

Society of Corporate Compliance and Ethics

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Compliance Systems in Higher
Education



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We Are Special!!—The Special Need for Contract Management for the Health Sciences Function of a University

Thursday, April 22, 2010
10:15—11:45 AM

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Today's Presenters

- **Brian Annulis**
 - Managing Director, Aegis Compliance & Ethics Center, LLP
 - Partner, Meade & Roach, LLP
 - 773-907-8343
 - bannulis@meaderoach.com
- **Janis Anfossi**
 - Associate General Counsel, HIPAA Privacy and Security Officer
 - Rush University Medical Center (Chicago, IL)
 - 312-942-8123
 - Janis_anfossi@rush.edu

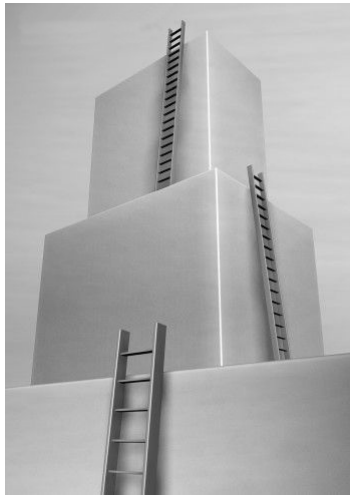
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Today's Agenda

- Statutes and Regulations Affecting Contracting/Procurement Issues in the Health Sciences Component of a University
- Health Care Contract Issues/Concerns
- Sample Agreements and Practical Considerations

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Today's Goals



- Knowledge Transfer
- Practical Advice/Suggestions

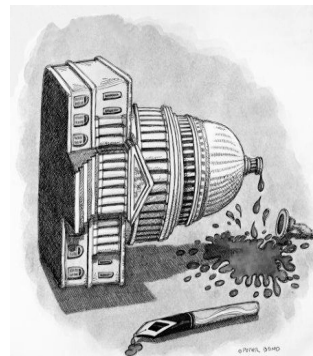
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So, Why Are We Special?

Proposed FY 2011 Federal Budget:

- Medicare Program Outlays: \$563 billion
- Federal Medicaid Program Subsidy: \$296 billion
- State Matching Medicaid Outlay: \$200 billion (est.)
- CHIP: \$10 billion

Total: \$1.069 trillion



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So, Why Are We Special?

FY 2011 Estimates

- **Medicare beneficiaries: 48 million**
- **Medicaid enrollees: 56 million (5 million also Medicare)**
- **CHIP enrollees: 8 million**
 - **CMS Total: 107 million covered persons**

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So, Why Are We Special?

- **Estimates of Fraud, Waste & Error:**
 - Unknown; government stopped estimating
- **FY 2011 Fraud Control Budget:**
 - **\$1.7 billion**



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So Why Are We Special?

- Those estimates and figures demand significant attention at all levels
 - Federal and state governments
 - US Department of Justice
 - US Attorney Generals
 - FBI
 - CMS
 - HHS, Office of Inspector General
 - State Attorney Generals
 - Program Safeguard Contractors
 - Recovery Audit Contractors
 - Medicaid Fraud Control Units

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So Why Are We Special?

- Those estimates and figures demand significant attention at all levels
 - Accreditation Organizations and Trade Associations
 - Joint Commission
 - Accreditation standards
 - PhRMA
 - Code on Interaction with Healthcare Professionals (Revised) (January 1, 2009)
 - AdvaMed
 - Code of Ethics (July 1, 2009)
 - Insurers

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So Why Are We Special?

- Those estimates and figures demand significant attention at all levels
 - Statutes, Rules and Regulations
 - Anti-Kickback Statutes (federal and state)
 - Stark law (self-referral prohibitions) (federal and state)
 - Patient/beneficiary inducement prohibitions
 - HIPAA and HITECH
 - Criminal Statutes (18 USC)
 - Health care fraud
 - False claims
 - Health care theft/embezzlement



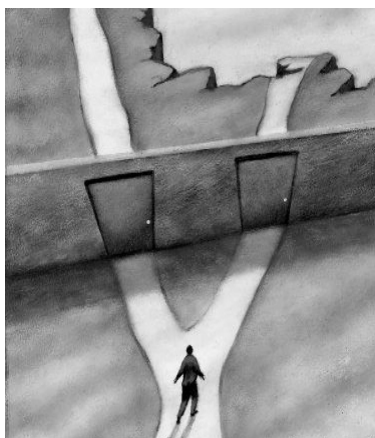
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So Why Are We Special?

