *United States, et al. ex rel. Howerton v. Covidien, et al.*, Case No. C 15-0559-EDL (N.D. Cal.).

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Recent Cases – Inform Diagnostics

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, January 30, 2019

Pathology Laboratory Agrees to Pay \$63.5 Million for Providing Illegal Inducements to Referring Physicians

Pathology laboratory company Inform Diagnostics has agreed to pay \$63.5 million to settle allegations that it violated the False Claims Act by engaging in improper financial relationships with referring physicians, the Justice Department announced today. Inform Diagnostics, formerly known as Miraca Life Sciences Inc., is headquartered in Irving, Texas, and was a subsidiary of Miraca Holdings Inc., a Japanese company, during the period relevant to the case. In 2017, majority ownership of the company changed, and the company was renamed.

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Recent Cases – Inform Diagnostics

- \$63.5 million dollar settlement for AKS violations
- Resolved allegations that laboratory provided referring physicians subsidies for electronic health records and free or discounted technology services
- Investigation prompted by three whistleblower lawsuits:
 - *United States ex rel. Dorsa v. Miraca Life Sciences, Inc.*, Case No. 13-cv-1025 (M.D. Tenn.); *United States ex rel. LPF, LLC v. Miraca Life Sciences, Inc., et al.*, 3:16-cv-1355 (M.D. Tenn.); and *United State ex rel. Heaphy, et al. v. Miraca Life Sciences, Inc.*, 3:18-cv-1027 (M.D. Tenn.).

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Recent Cases – Phony Foundations

<p>Department of Justice Office of Public Affairs</p> <p>FOR IMMEDIATE RELEASE Thursday, April 4, 2019</p> <p>Three Pharmaceutical Companies Agree to Pay a Total of Over \$122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations</p> <p>The Department of Justice today announced that three pharmaceutical companies – Jazz Pharmaceuticals plc (Jazz), Lundbeck LLC (Lundbeck), and Alexion Pharmaceuticals Inc. (Alexion) – have agreed to pay a total of \$122.6 million to resolve allegations that they each violated the False Claims Act by illegally paying the Medicare or Civilian Health and Medical Program (ChAMPVA) copays for their own products, through purportedly independent foundations that the companies used as mere conduits.</p>	<p>Department of Justice Office of Public Affairs</p> <p>FOR IMMEDIATE RELEASE Thursday, April 25, 2019</p> <p>Two Pharmaceutical Companies Agree to Pay a Total of Nearly \$125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations</p> <p>The Department of Justice announced today that two more pharmaceutical companies – Astellas Pharma US Inc. (Astellas) and Amgen Inc. (Amgen) – have agreed to pay a total of \$124.75 million to resolve allegations that they each violated the False Claims Act by illegally paying the Medicare copays for their own products, through purportedly independent foundations that the companies used as mere conduits.</p>
<p>Department of Justice Office of Public Affairs</p> <p>FOR IMMEDIATE RELEASE Thursday, December 6, 2018</p> <p>Drug Maker Actelion Agrees to Pay \$360 Million to Resolve False Claims Act Liability for Paying Kickbacks</p> <p>Pharmaceutical company Actelion Pharmaceuticals US, Inc. (Actelion), based in South San Francisco, California, has agreed to pay \$360 million to resolve claims that it illegally used a foundation as a conduit to pay the copays of thousands of Medicare patients taking Actelion's pulmonary arterial hypertension drugs, in violation of the False Claims Act, the Justice Department announced today.</p>	<p>Department of Justice Office of Public Affairs</p> <p>FOR IMMEDIATE RELEASE Tuesday, April 30, 2019</p> <p>Pharmaceutical Company Agrees to Pay \$17.5 Million to Resolve Allegations of Kickbacks to Medicare Patients and Physicians</p> <p>The Justice Department announced today that US WorldMeds LLC (USWM) has agreed to pay \$17.5 million to resolve allegations that it violated the False Claims Act, 31 U.S.C. §§ 3729 <i>et seq.</i>, by paying kickbacks to patients and physicians to improperly induce prescriptions of its drugs, Apokyn® and Myobloc®. USWM is a pharmaceutical manufacturer headquartered in Louisville, Kentucky.</p>

