

2022

BONES Society of Florida |  
Southeastern Association of Orthopaedic Executives |  
MidAtlantic BONES | Midwest AAOE

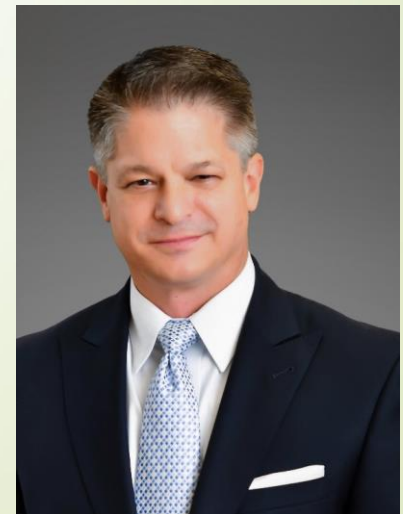
**PHYSICIAN FINANCIAL RELATIONSHIPS  
AND CONFLICT OF INTEREST POLICIES**

July 7, 2022

**GREGORY A. CHAIRES, ESQ.**  
BOARD CERTIFIED IN HEALTH LAW

**CHAIRES, BROODERSON & GUERRERO, P.L.**  
283 CRANES ROOST BLVD., SUITE 165  
ALTAMONTE SPRINGS, FLORIDA 32701  
(407) 834-2777

[www.chlawyers.com](http://www.chlawyers.com)





# EDUCATIONAL TOPICS

- Conflict of Interest
- What are financial relationships
- Brief overview of federal and state laws
- Why every practice should vet its providers
- Annual Review
- Compliance Programs

# CONFLICT OF INTEREST DEFINED

- “Conflicts of interest occur when physicians have motives or are in situation for which reasonable observers could conclude that the moral requirements of the physician’s roles are or will be compromised.” Jama January 25, 2006, Vol 295, No.4
- A conflict of interest occurs when an individual or organization has a financial or other interest that has the potential to interfere with their professional judgment, objectivity, or ethical responsibilities.
- A circumstance that creates a risk that professional judgment or actions toward primary interest will be unduly influenced by a secondary interest.
  - Primary Interests – welfare of patients, integrity or research, quality of medical education
  - Secondary Interest – financial gain, professional or personal advancement.
- In essence when an individual’s personal interest interferes in anyway with his/her professional obligations and judgment.

# TYPES OF CONFLICTS

- Conflicts arise in a variety of different ways. Examples:
  - Financial conflicts where placing financial self-interest in place of care or medical decision making including financial incentives. Practices routinely and unknowingly run afoul of this in compensation arrangements or other profit incentives.
  - Accepting benefits and gifts that that may be perceived to or influence decision making and compromise patient care.
  - Improper referral arrangements between providers or health care entities.
  - Misuse of confidential information acquired through the practice for his/her personal gain or influence.
  - Not so subtle arrangements that appear unrelated but have a quid pro quo component when examined closely.

# ISSUES THAT ARISE OUT OF PHYSICIAN CONFLICTS

- ▶ Patients can suffer harm and be subject to
  - ▶ Unnecessary risk related to procedures
  - ▶ Deprived of beneficial therapies
  - ▶ Receive inferior therapies
  - ▶ Provide ineffective or unsafe drugs or devices
  - ▶ Redundancy in testing, imaging and procedures that cause significant waste to Medicare/Medicaid and other third party payors

# FINANCIAL RELATIONSHIPS DEFINED

- ▶ 42 CFR 411.354 provides that a **financial relationship** means a **direct or indirect ownership or investment interest in any entity that furnishes DHS; or a direct or indirect compensation arrangement with an entity that furnishes DHS.**
  - ▶ A direct financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).
  - ▶ An indirect ownership or investment interest exists if there exists an unbroken chain of any number (but no less than one) of persons or entities having ownership or investment interests between the referring physician (or immediate family member) and the entity furnishing DHS. 42 CFR 411.354 (b)(5).

# FINANCIAL RELATIONSHIPS CONTINUED

➤ They are broad and can happen in many ways such as in:

- Employment agreements
- Consulting agreements
- Lease agreements
- Independent contractor agreements
- Research agreements

Each of these involves remuneration (compensation) which can be direct, indirect, over, or covert, or in cash or in kind.

➤ The concept being something of value flowing in the direction of a potential or actual referral source.

# IMMEDIATE FAMILY MEMBER DEFINED

- ▶ “**Immediate family member** or member of a physician’s **immediate** family means **husband or wife; birth or adoptive parent, child or sibling; stepparent; stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild.**” 42 CFR 411.351.



