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# Regulatory Considerations for the Non-Employed Medical Staff

## **MEDICAL STAFF SEMINAR 2021**

PRESENTED BY HALL RENDER'S MEDICAL STAFF SERVICES TEAM

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# Presenter Info



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# Fraud and Abuse

- Health care fraud is a serious problem
- Laws intended to address:
  - Fraud
  - Waste
  - Abuse
- Violating the fraud and abuse laws can result in:
  - Criminal penalties
  - Civil fines
  - Exclusion from the federal health care programs
  - Loss of medical license

# Hospital/Physician Arrangements

- Hospitals enter into a variety of compensation arrangements with physicians:
  - Employment
  - Recruitment
  - Medical Director
  - Personal services
  - Management agreements
  - Space/equipment leases
  - Etc.



# Areas of Legal Risk

- Physician-specific risks
- Hospitals providing physicians with items or services for free or < fair market value
- Hospitals relieve physicians of financial obligations they would otherwise incur
- Hospitals inflate compensation paid to physicians for items and services

# Newer Problems

- Arrangement is not memorialized in writing
- Incomplete agreement – the deal does not match the contract

But, what is more difficult to overcome:

- Incorrect fair market value analysis
- Bad statements of intent

Therefore,

- Arrangements must be for legitimate services and paid at fair market value

# Relevant Laws

- Stark Law – 42 U.S.C. §1395nn
- Anti-Kickback Statute – 42 U.S.C. §1320a-7b(b)
- Civil Monetary Penalties Statute – 42 U.S.C. 1320a-7a
- False Claims Act – 31 U.S.C. § 3729–3733



# Legal Primer

- **Stark**
  - Civil statute = financial relationship with physicians and family members must meet exceptions
- **Anti-Kickback**
  - Criminal statute = no payment in exchange for referrals
- **Civil Monetary Penalties Statute**
  - Civil statute = no payment to physician to reduce services
- **False Claims Act**
  - Civil statute = claims submitted must comply with laws (whistleblowers)

# Stark Law

- When a physician (or physician's immediate family member) has a financial relationship with an entity (\*unless an exception applies), the federal Stark Law provides that:
  - Physician may not make referrals to the entity for "designated health services"; and
  - Entity may not present a claim or bill to the government, patient, or any other party for designated health services furnished pursuant to a prohibited referral
- \*If Stark is implicated, an exception must be found

# Does Stark Apply?

Does the situation fall within Stark?

- Is there a Physician?
- Is the Physician making a Referral?
- Is the Referral for Designated Health Services?
- Are the Designated Health Services being furnished by an Entity?
- Does the Physician (or immediate family member of the Physician) have a Financial Relationship with the Entity?
- Are the Designated Health Services payable by Medicare or Medicaid?

If the answer to the above questions is "YES" then Stark is implicated and an Exception must be met

# Disproportionate Penalties

- Stark sanctions
  - Denial of payment/repayment of reimbursement
  - CMPs of up to \$15,000 per item or service provided
  - CMPs of up to \$100,000 for each arrangement considered to be a circumvention scheme
  - Exclusion from Medicare and Medicaid
- Potential for False Claims liability
  - A Stark violation renders all related claims false or fraudulent overpayments, thus giving rise to a False Claims Act violation
  - Retention of "identified" overpayments for over 60 days is a false claim unless repaid or self-disclosed
  - Mandatory CMPs of \$11,803 to \$23,607 for each claim
  - Plus, treble damages = 3 x the amount

# Exceptions

- Exceptions apply to either:
  - Both an ownership interest and compensation arrangement;
  - Only an ownership interest; or
  - Only a compensation arrangement
- When reviewing a particular physician arrangement, it is imperative that the correct type of exception is used

# Key Stark Exceptions

- Rental of Office Space
- Rental of Equipment
- Bona Fide Employment Relationships
- Physician Recruitment
- Non-Monetary Compensation [up to \$429 annually]
- Fair Market Value Compensation/Personal Service Arrangements
- Medical Staff Incidental Benefits [up to \$37 per occurrence]
- Limited Remuneration [up to \$5,000]
- Compliance Training
- Professional Courtesy