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Recent Cases – Phony Foundations

Settlement with seven pharmaceutical companies for \$624 million
Allegations

- Some prescription drugs covered under Medicare require significant co-payments by the beneficiary
- The companies used supposedly charitable foundations as conduit to make co-payments for beneficiaries that used their drugs

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Recent Cases – Price Fixing and AKS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, May 31, 2019

Pharmaceutical Company Admits to Price Fixing in Violation of Antitrust Law, Resolves Related False Claims Act Violations

Heritage Pharmaceuticals Agrees to Pay More than \$7 Million in Criminal Penalty and Civil Damages and to Cooperate with Ongoing Parallel Investigations in the Generics Industry

Heritage Pharmaceuticals Inc., a generic pharmaceutical company headquartered in Eatontown, New Jersey, was charged for conspiring with its competitors to fix prices, rig bids, and allocate customers, the Department of Justice announced today.

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Recent Cases – Price Fixing and AKS

- Antitrust case where Heritage Pharmaceuticals Inc. entered a deferred prosecution agreement with the United States for pricing fixing, bid rigging and allocating customers for generic drugs
- False Claims Act resolution in the amount of \$7.1 million was for violations of AKS based on theory that Heritage paid and received remuneration in the form of price, supply and allocation of customers with other pharmaceutical manufacturers

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Recent Cases – Sham Speakers Program

FOR IMMEDIATE RELEASE

Thursday, September 26, 2019

Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations

Avanir Pharmaceuticals Agrees to Pay More than \$108 Million in Criminal Penalties and Forfeiture and Civil Damages and Agrees to Cooperate with Indictments against Four Individuals

Avanir Pharmaceuticals (Avanir), a pharmaceutical manufacturer based in Aliso Viejo, California, was charged for paying kickbacks to a physician to induce prescriptions of its drug Nuedexta, the Department of Justice announced today. The Northern District of Ohio also announced indictments of four individuals, including former Avanir employees and one of the top prescribers of Nuedexta in the country, who were involved in the kickback scheme. Avanir has also agreed to pay over \$95 million to resolve civil False Claims Act allegations of kickbacks as well as its false and misleading marketing of Nuedexta to providers in long term care facilities to induce them to prescribe it for behaviors commonly associated with dementia patients, which is not an approved use of the drug.

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Recent Cases – Sham Speakers Program

Avanir Pharmaceuticals Paid Total of \$108 million to resolve criminal and civil liability

- \$95 million for civil False Claims Act liability
- Deferred Prosecution Agreement with company
- \$7.8 million criminal penalty
- Over \$5 million in forfeiture
- Four individuals indicted
- Corporate Integrity Agreement with HHS-OIG

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Recent Cases – Sham Speakers Program

- Drug Nuedexta was approved by FDA for treatment of pseudobulbar affect (PBA) – involuntary frequent and sudden episode of crying or laughing, often occur secondary to neurological disease or brain injury.
- Avanir alleged to have paid money, honoraria, travel and food to induce physicians to order the drug.
- One form of remuneration was payment to give talks about Nuedexta. The events were primarily social with no educational value.
- Investigation prompted by whistleblower cases by former employees of company: *United States ex rel. Kevin Manieri v. Avanir Pharmaceuticals, Inc. and Deepak Raheja*, Action No. 5:15-cv-611 (N.D. Ohio), and *United States ex rel. Duane Arnold and Mark Shipman v. Avanir Pharmaceuticals, Inc.*, Action No. 1:15-cv-01250 (N.D. Ga.)

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Recent Cases-EHR CDS Alerts

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, January 27, 2020

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.

