



ALSTON & BIRD

Stark and Anti-Kickback Compliance

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What We Will Cover

- Stark Law Primer
- Anti-Kickback Summary
- Common Pitfalls
- Some unfortunate cases
- Board and leader oversight

Stark Law Background

- Prevents otherwise “normal” business arrangements
- Between physicians and entities to which they refer or have other dealings
- Medicare and Medicaid reimbursement the entity received from referring physician (or group) during the relationship put at risk
- Physicians can be subject to penalties
- Strict liability – no proof of intent needed

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Stark Law Provisions

- Prohibits **physicians** from **referring patients** to receive "**designated health services**" payable by **Medicare or Medicaid** from entities with which the physician or an immediate family member has a **financial relationship**, unless an **exception** applies
- Financial relationships include both **ownership/investment** interests and **compensation** arrangements
- **Prohibits the submission**, or causing the submission, **of claims** in violation of the law's restrictions on referrals

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Designated Health Services

- Clinical laboratory services
- Physical therapy, occupational therapy, and outpatient speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- DME and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services;
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

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Stark Law Exceptions – If All Criteria Met

- Rental of office space
- Rental of equipment
- Bona fide employment
- Personal service arrangements
- Physician incentive plans
- Physician recruitment
- Isolated transactions
- Certain arrangements with hospitals (no DHS)
- Group practice arrangements with hospitals
- Charitable donations by physicians
- Nonmonetary compensation
- Fair market value compensation
- Medical staff incidental benefits
- Risk-sharing arrangements
- Compliance training
- Indirect compensation arrangements
- Referral services
- Obstetrical malpractice insurance subsidies
- Professional courtesy
- Retention payments in underserved areas
- Community-wide health information systems
- Electronic prescribing items and services
- Electronic health records items and services
- Assistance to a nonphysician practitioner
- Timeshare arrangements

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General Stark Compliance Concepts

- Arrangement in writing
- Services well-defined
- Fair market value (accompanied by third-party valuation)
- Commercially reasonable

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Consequences of a Stark Law Violation

- Difficult resolution path
- Medicare and Medicaid reimbursement received by entity tainted
- False Claims Act overlay – \$11,000 - \$22,000 penalty, treble damages, attorneys' fees
- Civil Monetary Penalties
- Exclusion
- Cost, uncertainty, disruption, harm to reputation

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Common Stark Law Vulnerabilities

- Medical directorships
- Office leases
- Joint ventures and other incentivizing interests
- Not updating the arrangement as things change
- Expired and unsigned agreements

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The Anti-Kickback Statute

- Federal criminal statute
- Prohibits the **knowing and willful** payment of "**remuneration**" to induce or **reward patient referrals** or the generation of business involving any **item or service payable by the Federal health care programs** (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).
- Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies.
- Criminal penalties and administrative sanctions include fines, jail terms, and exclusion from participation in the Federal health care programs.
- Under the CMPL, physicians who pay or accept kickbacks also face penalties of up to \$50,000 per kickback plus three times the amount of the remuneration.

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Anti-Kickback Safe Harbors

- Investment interests
- Space rental
- Equipment rentals
- Personal services and management contracts
- Sale of practice
- Referral services
- Warranties
- Discounts
- Bona fide employment
- Group purchasing organizations
- Certain copayment waivers
- Increased health plan coverage
- Discounts to health plans and MCOs
- Practitioner recruitment
- Obstetrical malpractice subsidies
- Investments in group practices
- Cooperative hospital service arrangements
- Investments in ASCs
- Referral arrangements for specialty services
- Arrangements not in a Safe Harbor may not be violations

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Common Anti-Kickback Vulnerabilities

- Hospital – physician relationships
- Hospital – vendor, manufacturer, supplier relationships
- Employed physician – vendor, manufacturer, supplier relationships
- Gifts, meals, entertainment
- Payment or relief of expenses
- Speaking engagements, honoraria, travel

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Some Unfortunate Stories: Combination of Stark/AKS/FCA

- Miscoded claims generate more compensation for physicians (\$115M)
- Inter-practice referral agreement (\$24.5M)
- Contracts with 19 specialists to refer to health system (\$237M)
- Arrangement with chief of staff and 92 physicians/groups (\$3.2M)
- No-work agreements, advance expenses, cost reports (\$18.8M)
- Above-FMV comp, upcoding, billing for unsupervised services (\$2.9M)
- Payment to patient recruiters (\$10M)
- Limiting and rewarding physicians based on referrals (\$108M)
- Payments above FMV for medically unnecessary services (\$22M)

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Board and Senior Leadership Oversight

- Who is responsible for Stark and AKS compliance?
- Meaningful Conflict of Interest identification and management
- Inventory of all contracts and arrangements
- Update arrangements when circumstances change
- Third-party FMV valuations
- High-risk contracts dealt with separately
- Formal process for reviewing exceptions or outliers
- Documenting decisions
- Education

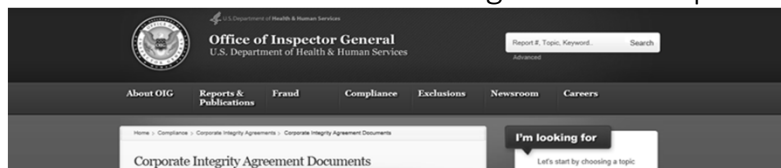
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What to do: Elements of an Arrangements Compliance Program



What Do Arrangement's CIA's Require?

