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**Implementing and Operating an Effective Physician Arrangements Compliance Program**

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**About Me**



- 30+ years health care industry executive experience
- 20+ years experience as an attorney, compliance officer and compliance consultant
- Compliance/legal experience spans 40+ organizations in various aspects of the healthcare industry (each of these had issues/interactions with the Stark and AKS laws.)
- Led/conducted/participated in several Stark/AKS self-disclosures (CMS, OIG & DOJ)
- Served as Arrangements IRO pursuant to Arrangements CIA
- Managed Arrangements CIA as Chief Compliance Officer
- Built and led multiple physician/referral source arrangements compliance programs



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**What Are Appropriate Strategies for an Effective Health Care Compliance Program?**

- Prevention
- Detection/Correction
- Defense



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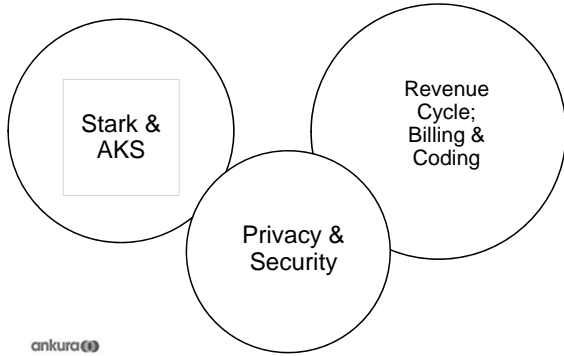
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### What Are Appropriate Strategies for an Effective Health Care Compliance Program?



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### Healthcare Anti-Kickback Statute (AKS)

Unlawful to:

- Knowingly and willfully
- Offer, give, solicit or receive
- Any remuneration (directly or indirectly, overtly or covertly, in cash or kind)
- In return for
  - referring for any item or service reimbursable by Federal health care programs, or
  - purchasing, leasing, ordering or arranging for (or recommending any of the same) any good, facility or service reimbursable by Federal health care programs

#### Penalties for AKS Violation

**CRIMINAL:** "shall be guilty of a felony and upon conviction"

- Fined not more than \$25,000
- Imprisoned not more than 5 years, or
- Both

**CIVIL:** OIG Civil Money Penalty and Exclusion Authorities

- Up to \$50,000 per violation
- Up to 3-times the amount of improper remuneration
- Exclusion

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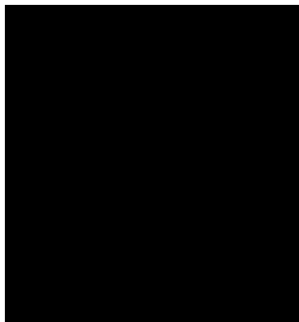
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### What Does the AKS Prohibit?

U.S. v. Anderson, 85 F.Supp.2d 1047 (Kan 1999)



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## Stark Law – Plain Language



If a **Physician** (or immediate family member) has a direct or indirect **Financial Relationship** with an **Entity**, unless an exception applies:

- the **Physician** may not **Refer** any **Designated Health Services ("DHS")** to the **Entity**,
- the **Entity** may not bill for any **DHS** referred by the physician,
- no Medicare payments may be made for **DHS** referred by the physician, and
- the **Entity** must refund all moneys collected for **DHS** referred by the physician (unless no actual knowledge or reckless disregard re: the physician's identity)

- FOCUS: Assure that arrangements meet requirements of an exception and manage to keep them there
- Stark Law is strict liability - intent is not an element of a violation




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## Who Should be Concerned About Stark & AKS?

Columbus Regional Health System and Dr. Pippas, Columbus, GA (Sept 4, 2015)

• Audits of physician billing found that Dr. Pippas billed at a higher level than was supported by documentation (Pippas billed largely level 5)

• Initial qui tam complaint against Columbus Regional Health System (CRHS) alleged improper billing

• Complaint details Dr. Pippas' resistance to correcting his documentation/coding & Billing practices

• Amended qui tam complaint alleges Dr. Pippas is paid in excess of FMV

OIG Fraud Alert (June 9, 2015) *Physician Compensation Arrangements May Result in Significant Liability*

• Fraud Alert followed a 2012 settlement with Dr. Jack Baker and Fairmont Diagnostic Center (TX)

• Medical director agreements and provision of office staff to physicians

• "Physicians did not provide the services" and arrangements was not FMV

• the "OIG determined that the physicians were an integral part of the scheme."

### Result

- CRHS enters settlement for \$35 million and enters into a five year corporate integrity agreement
- Dr. Pippas settles for \$425,000

### Result

- Dr Baker & Fairmont settle for \$650,000, and Dr. Baker is excluded for six years
- OIG collected settlements totaling \$1.4M from 11 physician/"medical directors" (\$50K to \$195K), and exclude one physician for three years




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## Who Should be Concerned About Stark & AKS?

### Stark & AKS

- **ENTITIES** that provide or bill for **DHS** and have **FINANCIAL RELATIONSHIPS** with **REFERRING PHYSICIANS**
- **REFERRING PHYSICIANS** (and physician organizations) that have **FINANCIAL RELATIONSHIPS** with **ENTITIES** that provide or bill for **DHS**

### AKS

- Any participant in the health care marketplace

### Designated Health Services (DHS)

1. Clinical Laboratory Services
2. Physical Therapy, Occupational Therapy and Speech-Language Pathology Services
3. Radiology and certain other imaging services
4. Radiation Therapy services and supplies
5. Durable medical equipment and supplies
6. Parenteral and enteral nutrients, equipment, and supplies
7. Prosthetics, orthotics, and prosthetic devices and supplies
8. Home health services
9. Outpatient prescription drugs
10. Inpatient and outpatient hospital services




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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)




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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 FMV**

- **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 FMV**

- 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

Fair Market Value (cont.)

Your organization has recently purchased several physician groups. FMV was established for the groups when they were purchased, and for the physician's compensation going forward. Does it matter that the physician practices are now losing money?



Horizontal lines for notes

Who Should be Concerned About Stark & AKS?

Employment Relationships

U.S. ex. rel. Drakeford v. Toumey Healthcare System, Inc. (Settled October 2015)

- Part-time employment arrangements with 19 physicians
Allegations that compensation was not FMV and not commercially reasonable

United States ex. rel. Baklid-Kunz v. Halifax Hospital Medical Center, et al. (Settled March 2014)

- Allegation - six employed oncologists bonuses varied with volume or value of referrals to the hospital because prescription drugs and radiology ordered by the physicians was included in calculating RVUs and bonuses
Allegation - three neurosurgeons were paid more than FMV for their work

Result

- 3/2010: Judgment for \$45M
10/3/13: Judgment for \$237M
10/17/15: Settlement w/DOJ for \$72.4M after acquisition by Palmetto Health
9/27/16: Former Toumey CEO pays \$1M and is excluded for four years for his involvement

Result

- Hospital settles for \$85M and enters a 5 year Corporate Integrity Agreement



Horizontal lines for notes

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)



Horizontal lines for notes

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?

Reviewing Timesheets and Activity Logs

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

Monitoring Use of Space, Supplies, Equipment, etc.

- 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?**
  - 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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