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New York State Bar Association Health Law Section

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Key Provisions of the Anti-Referral Laws

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The Federal Anti-Kickback Statute

- The Basic Rule
  - It is a crime to knowingly and willfully solicit, receive, offer or pay any remuneration to induce or reward referrals for which payment may be made in whole or in part under a Federal health care program.

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The Federal Anti-Kickback Statute

- What is a Federal health care program?
  - Any plan or program that provides health benefits whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government.
  - The definition also includes certain State health care programs.
    - Examples include: Medicare, Medicaid, Veterans' programs and the State Children's Health Insurance Programs.

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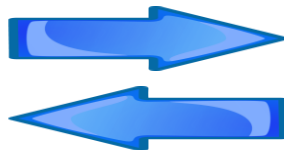
The Federal Anti-Kickback Statute

- What is Remuneration?
  - Includes virtually anything of value, whether given directly or indirectly, overtly or covertly, in cash or in kind.
    - (*E.g.*, cash equivalents, kickbacks, bribes, rebates, etc.)
  - Both sides of an illegal arrangement are liable.



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The Federal Anti-Kickback Statute

- Violations of the AKS constitute felony crimes -
  - Subject to up to 10 years imprisonment, $100,000 in fines, or both.
  - Civil and administrative penalties may also result. The OIG may:
    - Exclude individuals/entities from participating in Federal health care programs; and
    - Impose civil monetary penalties -- currently a maximum of $100,000 (for acts committed after February 9, 2018) for each offer, payment, solicitation, or receipt of remuneration that violates the AKS.

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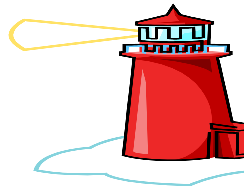
The Federal Anti-Kickback Statute

- "Safe harbors" were enacted in the statute and adopted in regulations to protect certain types of arrangements where the potential for abusive referral practices is deemed to be minimal.



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The Federal Anti-Kickback Statute

- Must meet all of the relevant safe harbor's requirements to be protected.
  - If not, totality of the facts will be examined to determine if there is a violation of the law;
    - in particular, the parties intent.
    - But also:
      - Overutilization of/increased costs to Federal health care programs.

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Safe Harbors to the AKS

• Investment Interests • Space Rental • Equipment rental • Personal services and management contracts • Sale of practice • Referral services • Warranties • Discounts • Employees • Group purchasing organizations	• Waiver of beneficiary copayment, coinsurance and deductible amounts • Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans • Price reductions offered to health plans • Practitioner recruitment • Obstetrical malpractice insurance subsidies • Investments in group practices

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Safe Harbors to the AKS

• Cooperative hospital service organizations • Ambulatory surgical centers • Referral arrangements for specialty services • Price reductions offered to eligible managed care organizations • Price reductions offered by contractors with substantial financial risk to managed care organizations • Ambulance replenishing	• Health Centers • Electronic prescribing items and services • Electronic health records items and services • Federally Qualified Health Centers and Medicare Advantage Organizations • Medicare Coverage Gap Discount Program • Local Transportation

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NY State Anti-Kickback Laws

- Prohibit a Medicaid provider or any person acting in concert with a Medicaid provider from:
  - soliciting, receiving, accepting, agreeing to receive or accept, or offering, agreeing to give, or giving, any payment or other consideration in any form . . .
    - for the referral of services for which payment is made under the Medicaid program, or
    - to purchase, lease or order any good, facility, service or item for which payment is made under the Medicaid program.

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The Federal "Stark" Law

- Basic Self-Referral Prohibition:

  1. A physician may not make a referral,
  2. to an entity for the furnishing of designated health services ("DHS") for which Medicare payment may be made (and the entity may not present or cause to be presented a claim or bill for DHS provided as a result of such referral),
  3. if the physician or immediate family member of the physician has a financial relationship with the entity,
  4. unless an exception to the Law applies.

- **Applies to Medicaid?**

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The Federal "Stark" Law

- Strict Liability Law
  - No requirement of intent to induce referrals.
  - If the basic prohibition is implicated and an exception to the Law is not satisfied, Stark is violated.

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The Federal "Stark" Law

- Penalties include:
  - The denial of, or the requirement to refund, any payments for DHS that resulted from an unlawful referral;
  - Civil monetary penalty of up to $15,000 for each claim; *
  - For "circumvention schemes," a civil monetary penalty of up to $100,000 per "scheme."*
  - Exclusion from Federal health care programs.
  - Liability under the False Claims Act

    * These penalties amounts are statutory, but are subject to adjustments for inflation. The current penalties are $24,253 and $161,692, respectively.