# Common Elements of Stark Exceptions

- Arrangement is set out in writing
- Arrangement is signed by all parties (signatures should be obtained before the effective date)
- Arrangement describes the specific items/services to be provided
- Amount of remuneration is consistent with fair market value
- Remuneration does not take into account the volume or value of referrals or other business generated by the referring physician/entity
- Terms of the agreement are commercially reasonable

# Anti-Kickback Statute

- 42 U.S.C. §1320a-7b(b)
  - Designed to prevent certain payments in connection with the furnishing of services reimbursable under the Medicare and Medicaid programs as well as other governmental health care initiatives
  - Prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other government health programs

# Anti-Kickback Statute

- Violation is a **felony**, punishable by fines up to \$25,000 and up to 5 years imprisonment. Violation can also result in imposition of civil monetary penalties and/or exclusion from such government health care programs
- Safeguards:
  - It is imperative that any arrangement not be pursued for the purpose to induce referrals
  - It is always possible that a trier of fact, such as a judge or jury, could misconstrue the facts and find differently
  - Intent and structure of an arrangement are vital!

# Intent Test

- *Greber* test
  - If **one purpose** of the arrangement or deal is to induce referrals, the Anti-Kickback Statute is violated. *U.S. v. Greber*, 760 F.2d 69 (3rd Cir. 1985)
- The ACA test
  - There is no requirement of actual knowledge of or specific intent to commit a violation of the Anti-Kickback Statute
- **Be careful with communications to avoid risk that illegal intent could be misconstrued!**

# Compliance/Safe Harbors

- An arrangement must meet each element of a Safe Harbor in order to be safe from investigation or prosecution as a criminal offense or as a basis for exclusion from participating in the government health care programs
- However, an arrangement does not necessarily violate the Anti-Kickback Statute if it does not satisfy a Safe Harbor. Such an arrangement is judged under the language of the Anti-Kickback law itself

# Key Safe Harbors Exceptions

- Space rental
- Equipment rental
- Personal services and management contracts
- Practitioner recruitment
- Employees



# Differences between Anti-Kickback Law and Stark Law

## Anti-Kickback

- Intent-based
- Criminal liability
- Broader application—implicates more relationships
- Safe-Harbors— "Should"

## Stark


- Strict liability
- Civil liability
- Applies only to financial relationships with "physicians" or immediate family members
- Exceptions— "Must"

# Civil Monetary Penalties Law

- Substantial civil money penalties may be imposed if an entity:
  - knowingly presents a false or fraudulent claim for services;
  - knowingly gives false or misleading information reasonably expected to influence the decision to discharge a patient;
  - offers/gives remuneration to any beneficiary likely to influence the receipt of reimbursable items or services;
  - arranges for reimbursable services with an entity which is excluded from participation from a federal health care program;
  - knowingly or willfully solicits or receives remuneration for a referral of a federal health care program beneficiary; or
  - uses a payment intended for a federal health care program beneficiary for another use
- OIG is authorized to seek different amounts of CMPs based on the type of violation at issue

# False Claims Act

- Knowingly presents, or causes to be presented, a false or fraudulent claim for payment
- Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money to the government
- A person can act "knowingly" by acting with actual knowledge of the truth or falsity of the information or by acting in deliberate ignorance or reckless disregard of its truth or falsity
- Severe criminal and civil penalties
- Whistleblowers can file qui tam actions on behalf of the government
- Used as a vehicle to assert Stark/AKS claims



# Establishing Compliant Hospital/Physician Arrangements

# Common Hospital-Physician Relationships and How to Protect Them

## Employment Relationships

- All employment relationships should be covered by a written contract (not technically required under Stark but absolutely recommended)
- The employment must be for identifiable services
- Remuneration under Contract must be fair market value and not determined to reflect the volume or value of physician's referrals
- Arrangement must be commercially reasonable even if no referrals made to employer
- Productivity bonuses based on physician's personally performed services permissible

