



# Implementing and Operating an Effective Arrangements Compliance Program

*Assuring Stark and AKS Compliance in Arrangements with Referral Sources*



Helping You Succeed.

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

Experience with Stark & AKS and referral source arrangements compliance



- 30+ years executive level health care industry experience
- 20+ years experience as an attorney, compliance officer and compliance consultant
- Compliance/legal experience with 40+ organizations in various parts of the healthcare industry (most of these had issues or interactions with the Stark and AKS law compliance)
- Led/conducted/participated in significant Stark/AKS investigations and/or self-disclosures (CMS, OIG & DOJ)
- Built and led multiple physician/referral source arrangements compliance programs
- Managed Focus Arrangements CIA requirements as Chief Compliance Officer
- Served as Focus Arrangements IRO pursuant to Arrangements CIAs

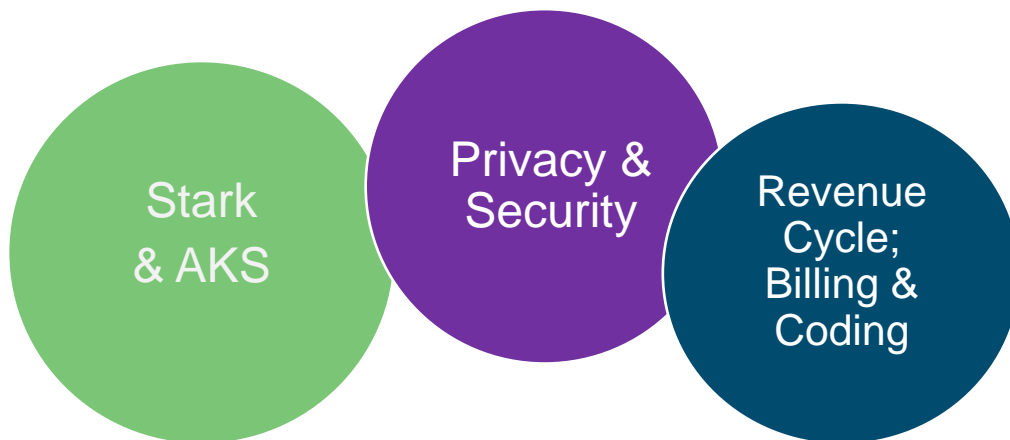


# What Are Appropriate Strategies for an Effective Health Care Compliance Program?



- Prevention
  - Detection/Correction
  - Defense
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## What Are Appropriate Strategies for an Effective Health Care Compliance Program?



# 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”

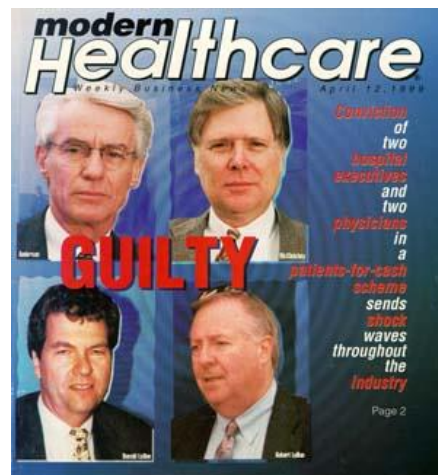
- Fined not more than \$100,000
- Imprisoned not more than 10 years, or
- Both

## OIG Civil Money Penalty and Exclusion Authorities

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

## What Does the AKS Prohibit?

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



## 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 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

#### Result

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

### 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

- 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

- **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**



**X-Ray**

## 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



## AKS

- Any participant in the health care marketplace



## Elements of an Arrangements Compliance Program: What do Focus Arrangements CIAs Require?

- A compliance program consistent with the seven elements;
- 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;
- IRO review of the organization's systems and policies (Systems Review)
- IRO review of a sample of Focus Arrangements (Transactions Review)

## 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.”

## 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?
- Training Programs & Communication
  - General Stark and AKS training for the entire workforce?
  - Specific training for personnel charged with managing parts of the arrangements processes?
  - Training for parties to referral source arrangements?
- Investigation & Response
  - Enforcement of standards & discipline?
  - Self-disclosure and overpayments?

## What to do: Elements of an Arrangements Compliance Program



### Get it Right up Front: 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/review for?
- What does up front legal review generally NOT cover?
- Documentation

#### Management and/or Board Review & Approval

- Who has authority to initiate a new referral source arrangement?
- Who is required to approve a new arrangement?
- When is approval given/required?
- How are approvals documented?

## What to do: Elements of an Arrangements Compliance Program



### Get it Right up Front: 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

## What to do: Elements of an Arrangements Compliance Program



### Get it Right up Front: Establishing Fair Market Value

- What evidence of FMV will you require?
  - What happens if the arrangement changes?
  - Documentation
  - 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).
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## 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

#### 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

#### *US 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
- Possible damages near \$1 Billion

#### Result

- Hospital settles for \$85M and enters a 5 year Corporate Integrity Agreement
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## What to do: Elements of an Arrangements Compliance Program



### Contract Database/Focus Arrangements Tracking System

- What is required?
  - Who owns and maintains?
  - Who has access?
  - Core functions:
    - Ability to store/track/report on key contract terms
      - ✓ Contract parties
      - ✓ Compensation
      - ✓ Contract type (what is provided/required)
      - ✓ Effective, expiration & renewal dates
      - ✓ Responsible parties
    - Ability to store key documents
      - ✓ Signed contracts/addendums
      - ✓ FMV and other supporting documentation
      - ✓ Time sheets/activity logs
      - ✓ Documentation of reviews & approvals
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## What to do: Elements of an Arrangements Compliance Program



### Keeping the Jeanie 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



## Auditing & Monitoring

### Focus Arrangements CIA Audit Requirements:

- (1) Compliance Officer Annual Review of Focus Arrangements Procedures; and
- (2) IRO Arrangement's Systems Review (external) in year one and four;
- (3) IRO Arrangements Transactions Review (external) annually

Is this a good model?

### The role of monitoring in Focus Arrangements Compliance Programs

- Who conducts monitoring?
- How frequently?
- Where are results reported?



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## Questions?



Helping You Succeed.

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