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"Stark" Law Exception Categories

- **All Purpose Exceptions:**
  - Physician Services
  - In-Office Ancillary Services
  - Prepaid Plans
  - Academic Medical Centers
  - Implants Furnished by ASCs
  - Dialysis-Related Outpatient Prescription Drugs
  - Preventive Screening, Immunizations, and Vaccines
  - Eyeglasses and Contact Lenses following Cataract Surgery and
  - Intra-Family Rural Referrals

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“Stark” Law Exception Categories

- **Ownership Interest Exceptions:**
  - Publicly Traded Securities
  - Mutual Funds
  - Rural Providers
  - Hospitals in Puerto Rico and
  - Whole Hospital Ownership/Investment

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“Stark” Law Exception Categories

- **Direct Compensation Arrangement Exceptions:**
  - Rental of Office Space
  - Rental of Equipment
  - Bona Fide Employment
  - Personal Services Arrangements
  - Physician Recruitment
  - Isolated Transactions
  - Remuneration Unrelated to DHS
  - Group Practice Arrangements with Hospitals
  - Payments by a Physician

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"Stark" Law Exception Categories

- **Direct Compensation Arrangement Exceptions:**
  - Charitable Donations by a Physician
  - Non-monetary Compensation
  - Fair Market Value
  - Compliance Training
  - Referral Services
  - Obstetrical Malpractice Insurance Subsidies
  - Professional Courtesy
  - Retention Payments in Underserved Areas

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"Stark" Law Exception Categories

- **Direct Compensation Arrangement Exceptions:**
  - Community-Wide Health Information Systems
  - Electronic Prescribing Items and Services (42 C.F.R. § 411.357(v));
  - Electronic Health Records Items and Services Exception
  - Assistance to Compensate a Non-Physician Practitioner and
  - Timeshare Arrangements
- **Indirect Compensation Arrangement Exception**

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New York State "Stark" Law

- New York's "Stark" law covers **all payers**.
- Applies to "practitioner" referrals to a "health care provider" for the following services:
  - clinical laboratory
  - pharmacy
  - radiation therapy
  - x-ray or imaging services
  - physical therapy
- Exceptions (types).
- But . . . may still apply to other services (look to nature of financial relationship, whether disclosure is made, exceptions).

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False Claims Act Liability

- Claims submitted for items or services resulting from a violation of the AKS constitute a "false claim" for purposes of the Federal False Claims Act.
- Claims submitted as a result of violations of the Stark Law have also been used to support False Claims Act law suits.

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The Federal False Claims Act (FCA)

- The Federal Government's "Weapon of Choice."
- Provisions prohibit any person from (among other things):
  - knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
  - knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;
  - knowingly concealing or knowingly and improperly avoiding or decreasing an **obligation** to pay or transmit money or property to the Government.
    - Obligation: includes an established duty arising from the retention of any overpayment after the deadline for reporting and returning the overpayment has passed.

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What is "Knowingly"

- The terms "knowing" and "knowingly" mean that a person, with respect to information--
  - has actual knowledge of the information;
  - acts in deliberate ignorance of the truth or falsity of the information; or
  - acts in reckless disregard of the truth or falsity of the information; and
- requires no proof of specific intent to defraud.

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The Federal False Claims Act (FCA)

- Permits private parties known as *qui tam* relators to bring an action on behalf of the United States.
- *Qui tam* relators may share in a percentage of the proceeds from the FCA action or settlement.

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Major Increase in FCA Penalties (DOJ)

- Effective: For assessments made after January 29, 2018, based on associated violations that occurred after November 2, 2015.
  - Minimum penalty: increased to $11,181.
  - Maximum penalty: increased to $22,363.
  - Per claim.
- Treble damages can also be imposed.

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Recent Enforcement Actions

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Headlines

- August 2018: Operator of long term care/rehab hospitals agreed to pay the U.S., Louisiana and Texas $13.7 million to settle allegations that it knowingly submitted claims to Medicare/Medicaid that resulted from unlawful kickbacks to physicians.
  - It was alleged that the hospital had entered into numerous physician service contracts intended to retain them in various administrative/medical roles but that in reality the payments under these contracts were to induce physician referrals.
    - Also alleged to have entered into illegal "reciprocal referral relationships" with unaffiliated health care providers (e.g., home health agencies).

