

Hospital and Physician Arrangements: Stark and Anti-Kickback Compliance

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Introductory Scenarios

CLASSIC: An agreement between a Hospital and several physicians provided bonuses based upon the referrals that the physicians made to the hospital for outpatient services.



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Introductory Scenarios

HIDDEN: In order to secure patient referrals from a particular physician, the Hospital agreed to “rent” office spaces in a building owned by the Physician. Although a formal contract was written, the leased offices remained empty and/or were used by the physician for personal matters. The Hospital was not using the offices leased.

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Introductory Scenarios

NOT SO OBVIOUS: In order to entice a Physician to refer patients, the Hospital offers her a Directorship Agreement within a particular department. The hourly rate is set at fair market value and requires the Physician to perform certain services in a specific set of time. The Physician never perform such services, only presides one meeting every six months and does not keep track of the time allotted to the agreement.

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Introductory Scenarios

THE GOODIES: As part of the recruitment process of a Physician, the Hospital invites him and his wife to a conference to be held in Las Vegas. The conference is for one day and the physician is NOT a speaker. The Physician, his wife and the Hospital representative stayed in Vegas for 3 days, attended shows, golf rounds and dinners all paid by the Hospital.



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Overview of Presentation

- Introduction (5 minutes)
- Stark and Anti-Kickback Basics (10 minutes...YOU GOT THIS!)
- The Core Elements of Stark Compliance (10 Minutes)
- Pre-Payment Review: Legal Take (5 Minutes)
- The New Safe Harbors and Exceptions (10 Minutes)
- Monitoring & Auditing: Effectiveness (10 Minutes)
- Disclosure Basics and the 60 Days Rule (5 Minutes)
- Questions & Answers (5 Minutes...then again,
you can call us later!)



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Common Financial Arrangements

Common financial arrangements an entity may have with physicians include but are not limited to:

- Employment arrangements
- Personal service arrangements
 - o Call coverage
 - o Medical directors
 - o Consulting services
- Office/equipment leases

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THE BASICS

STARK LAW AND ANTI-KICKBACK STATUTE

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Stark Law: The Basics

➤ The Stark Law prohibits:

- A physician
- From making a referral
- Of a Medicare / Medicaid patient
- To an entity that furnishes “designated health services”
- If the physician has a **financial relationship** with the entity
- Unless an exception applies

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- **Physician**: includes immediate family members
 - All immediate family members of a physician must have Stark compliant arrangements with health care providers
- **Designated Health Services**: a detailed list of items and services that fall under Stark Law
 - All hospital services are DHS
 - Also: radiology, lab, PT/OT, DME, outpatient drugs, home health
- **Financial Relationship**: any ownership or investment interest or compensation arrangement with the entity receiving the referrals

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☐ Short version:

- Any financial relationship between a physician and a hospital must be structured to meet one of 42 arrangements or the billing from the referrals is subject to False Claims Act liability
- Financial relationship means ownership interest or compensation relationship
 - In **Puerto Rico** physician ownership in hospitals is not considered an ownership interest
 - **But in Puerto Rico, anything of value exchanged between a physician and a hospital is considered a compensation relationship and implicates Stark**

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- The Stark Law is a **strict liability law**.
 - Non-compliance does not require intent to violate the law or engage in non-compliant acts
 - Non-compliance is a factual question
- The Stark Law regulates financial relationships between physicians and certain entities to which the physician refers

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STARK EXCEPTIONS

Commonly used exceptions include:

- Personal service and fair market value (FMV) exceptions
- Rental of office space or equipment
- Physician recruitment
- Isolated transactions
- Bona-fide employment
- Non-Monetary Compensation (Gifts, Donation, etc.)
- *New in 2016: Assistance to compensation of non-physician practitioner (NPP)*
- *New in 2016: Time share arrangements*

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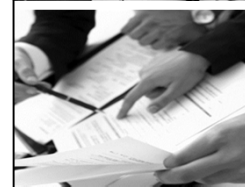
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Anti-Kickback Statute – Basics

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b))

- Prohibits anyone from purposefully **offering, soliciting, or receiving** anything of value to induce (or reward) referrals for items or services payable by any Federal health care program (aka Medicare and Medicaid).
- A referral source is broadly construed and does not need to be another health care provider. A referral source could be:
 - Vendors
 - Drug companies
 - Patients (also known as beneficiary inducement)

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- Anti-Kickback Statute is a criminal law
- The government must prove **intent**, but there are numerous situations which could have the “appearance” of intent
- Anti-Kickback Statute offers two dozen “safe harbors” to structure an arrangement in order to avoid the appearance of a kickback
- The Office of the Inspector General (OIG) offers “Advisory Opinions” on arrangements at the request of the parties