# THE BASIC STATUTES THAT MATTER

## STARK AND ANTI-KICKBACK STATUTE

- These are two main federal laws created to address financial relationships between health care providers and entities.
- Fundamental issue being address is the conflict of interest between a physicians financial self-interest and the best interest of the patient.
- They are not the same but frequently mistaken by people to be the same.

# STARK LAW

- Basic concept is that certain services, many that can be performed in a physician office, and other ancillary items and services are called designated health services (“DHS”).
- DHS includes things like clinical lab services, PT and OT services, radiology and certain imaging studies and DME. CMS produces a biannually list of CPT Codes that are considered DHS. This list drives the train in the initial analysis.
- If a physician (or immediate family member) has a financial relationship with any entity, the physician cannot refer DHS to the entity, and the entity cannot bill for the DHS, unless there is an applicable exemption.
- There are severe financial penalties and potential exclusion at play, and liability under the Federal False Claims Act.
- It is a civil statute with no intent. It is prospective.

# STARK LAW EXCEPTIONS

## THESE DRIVE MANY PRACTICE ARRANGEMENTS

- The Stark Act provides specific and important safe harbors where the government has put in adequate safeguards to address the conflicts that financial relationship can trigger.
- Examples –
  - Leases
  - FMV
  - Personal Services
  - Employment
  - In office ancillary services exception (very important one)

# ANTI-KICKBACK STATUTE

- This statute prohibits the knowing and willful offer or payment of remuneration to induce referrals, or in return for purchasing or recommending the purchase of any item or service that may be paid by a federal health care program.
- This a criminal statute and violation of it is a felony; this means potential jail time. There are additional penalties that can occur including Civil Monetary Penalties, exclusion from participation in any federal health care program.
- You can be required to repay Medicare or Medicaid, be fined up to \$100,000 and go to prison for up to 10 years (per violation).
- There is also the potential for civil penalties under the Federal False Claims Act.
- It is retrospective statute and can be used civilly or criminally. Beware of the One-Purpose Test.

# FALSE CLAIMS ACT

- False Claims – Presenting, or causing the presentment, of a false claim for payment or approval. [31 U.S.C. §§ 3729\(a\)\(1\)\(A\)](#).
- False Records or Statements – Making, using, or causing others to make or use, a false record or statement that is material to a false or fraudulent claim. [31 U.S.C. §§ 3729\(a\)\(1\)\(B\)](#).
- Conspiracy – Conspiring to violate the False Claims Act. [31 U.S.C. §§ 3729\(a\)\(1\)\(C\)](#).
- Conversion – Failing to return government property. [31 U.S.C. §§ 3729\(a\)\(1\)\(D\)](#).

# FCA CONTINUED

- False Receipts – Making or delivering a receipt of government property without completely knowing that the information in it is true. [31 U.S.C. §§ 3729\(a\)\(1\)\(E\)](#).
- Reverse False Claims – Making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government; or conceals, avoids, or decreases an obligation to pay money to the government. [31 U.S.C. §§ 3729\(a\)\(1\)\(G\)](#).

# FCA PENALTIES

- Treble (triple) damages PLUS
- On May 9, 2022, DOJ adjusted the FCA 2022 False Claims Act penalties. 87 FR 27513. The adjustment was less than six months after its prior increase in December 2021 and aligned with the penalty amounts in Railroad Retirement Board and Commerce Department cases. The current rate is from \$12,537 to \$25,076 (determined by a judge) per false claim (determined by a jury).

# VARIOUS STATE LAWS

- Many states have their own versions of self-referral laws and anti-kickback statutes that relate to medicine and the delivery of health care services.
- States like Georgia, South Carolina, North Carolina have specific statutes.
- Some states call such referrals unprofessional or unethical conduct and take that approach.
- Many have provisions that allow the applicable medical boards to discipline a physician for such referrals.



# IMPORTANT ANALYSIS CONSIDERATIONS

- Our analysis is first to look at state law. Can what is proposed by the physician or parties be accomplished first under the state law? If it cannot get out of the Florida house for example, the federal law does not matter.
- Once it appears compliant with the given state law, then the analysis of the various federal laws above comes into play.
- Is it a referral? This is broadly defined and utilized.
- It is very easy to get into a “**Kickback Trap**” as referenced in the recent AAOS Now newsletter of May 2, 2022.