- A compliance program consistent with the seven elements;
- Implementation of a centralized tracking system (i.e., a contract database);
- Tracking of remuneration to and from parties to Focus Arrangements;
- Tracking service and activity logs to assure services are provided;
- Monitoring the use of space, supplies, services, etc.;
- Policies addressing compliance with AKS & Stark;
- A written procedure for review and approval of Focus Arrangements that includes:
 - Legal review of arrangements (incl written agreements);
 - A process for specifying business need; and
 - A process for determining and documenting fair market value.
- Annual CO review of contract database and other Focus Arrangements procedures;
- Effective response to instances of non-compliance (incl. return of Overpayments);
- Annual AKS/Stark training for all parties to Focus Arrangements;
- An external (Independent Review Organization or "IRO") review of the organization's systems and policies (Systems Review)
- An external (IRO) review of a sample of Focus Arrangements (Transactions Review)

Recent Arrangements CIAs

- William Beaumont Hospital (7/31/18)
https://oig.hhs.gov/fraud/cia/agreements/William_Beaumont_Hospital_07312018.pdf
- Post Acute Medical, LLC (8/13/18)
https://oig.hhs.gov/fraud/cia/agreements/Post_Acute_Medical_LLC_et_al_08132018.pdf

What to do: Elements of an Arrangements Compliance Program

Leadership & Culture

- Board/Governance Oversight
- Compliance Committee
- Executive/Management
- Legal Counsel
- Compliance Officer

The harder part . . .

“I want everyone in this organization to be able to go to bed every night knowing that we did the right thing – even if it wasn’t the easy thing to do.”

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What to do: Elements of an Arrangements Compliance Program

Core Structural Elements

➤ Risk Assessment

- What kinds of Arrangements does your organization have?
- How many Arrangements?
- Who has responsibility in your organization for the various types of Arrangements?
- Do you have a marketing/business development group? What activities are they engaged in?
- Are there areas of particular concern?

➤ Creating a Workplan & Identifying Owners

➤ Written Standards (Policies & Procedures)

- General policies on Stark and AKS compliance?
- Specific policies to address specific risk areas?

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What to do: Elements of an Arrangements Compliance Program

Review & Approval Process

Business Review & Establishing Business Purpose/Need

- How related to legal standards for arrangements?
- Who is responsible?
- Policy requirements/guidelines?
 - Standardized requirements?
 - Central review?
- Documentation

Legal Review

- What do attorneys review?
- What does up front legal review generally NOT cover?
- Documentation

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What to do: Elements of an Arrangements Compliance Program

Review & Approval Process – Establishing Fair Market Value

- What is Fair Market Value (“FMV”)?

Section 1877(h)(3) of the Social Security Act defines Fair market value as the value in arms-length transactions, consistent with general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use or proximity to a lessor who is a potential referral source).

“Usually the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of the acquisition . . .”
- Why is it important to establish FMV?
 - “Whenever [someone] offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business.” *OIG Special Fraud Alert, Arrangements for the Provision of Laboratory Services* (Oct 1994), quoted in *OIG Special Fraud Alert, Laboratory Payments to Physicians* (June 2014)
- Who will be responsible for establishing and documenting?
 - Leases
 - Physician employment
 - Physician contract arrangements
 - Other

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What to do: Elements of an Arrangements Compliance Program

Review & Approval Process – Establishing Fair Market Value

- What evidence of FMV will you require?
- When will you require a third party opinion vs. internal collection of relevant supporting data and reasoning?
 - “However, while internally generated surveys can be appropriate as a method of establishing fair market value in some circumstances, due to their susceptibility to manipulation and absent independent verification, such surveys do not have strong evidentiary value and, therefore, may be subject to more intensive scrutiny than an independent survey.” (Preamble to the Stark Phase I Final Rule).
- What happens if the arrangement changes?
- Documentation

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What to do: Elements of an Arrangements Compliance Program

Tracking Mechanisms/Contract Database

- What is required?
- Who owns and maintains?
- Who has access?
- Core functions:
 - Ability to track/report on key contract terms
 - contract parties,
 - compensation,
 - contract type,
 - expiration & renewal dates,
 - responsible parties
 - Ability to store key documents
 - Signed contracts/addendums,
 - FMV and other supporting documentation,
 - Time sheets/activity logs,

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What to do: Elements of an Arrangements Compliance Program

Keeping the Genie in the Bottle: Managing to Maintain Compliance

Keeping Track of What Has Been Paid

- When is this required?
- Why is it important?
- What is required?
- Who should be responsible?

Monitoring Use of Space, Supplies, Equipment, etc.

- When is this required?
- Why is it important?
- Who should be responsible?

Reviewing Timesheets and Activity LOGS

- When is this required?
- Why is it important?
- Who should be responsible?

Payment Approval

- Payment is being made pursuant to a written/effective agreement
- Payment is consistent with the agreement
- Documentation supports the payment

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What to do: Elements of an Arrangements Compliance Program

Training / Auditing & Monitoring

Training

- Who Should be Trained?
 - Board and management
 - Personnel who manage Arrangements
 - Parties to Arrangements
 - Other?
- Training on What?
 - Law & regulations
 - Potential consequences of compliance failures
 - Organization's policy/procedure requirements

Auditing & Monitoring

- CIA: Compliance Officer annual review and two external reviews (1) Arrangement's Systems; and (2) Transactions Review. Is this a good model?

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Questions & Discussion

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