# Common Hospital-Physician Relationships and How to Protect Them

## Personal Service Arrangements

- Applies to many types of services provided by physicians to Hospital. Arrangement is in writing and specifies services
- All arrangements between parties are cross referenced (Hospital must keep master list of all contracts centrally located)
- Contracted for services are reasonable, necessary and serve legitimate business purposes
- The term must be at least one year
- Compensation is set in advance, fair market value, does not take into account physician's referrals
  - Payment must be for identifiable and verifiable services
- "Hold-over" personal services arrangement OK for an indefinite period following expiration of a contract of at least one year so long as all terms and conditions in hold-over period same as those of previous contract period
- Amendments are okay so long as new compensation is "set in advance"



# Common Hospital-Physician Relationships and How to Protect Them

## Lease of Office Space or Equipment

- All leases should be covered by a written contract
- The term of the lease must be at least one year
- Space or equipment rented must not exceed that which is reasonable and necessary for legitimate business purpose of the lease and must be used exclusively by lessee (to exclusion of lessor)
- Rental charges are set in advance, fair market value, and don't take into account referrals – no per clicks!
- Agreement is commercially reasonable even if no referrals made
- A "hold-over" month-to-month rental is OK if follows an agreement of at least one year and is on same terms

# Common Hospital-Physician Relationships and How to Protect Them

**Medical Staff "Incidental Benefits"** (e.g., meals, parking, internet access, pagers, 2-way radios)

- Compensation in the form of items or services (no cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus OK if it meets following conditions:
  - Offered to all members of medical staff of same specialty without regard to referral numbers
  - Compensation provided while medical staff members are rounding or engaged in services to benefit hospital and while members are on campus
  - Compensation reasonably related to provision of medical services at hospital
  - Compensation = less than \$37 per occurrence for CY 2021 (\$39 for 2022)

# Common Hospital-Physician Relationships and How to Protect Them

## Non-Monetary Compensation

- Compensation in the form of items or services (no cash or cash equivalents) that does not exceed an aggregate of \$429 per calendar year (CY 2021) (\$452 for 2022)
  - A dinner at a restaurant or catered event
  - Tickets to a theatrical or sporting event
  - Golf greens fees or other types of admission or entry fees
  - Holiday or other gifts
- Compensation is not related to physician's referrals
- Compensation cannot be solicited by physician or physician's practice
- **Hospitals must track to avoid going over the limit.** If Hospital inadvertently goes over limit, hospital still compliant with exception if the excess compensation is no greater than 50% of limit and physician repays hospital the excess the earlier of the end of calendar year or within 180 days following date excess comp received
  - Can employ the excess payment "fix" once every 3 years per physician
- One medical staff appreciation event each year may be provided outside the non-monetary compensation limits!

# Common Hospital-Physician Relationships and How to Protect Them

## Limited Remuneration to a Physician

- \$5,000 in the aggregate per calendar year (\$5,270 for 2022)
- Protects short term/low dollar/unwritten arrangements
- No writing, signature or set-in advance requirements
- Must be FMV and commercially reasonable

# Common Hospital-Physician Relationships and How to Protect Them

## COVID-19 Blanket Stark Waivers

- On March 30, 2020, CMS issued blanket waivers of several Stark Law requirements related to COVID-19 physician arrangements
- Exempt providers from sanctions for noncompliance with the Stark Law, including remuneration that exceeds the current Non-Monetary Compensation limit and Medical Staff Incidental Benefits amount
- Apply only to financial arrangements related to a proper “COVID-19 Purpose”
  - Diagnosis or treatment of COVID-19 for any patient, whether or not diagnosed with a confirmed case of COVID-19;
  - Securing the services of physicians to furnish medically necessary services;
  - Ensuring the ability of health care providers to address patient and community needs;
  - Expanding the capacity of health care providers to address patient and community needs;
  - Shifting the diagnosis and care of patients to appropriate alternative setting; or
  - Addressing medical practice or business interruption due to the COVID-19 outbreak in order to maintain the availability of medical care and related services for patients and the community
- The Stark waivers can be relied upon retroactively to March 1, 2020, until the expiration or termination of the declared public health emergency