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Sample Case

- **Tuomey Healthcare System**
 - In 2013, a jury found \$39 million Stark Violation by Tuomey Healthcare System, a South Carolina hospital that paid part-time employed physicians above fair market value, despite hospital's reliance on third-party fair market valuation
 - Under the False Claims Act, DOJ requested treble damages, plus \$5,500 per claim, for a total of \$237 million
 - CEO of Tuomey also assess a person \$1 million fine



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THE CORE ELEMENTS

STARK AND ANTI KICKBACK COMPLIANCE

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1. Arrangement is in a written contract
2. Contract is signed by all parties
3. Contract is current (not expired)
4. Contract has a term of at least 1 year
5. Services are specified
6. Compensation is set in advance and does not vary based on volume or value of referrals from the physician
7. Compensation is Fair Market Value
8. Terms are Commercially Reasonable

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1.- Written Contract

- **Old Interpretation:** ONE Contract to Comply
- **New Interpretation:** Depending on the facts and circumstances, a collection of documents, e.g., e-mails, drafts, invoices, cancelled checks, timesheets, etc. can constitute a “written agreement”
- **Consider:** *U.S. ex rel. Tullio Emanuele v. Medicor Associates Inc. et al.*

“[T]he Stark Law “insist[s] on the transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the physician and all of the remuneration to be received for those services.”

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Written Contract (cont.)

- Final Rule: 80 Fed. Reg. 70885, 71300-71341 (Nov. 16, 2015)
- Examples of Complementary Documents:
 - Board meeting minutes or other documents authorizing payments
 - Hard copy and electronic communications between the parties
 - Fee schedules for specified services
 - Check requests or invoices identifying items or services provided, relevant dates and/or rate of compensation
 - Time sheets documenting services performed
 - Call coverage schedules or similar documents providing dates of services
 - Accounts payable or receivable records
 - Checks issued for items, services or rent

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2.- Signature by All Parties

- **Old Interpretation:** The old rule allowed arrangements where only a signature was missing, for up to 90 days if inadvertent and 30 days if advertent
- **New Interpretation:** Now, all arrangements are allowed, when only a signature is missing, for up to 90 days
- This grace period is still limited to once per physician every 3 years
- Effective as of January 1, 2016

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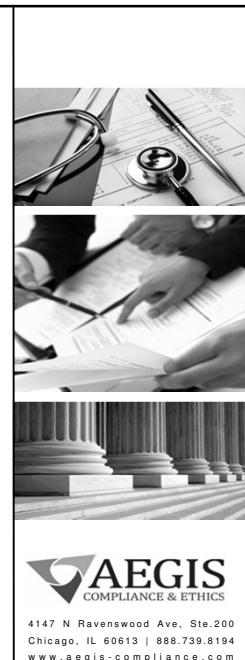


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3.- Contract is Current (expire v. holdover)

- **Old Interpretation:** The old rule allowed **expired leases and personal services** arrangements to continue after expiration on the same terms for up to 6 months, if exception otherwise satisfied
- **New Interpretation:** The new rule extends the 6 months to an unlimited period of time
- But, **beware** of fair market value issues and **changes in services and/or compensation**
- Effective as of January 1, 2016

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4.- Contract has a Term of 1 Year

- **Old Interpretation**: Term has to be specified in the Contract.
- **New Interpretation**: The “one-year term” requirement can be satisfied if the arrangement lasted one year, even if the written agreement does not specify a term



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5.- Services are specified

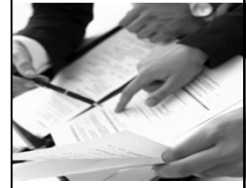
- Directorship Agreements must state expectations
- On Call Services must be specifically delineated
- **Beware** of Amendments changing the scope of services (compare and contrast terms of agreement with the actual services provided).



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6.- Compensation is set in advance

- Can not vary based on volume or value of referrals from the physician
- **Beware** of bonus or additional compensation that may be directly or indirectly linked to referral sources or dependent upon new business to the hospital.