# EXAMPLE

## FLORIDA ANTI-KICKBACK STATUTE

- It is unlawful for any health care provider or any provider of health care services to offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients.
- It is unlawful for any person or any entity to pay or receive, directly or indirectly, a commission, bonus, kickback, or rebate from, or to engage in any form of a split-fee arrangement with, a dialysis facility, health care practitioner, surgeon, person, or entity for referring patients to a clinical laboratory as defined in 483.803, F.S.
- Violations are considered patient brokering punishable under Section 817.505, F.S. (the Patient Brokering Statute)



# INTERNAL OFFICE CONTROLS

- Monitor physician arrangements -
  - Physician contracts
  - Payments to physicians through various arrangements
  - FMV and commercial reasonableness
  - Legal review
  - Policies for physician relationships
  - Annual Disclosure



# AUDITS OF FINANCIAL RELATIONSHIPS

- ▶ First question is who performs them – President of practice, a committee, legal counsel or outside auditors.
- ▶ Second – important to have legal counsel involved to protect findings and outcomes and further to be advised how to address issues.
- ▶ Third – scope of review, who all should be looked at? What financial relationships?



# WHERE TO START

- Physician Employment Agreements
- Medical Director Agreements
- Recruitment Agreements
- Lease Arrangements
- Professional Service Agreements
- Joint Ventures
- Family Relationships with health care items or service providers
  - Sales Reps, Pharmacies, Device Companies, other Supply Companies



# DO THE AGREEMENTS MEET SAFE HARBORS

- There are several different ones but by example -
- Are they in writing?
- Are they Fair Market Value?
- Are they Commercially Reasonable?
- Are they for real, identifiable, actually provided services?
- Is the Agreement signed?
- Does the compensation take into account the value or volume or referrals, or the business generated between the parties?

# WHAT SHOULD YOU DO?

- Create or update your conflict of interest policies and share them with your organization and your employees. Define financial interest, related business interests, interested persons and immediate family members (follow federal law on this).
- The policies should require disclosure and management of individual and industry financial relationships. This includes annual disclosures by physicians, mid-levels and key management personnel, that include the person or entity, name of the company, position, term and compensation.
- If your practice is big enough, create a conflict of interest committee to evaluate ties and arrangements.
- Consider restrictions regarding gifts, meals and other non-cash remuneration items.
- Create procedures for addressing such conflicts.
- Establish a culture that avoids such issue. Remember that the “fish stinks from the head down.” The trouble an organization or practice has can generally be traced back to its leaders.

# ANNUAL REVIEW

- Provide a copy of the Conflict of Interest Policy which such policy should include its purpose, definitions, and procedures for duty to disclose, determining whether a conflict of interest exists, addressing any such conflicts, and addressing violations of the Conflict of Interest Policy.
- Provide instructions for disclosure to ensure that adequate and appropriate information is provided for review.
- Make the physicians, mid-levels and leadership attest to no violations of the policy in writing and maintain it at the practice.





# KEY OVERSIGHT QUESTIONS

- Is the conflict disclosure with a referral source of vendor?
- Does the conflict involve making patient care decisions that may be influenced by the financial or other conflict?
- Is the amount of benefit sufficient to influence the person's behavior?
- Does the conflict involve competition with the practice?
- Does the conflict involve violation of the practice's code of conduct or other law?

# COMPLIANCE PROGRAM

- ▶ These are key and in making sure a practice complies with all federal, state and local laws, rules and regulations, both civil and criminal and to ensure that a practice is fair, honest, and ethical in its dealings with patients, professional individuals and organizations, and other customers and clients.
- ▶ The OIG has published guidance for Individual and Small Group Physician Practices which can be found on the internet here With the passage of the Patient Protection and Affordable Care Act of 2010, physicians who treat Medicare and Medicaid beneficiaries will be required to establish a compliance program

# COMPLIANCE PROGRAM OBJECTIVES

- Conduct internal monitoring and auditing.
- Implement compliance and practice standards.
- Designate a compliance officer or contact.
- Conduct appropriate training and education.
- Respond appropriately to detected offenses and develop corrective action.
- Develop open lines of communication with employees.
- Enforce disciplinary standards through well-publicized guidelines.



Make vetting financial relationships and conflict of interest policies part of your overall compliance plan. Have at least an annual statement from your providers, owners and leadership regarding the policy.



**IS THAT ALL?**





We are pleased that we are able to offer our clients fast and cost-effective representation.

We use our intimate knowledge of the health care industry and relationships that we have built with various specialists and consultants to provide quality service.

We are mindful that the practice of law is a service business and we treat each of our clients that way.



[www.cbglaw.net](http://www.cbglaw.net)

407.834.2777

Serving all of Florida

