Healthcare Leadership Council: Stark & Anti-Kickback Briefing

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Health Care Fraud & Abuse Laws

• Physician Self-Referral Law (Stark Law)
• Anti-Kickback Statute
• Civil Monetary Penalty Law
• False Claims Act
Stark Law

• Physician Self-Referral (Stark) Law prohibits a physician from making a referral to an entity for designated health services payable by Medicare or Medicaid if the physician (or an immediate family member) has a financial relationship with the entity.

• “Financial relationship” includes an ownership or investment interest or compensation arrangement.

• “Designated Health Services” include, but are not limited to, inpatient and outpatient hospital services, clinical lab services, physical therapy, DME, home health services and outpatient prescription drugs.
Anti-Kickback Statute

- The Anti-Kickback Statute (AKS) prohibits providing/offering or soliciting/receiving remuneration (i.e., *anything* of value) to induce a referral from anyone for federal health care program business.

- Federal health care programs include Medicaid, Medicare Advantage, and Medicare Part D.
"Referral" means referral of a patient or the purchasing, leasing, ordering (or arranging for or recommending purchasing, leasing, or ordering) of any good, facility, service or item if any portion of that patient's care or the cost of the good, facility, service or item may be paid in whole or in part by Medicare, Medicaid, or any other Federal health care program.

The AKS specifically provides that a violation constitutes a false or fraudulent claim under the False Claims Act.
Fraud and Abuse Laws – A Bit of History

- Designed for a fee-for-service world
- Goal is to combat over-utilization and unnecessary care and to keep parties financially separated
- Never designed for the new healthcare economy of integration, population health payments, and value based arrangements.
- Federal agencies can make incremental change through regulations, but these laws continue to be a significant barrier to healthcare innovation