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Recent Cases-EHR CDS Alerts

- Criminal and Civil resolution.
- Practice Fusion admitted that it solicited and received kickbacks from a major opioid company in exchange for utilizing its EHR software to influence physician prescribing of opioid pain medications through CDS alerts.
- Practice Fusion has executed a deferred prosecution agreement and agreed to pay over \$26 million in criminal fines and forfeiture.
- In separate civil settlements, Practice Fusion has agreed to pay a total of approximately \$118.6 million resolve allegations that it, among other things, accepted kickbacks from the opioid company and other pharmaceutical companies.
- In exchange for “sponsorship” payments from pharmaceutical companies, Practice Fusion allowed the companies to influence the development and implementation of the CDS alerts in ways aimed at increasing sales of the companies’ products.
- Investigation was not predicated on a qui tam.

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Recent Cases- MSOs

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, November 26, 2019

Laboratory to Pay \$26.67 Million to Settle False Claims Act Allegations of Illegal Inducements to Referring Physicians

Laboratory Boston Heart Diagnostics Corporation (Boston Heart), of Framingham, Massachusetts, has agreed to pay \$26.67 million to resolve False Claims Act allegations involving payments for patient referrals in violation of the Anti-Kickback Statute and the Stark Law, as well as claims otherwise improperly billed to federal healthcare programs for laboratory testing, the Department of Justice announced today.

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Recent Cases- MSOs

- Boston Heart allegedly agreed to provide laboratory testing services to small Texas hospitals in exchange for per-test payments.
- Boston Heart allegedly coordinated with the hospitals' independent marketers, who set up companies known as management service organizations (MSOs), to make payments to referring physicians that were disguised as investment returns but were actually based on, and offered in exchange for, the physicians' referrals.
- Boston Heart allegedly helped the MSOs identify physician targets, referred interested physicians to the MSOs to secure their business, and participated with the MSOs in sales pitches to offer physicians money in exchange for referrals. As a result, physicians allegedly referred patients to the Texas hospitals and Boston Heart for laboratory tests performed by Boston Heart, which were then billed to Medicare, Medicaid, and TRICARE.
- Investigation prompted by whistleblower cases: *United States ex rel. Riedel v. Boston Heart Diagnostics Corp.*, No. 1:12-cv-1423 (D.D.C.) and *United States ex rel. FBH1 LLC v. Boston Heart Diagnostics Corp.*, No. 2:17-cv-2061 (E.D. Cal.).

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Practice Pointers

Compliance Program/Policies

- Different programs for different organizations (OIG guidance for various types of organization)
- Baseline policies regarding AKS/Stark
- Legal/compliance review of any financial transaction with referral source
- Hard stops in place for certain transactions until review by legal/compliance

Scrutinize all relationships and transactions with referral sources

- Compensation and bonus arrangements
- Office space leases
- Direct and indirect relationships, including downstream marketing
- Analyze FMV in advance of every relationship or transaction
 - Failure to conduct FMV analysis is major red flag in subsequent investigation
 - On the other hand a credible FMV analysis can cut an investigation short early

Speakers Bureaus, CME, and Training Programs

- Fair exchange of money for services
- Tracking of referral patterns – double edge sword

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Practice Pointers

- Remuneration – can be just about anything.
 - Prosecutors are going to ask if the referral source gained a benefit
 - Practice Development example
 - Anti-Trust case considered remuneration the price fixing conspiracy
 - DOJ will go beyond the face of the relationship
 - Charitable Foundations linked to pharma
 - Management Services Contracts – what services are being provided in exchange for the amounts being paid
 - Purpose behind a relationship that appears to meet a safe harbor
- Engage all relevant government players in resolutions.

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New World -- Proposed Rules

- Regulatory Sprint Proposed Rules
- Potential opportunities for new and innovative relationships to coordinate care
- Potential opportunities for evolving kickbacks despite safeguards

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