# Physician Marketing

- **Marketing Activities – No Value/Benefit Attributed to Non-Employed Physician:**
  - Identification on hospital website/medical staff directory
  - Identification in print, billboard, radio, or television advertising campaigns
  - Identification by hospital phone line for hospital-based services
- **Marketing Activities – Value/Benefit Attributed to Non-Employed Physician:**
  - Advertising beyond mere identification; value below \$429
    - Non-monetary compensation exception
  - Advertising beyond mere identification; value in excess of \$429
    - Fair market value compensation exception
  - Hospital referral services line
    - Referral services exception
    - Anti-Kickback Statute Safe Harbor



# Continuing Medical Education

- On-site CME that is primarily for the benefit of the hospital's patients, such as traditional on-site grand rounds or other similar in-house education, can be provided at no cost to the participating physician attendees
- Topics "primarily for the benefit of hospital patients" are programs that address issues relevant to the care of hospital inpatients as well as outpatients, as long as the information will assist physicians in providing patient care. Additionally, sessions that provide ethics education also provide the required patient benefit under this analysis

# Continuing Medical Education

- A CME topic that highlights a new technology, a new service line, or a new physician specialty available at a hospital-affiliated location, may be determined to be "primarily for the benefit of patients of the hospital" based on the facts and circumstances and are eligible for consideration as a CME topic.
- Topics which focus primarily on an aspect of the physician office practice are not "primarily for the benefit of hospital patients."

# Continuing Medical Education

- Other CME credit offered to physicians should be structured to fit within a valid Stark exception
  - This must be tracked in accordance with the Non-Monetary Compensation Exception
  - Or provided in exchange for a fair market value payment by the physician
- At the discretion of the CME Coordinator and CME committee, the hospital may sponsor certain off-site CME programs that support the mission of the hospital



# Enforcement Actions

## *U.S. v. Anderson (1997)*

- **Defendants:** Physicians (Drs. Robert and Ronald LaHue); Hospital Executives (CEO, COO, VP); and Attorneys who represented the Hospital (alleged to be a part of the conspiracy) (Kansas)
- Defendants were indicted by a grand jury and tried
- The LaHue's were paid \$75,000 each per year to be Co-Directors of Gerontology
  - After entering into this arrangement, the LaHue's referrals to the Hospital increased dramatically
  - Only minimal services were provided under this contract
- Trial testimony showed that the LaHue's only consulted at Baptist approximately two hours per week – giving them an effective compensation of \$1,442 per hour
- The defendants were found to have violated the Anti-Kickback Statute:
  - Dr. Robert LaHue was sentenced to 70 months in prison
  - Dr. Donald LaHue was sentenced to 51 months in prison
  - The Hospital CEO was sentenced to 51 months in prison

## *Pacific Alliance Medical Center (2017)*

- \$42 million settlement (\$31.9 million to the Federal Government, \$10 million to the State of California)
- Whistleblower was employed as a manager by Pacific Alliance. He received over \$9.2 million as his share of the recovery
- Alleged improper relationships:
  - Arrangements under which Pacific Alliance paid above-market rates to rent office space in physician's offices
  - Marketing arrangements that allegedly provided undue benefits
- In announcing the settlement the DOJ stated "[t]his settlement is a warning to health care companies..."