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Headlines

- August 2018: NY health care system agreed to pay $14.7 million to resolve several allegations, including that a subsidiary hospital submitted false claims for inpatient and outpatient services referred to it by physicians in violation of the AKS and Stark Law.
  - Two physicians had a direct financial relationship with the hospital for providing administrative services and received compensation from the hospital.
  - The government alleged that the compensation was above fair market value and one purpose of that excessive compensation was to induce referrals.

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Headlines

- August 2018: Detroit area hospital system agreed to pay to the U.S. and Michigan $84.5 million to resolve False Claims Act violations based on allegations that the system compensated doctors “substantially in excess of fair market value” and provided “free or below market value office space and employees” to doctors in return for referrals.

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Headlines

- August 2018: National company that provides rehabilitation services agreed to settle False Claims Act violations by paying $6.1 million to the U.S.
  - The government had alleged that the rehab company offered inducements, in the form of company-employed nurse practitioners who would work at client nursing homes without charge or for a nominal, below fair market fee to reward the nursing homes for contracting with the company to provide rehab therapy to their residents.

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Headlines

- August 2018: California physician convicted after a jury trial for his role in a kickback conspiracy whereby he received cash payments in exchange for referring Medicare patients to a certain home health agency.

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Headlines

- March 2018: Rhode Island physician sentenced to over 4 years in federal prison for committing health care fraud and violating the AKS.
  - The physician had admitted to conspiring with a pharmaceutical company to receive kickbacks in the form of purported speaker fees in excess of $188,000 – a "significant motivation" – for his continued prescribing of a highly-addictive version of the opioid drug Fentanyl.

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Headlines

- July 2018: NYS Attorney General and State Comptroller announce jail sentence for Queens pharmacy owner.
  - Sentenced to 6 months in jail and ordered to pay $3 million after pleading guilty to Health Care Fraud in the 2°, a class C felony, and to violating State prohibition on the payment of kickbacks related to the Medicaid program, a class E felony.
    - The government had alleged that the pharmacist paid a hospital employee a monthly cash referral fee and provided him with other items of value, including tickets to sporting events, an iPad, and free meals. In exchange, the hospital employee steered patients with expensive cancer-related prescriptions to this pharmacy.

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Key Items to Look For When Reviewing Contracts for AKS and Stark Compliance

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Contracting Compliance

- Clients should have a process in place for legal review/ approval by appropriate management/legal team/government body prior to executing.
- Periodic reviews should be conducted to maintain compliance with regulatory changes.
  - Clients should:
    - maintain a database of agreements/ documentation of FMV
    - Identify who has the expertise to perform such audits
    - Define the scope of the audit
  - Attorney-client privilege?

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Key Contracting Issues

- Fair Market Value – ensure compensation is consistent with FMV and commercially reasonable.
  - May not take into account the value or volume of any past or future referrals
  - Use of benchmarks/consultants
- Determine potential safe harbor/exception to the AKS/Stark Law that may be applicable.
  - Are all terms of the safe harbor/exception met?

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Key Contracting Issues

- Was the contract negotiated at arm's length?
- Has the compensation been set in advance?
- Is the length of the contract at least one year?
- Are there "side agreements" not memorialized in writing?
- Non-monetary compensation to physicians must also be tracked.

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Key Contracting Issues

- Determine if there is a justified need for the service.
- Does the contract(s) accurately spell out all services to be provided in sufficient detail?
  - Determine if there has been any change in the relationship or arrangement.
- Has the contract actually been executed by both parties.
- Ensure there aren't duplicate contracts.

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Key Contracting Issues

- Determine that all terms are being met.
  - Is the physician performing the administrative/medical duties contemplated by the arrangement?
  - Are written time records tracked/maintained to document the dates/hours services were performed as well as the nature of the services?
  - Are payments consistent with the terms of the contract?
- Ensure the contract is current (not expired).
  - Also -- Be aware of "auto-renewals"

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Non-Compliance

- Non-compliance requires corrective action.
  - Stark allows for certain temporary non-compliance
  - Self-disclosure to CMS, OIG, OMIG
  - Refund of payments received in violation of the AKS, Stark and/or False Claims Act.
    - Medicare and Medicaid overpayments must be reported and returned within 60 days of identification of the overpayment.
- The threat of whistleblowers is real.

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What's Next?

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Coordinated Care

- Value based systems - The new wave in health care delivery
- Removing unnecessary government obstacles to care coordination = key priority for HHS.
- In August 2018, OIG solicited public comment on:
  - new or modified safe harbors to the AKS, particularly:
    - Arrangements that providers want to pursue that could implicate the AKS and how such arrangements would promote value and avoid distorted decision making.
- CMS made similar solicitation in June regarding Stark Law.

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QUESTIONS?

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