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7.- Compensation is Fair Market Value

- **Fair Market Value (FMV)**: Stark Statute has defined FMV as, “The value in arm’s length transactions, consistent with the general market value...” (1877 (h)(3) of the Social Security Act).
- **Ask yourself**: “Will other players in the market that do not need the referrals would pay a similar amount”.
- Document FMV Determination



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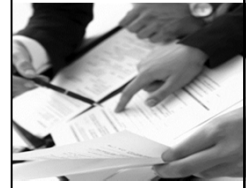
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8. Terms are Commercially Reasonable

- **NOT THE SAME AS FAIR MARKET VALUE**
- **Commercial Reasonableness**: Entails for example that the contract is for necessary services and number of hours are not more than needed to complete the services
- **Ask yourself**: Is this agreement necessary? Essentially, one should ask themselves, “Would the parties agree to this deal if there were no referrals made?”

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PRE-PAYMENT REVIEW

LEGAL TAKES

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Common Issues with Stark Compliance

Technical Issues:

1. lack of documentation,
2. non-signed contracts,
3. non-exclusivity use of rental space,
4. failure to accurately describe services rendered, or duties
5. compensation changed without changing the terms in writing.

Substantial Issues:

1. lack of documentation to support fair market value,
2. Lack of documentation to support commercial reasonableness,
3. taking into account DHS referrals,
4. Lack of evidence supporting provision of services (i.e. timesheets)

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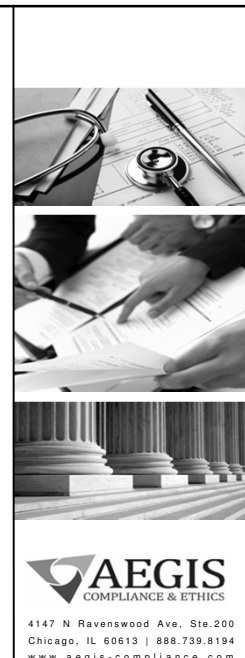


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PRE-AGREEMENT LEGAL CONSIDERATIONS:

- Key Consideration: Am I paying for **New Referrals**?
- Key Consideration: Is it **Commercially Reasonable**?
- Key Elements:
 - Centralized approval process (should be organized by type of contract)
 - arrangements must be evaluated by legal counsel **with experience in healthcare law**
 - Policies and procedures (INCLUDING self-disclosure)
 - Education to Management and Accounts Payable on Stark compliance
 - Plan to audit and monitor all physician compensation arrangements.

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NEW STARK EXCEPTIONS AND AKS SAFE HARBORS

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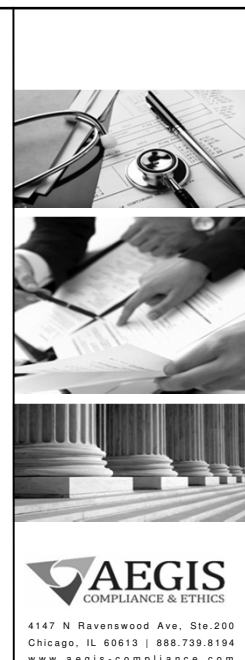


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STARK: NEW EXCEPTION Non-Physician Practitioner (NPP) Recruitment

- Previously, there was just a “physician” recruitment exception
- Now, hospitals (and FQHC/RHC) can recruit **mid-levels** to provide primary care or mental health services to a physician’s practice
- Covers PAs, NPs, clinical nurse, specialists, certified nurse, midwives, LCSWs and psychologists
- Up to 50% of compensation, once every 3 years (and other restrictions apply)
- Effective as of January 1, 2016

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STARK: NEW EXCEPTION Timeshare Arrangements

- Protects certain “timeshare” arrangements (not leases, which are subject to a different exception) between hospital or physician organization and a physician or medical group
- Space, equipment and other items are predominantly for evaluation and management (E/M) visits
- Any equipment is in the same building as E/M visits and used for diagnostic imaging only if incidental to E/M visit, and not used advanced imaging, radiation therapy or clinical laboratory services (other than CLIA-waived tests)
- Effective as of January 1, 2016

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ANTI KICKBACK STATUTE New Safe Harbors (December 7, 2016)

Section	Brief Summary
1001.952(f)	Technical correction to the referral services safe harbor.
1001.952(k)(3)	Interprets statutory exception to the anti-kickback statute permitting pharmacies to waive cost-sharing based on financial need or failure to collect.
1001.952(k)(4)	Protects certain waivers or reductions of cost-sharing by ambulance providers or suppliers owned and operated by a State or a political subdivision of a state.
1001.952(z)	Protects remuneration between a federally qualified health center (FQHC) and a Medicare Advantage organization pursuant to an agreement related to payment for certain FQHC services.
1001.952(aa)	Protects discounts on the price of certain drugs furnished in connection with the Medicare Coverage Gap Discount Program.
1001.952(bb)	Protects free or discounted local transportation services provided to Federal health care program beneficiaries.