## *Belmont (2014)*

- **Defendants:** Devender Batra, M.D. and Belmont Cardiology, Inc.
- The investigation arose after the DOJ settled with an Ohio hospital for \$3.8 million
- The government alleged that the Defendants "*caused*" the hospital to violate the FCA by entering into arrangements they "*knew or should have known*":
  - Were not at fair market value;
  - Were not commercially reasonable; and/or
  - Took into account the volume or value of referrals or other business generated by the referring physician
- Outcome
  - Batra, M.D. and Belmont Cardiology, Inc. settled with DOJ for \$1 million



## *William Beaumont (2018)*

- \$84.5 million settlement (\$82.74 million to the Federal government, \$1.76 million to the State of Michigan)
- Beaumont allegedly:
  - Provided compensation above fair market value and free or below fair market value office space and employees to certain physicians from 2004 to 2012
  - Misrepresented that a CT radiology center qualified as an outpatient department of Beaumont
- In addition to the settlement, Beaumont entered into a **5 year** CIA with the HHS OIG which includes an arrangements review to be conducted by an Independent Review Organization

## *UPMC Hamot & Medicor (2018)*

- \$20.75 million settlement
- Claims were originally brought by a whistleblower Dr. who previously worked for UPMC Hamot (PA) for four years. The government declined to intervene. The whistleblower proceeded on his own and won summary judgement that some of the claims submitted violated Stark, and therefore, the FCA
- The complaint alleged that UPMC Hamot paid cardiology group Medicor up to \$2 million per year under 12 physician and administrative services agreements that were allegedly created to secure Medicare patient referrals
- The hospital allegedly had no legitimate need for the services contracted for, and in some instances the services either were duplicative or were not performed

# OIG Fraud Alert – June 9, 2015

- **Settlement:** 12 *individual physicians* violated AKS
- OIG is critical of compensation arrangements with physicians, such as medical directorship arrangements
- Compensation paid to physicians under medical director and office staff arrangements was improper remuneration because:
  - Took into account volume/value of physicians' referrals; and
  - Exceeded fair market value
- OIG determined physicians were an integral part of the scheme and subject to liability under the CMP Law
- **Penalties:**
  - Imaging Company paid \$650,000 and radiologist agreed to 6-year Medicare exclusion (settlement with DOJ)
  - Physicians' settlements ranged from \$50,000 to \$195,000, plus 1 physician was excluded from Medicare

# The Yates Memo

- On September 9, 2015, the DOJ published a Memorandum from the Deputy Attorney General to all DOJ attorneys (the Yates Memo)
- The Yates Memo announced a DOJ initiative to hold individuals responsible for civil and criminal corporate misdeeds
- The goal of this initiative is to deter corporate misconduct by putting individuals at risk of civil action and/or criminal prosecution
- The Yates Memo was developed in response to issues in the financial services industry; however, it applies to all types of entities and activities

# Policy Rationale for Yates Memo

DOJ believes individual accountability is important to:

- Deter future illegal activity;
- Incentivize changes in corporate behavior;
- Ensure that proper parties are held responsible for their actions; and
- Promote the public's confidence in the federal justice system

# Key Takeaways

- Compliance is everyone's responsibility
- Everyone should be expected to understand and comply with applicable laws, regulations and organization policies
- Whether an activity presents potential compliance concerns often depends on the specific facts and circumstances
- Documentation must accurately reflect the arrangement



# Questions?





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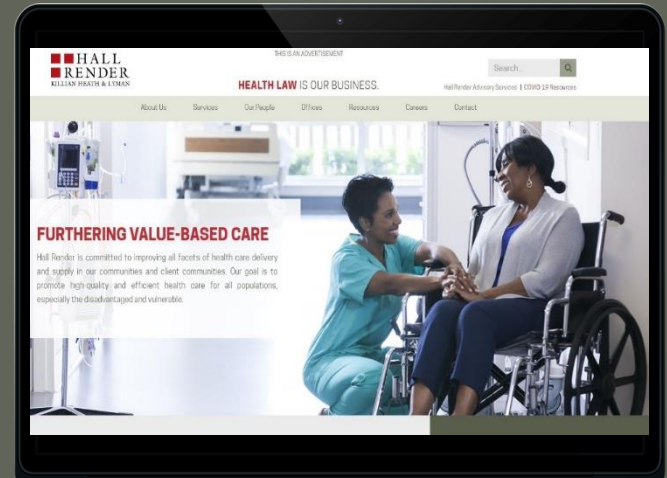
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