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MONITORING & AUDITING

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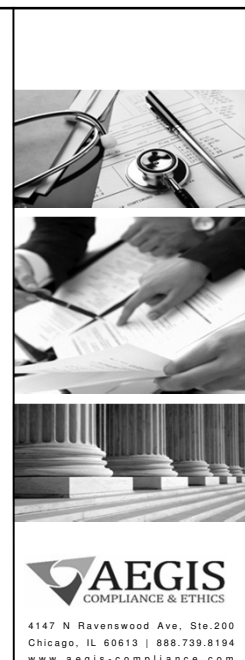
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EXPECTATIONS: DEFINE GOALS

- **Create Formalized Plan**
 - ❑ Who is accountable?
 - ❑ Use SMART Goals
- **Decide How Often?**
 - Monthly, Quarterly, Semi-annually, it's your choice!
 - Have a routine in which there is an even flow
- **Layout Scope of Payments**
- **Determine your Sample Size and Method**
- **Get backing from Legal, AP, Governing Body for Corrective Action Plan**

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Physician Arrangements

Question Sets


Does the agreement comply with the averages for services performed by other MDs of the same specialty for the Hospital?

Does the agreement specify the amount of Physician compensation?	Is there a properly signed agreement specifying services?	Does the agreement replace the pre-existing agreement?	
Does the compensation structure measure the volume or value of the physician's referrals?		Does the agreement incorporate or otherwise reference other agreement between hospital and physician?	
Is there evidence of FMV determination?	Did the appropriate parties sign?	Is the agreement currently effective?	Is the term of the agreement for at least 1 year?

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Physician Arrangements


The Value of Knowing Your Leaders to Ensure a Resolution

- Results from these audits can be humbling for many in leadership.
- Present your findings in the way your leader will best perceive the information as an opportunity, rather than an attack.
- Use graphs and be prepared to show cause of why the audit & its questions were structured that way.

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- **Work Product Privilege:** provides protection to any material created by a lawyer “in the course of his [or her] legal duties, provided that the work was done with an eye toward litigation. Rule 502, Federal Rules of Evidence
- **Attorney Client Privilege:** protects private communication concerning legal representation between an attorney and his or her client. Rule 502, Federal Rules of Evidence
- **Peer Review Privilege:** the process that engages health care providers and other medical personnel to analyze critically how health care activities are performed in order to decrease medical error and improve overall quality. HCQIA
- **BEWARE OF MIX RULINGS BUT USE IT NEVERTHELESS!**

<http://law.emory.edu/elj/content/volume-65/issue-4/comments/how-know-auditing-privilege-health-care-compliance.html#section-7bbae425ebd3aca54819ce8abecfb013>

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DISCLOSURE

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DISCLOSURE TO GOVERNMENT? Factors to Consider

- Follow Compliance Plan / Minimize Impact of Liability
- Strength /weaknesses of Legal Argument that no violation has occurred
- Amount of Monetary Re-payment
- Possible negative publicity. Is violation high-profile?
- Sympathy (or lack thereof) anticipated from enforcement agency.
- Is disclosure consistent with physician's agreement?

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DISCLOSURE TO GOVERNMENT? Technical Considerations

- 60 Days Notification Rule: 42 C.F.R. 401.301-5
- Deadline for reporting and returning overpayments, the later of:
 - ❑ the date which is 60 days after the date on which the overpayment **was identified**; or
 - ❑ the date any corresponding cost report is due, if applicable
- -lookback period that Government can review = **6 years**.

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DISCLOSURE TO GOVERNMENT? Technical Considerations

- **Enforcement:** If an overpayment is retained past the deadline, it may constitute an “obligation” under the False Claims Act.
- CMS said providers have time to conduct the “**reasonable diligence**” before the 60 days clock starts running:
 - ❑ -after receiving credible information then provider needs to undertake reasonable diligence;
 - ❑ -CMS articulates 6 months “benchmark” for conducting reasonable diligence. May be extended under “extraordinary circumstances”.

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DISCLOSURE TO GOVERNMENT? Technical Considerations

- Disclosure to certain government agencies may resolve enforcement of some violations, but not others:
 - ❑ Fiscal Intermediaries: Routine billing errors but may not cut off whistleblower or FCA.
 - ❑ CMS: Stark Only Protocol, no criminal or FCA.
 - ❑ OIG: Voluntary Disclosure Protocol –AKS or Stark Violations; no FCA.
 - ❑ Department of Justice: Can resolve all claims but potentially will be for higher profile cases.

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QUESTIONS?

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