- Those estimates and figures demand significant attention at all levels
 - Statutes, Rules and Regulations
 - Civil Remedies
 - Medicare program fines and penalties
 - False Claims Act (federal and state)
 - » Qui tam relators
 - Administrative Remedies
 - Debarment, Exclusion and Suspension
 - Corporate Integrity Agreements
 - Loss of license
 - State Laws
 - Fee splitting

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And So . . .



- An effective compliance plan/program within the health sciences component of a University must, among other things, include an effective **contracts management process** that both:
 - Addresses the required terms and provisions; and
 - Manages/tracks those contracts for required ongoing compliance concerns

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Federal AKS—Overview

- Intent-based statute
- Makes it illegal to
 - knowingly and willfully
 - offer, pay, solicit or receive any remuneration, directly or indirectly,
 - intended to induce the recipient to refer (or arrange for the referral) of a patient to the payor for the furnishing of items or services
 - for which payment may be made by Medicare, Medicaid or certain other federal health care programs. 42 U.S.C. § 1320a-7b(b)(2)(A).

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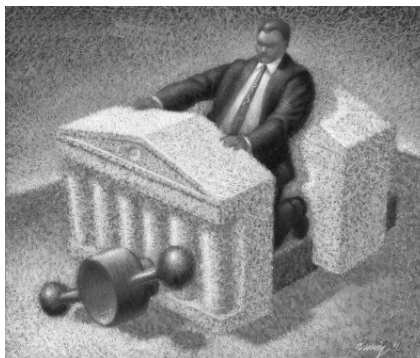
Federal AKS—Overview

- “Remuneration” has been defined broadly to include anything of value in any form; and
- “Inducement” has been broadly interpreted to cover any act that is intended, even in part, to influence the reason or judgment of another in an effort to cause the referral of federal health care program business.

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Federal AKS—Enforcement

- Violations of the AKS are punishable by **criminal** fines of up to \$25,000, imprisonment and mandatory exclusion.
- Offenders are also subject to **civil money penalties** of up to \$50,000 per violation and **treble damages**
- Offenders may also be excluded from participation in the Medicare and Medicaid programs.



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Federal AKS—Safe Harbor Regulations

- Because of the broad scope of the statute, Congress passed legislation which required the Office of Inspector General ("OIG") for the U.S. Department of Health and Human Services to promulgate "safe harbor" regulations
 - Specify those practices and arrangements which may implicate the statute but which will not be subject to criminal prosecution, civil fines or administrative sanctions.
 - Failure to comply with safe harbor regulation does NOT mean arrangement is illegal per se

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Federal AKS—Safe Harbor Regulations

- Safe Harbor Regulations include:
 - Space and Equipment Rental
 - Personal Services and Management Contracts
- Common components
 - Written agreements
 - Minimum term of 1-year
 - **Aggregate** rental charge is set in advance, consistent with FMV in an arms-length transaction and not determined in a manner that takes into account the volume or value of referrals
 - Space and equipment to be leased is what is necessary to accomplish commercially reasonable business purpose

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Stark Law—Overview



- Provides, in pertinent part, that
 - "if a physician (or an immediate family member of a physician) has a financial relationship with an entity [that furnishes designated health service],
 - then the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under [the Medicare program]."
- 42 USC 1395nn; 42 C.F.R. Part 411, Subpart J.

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Stark Law—Overview

- The Stark Law and its attendant regulations offer "exceptions" to this referral prohibition.
- If the Stark Law is triggered, then the financial relationship **must** fit within one of the specific exceptions in order for the financial relationship to be compliant.
 - Compare with AKS Safe Harbor regulations

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Stark Law—Overview

- Three critical issues in deciding whether a particular arrangement or agreement violates the Stark Law:

1. Are there **referrals** of Medicare patients to the entity by the physician for the provision of "**designated health services**"?

"Designated health services" ("DHS") are defined to include: clinical laboratory services; physical and occupational therapy services; radiology services; radiation therapy services and supplies; infusion therapy and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient services .

The referrals need not relate to the compensation arrangement or ownership interest (as described in item (2) immediately following)

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Stark Law—Overview

- Three critical issues in deciding whether a particular arrangement or agreement violates the Stark Law:

2. Is there a "**financial relationship**" between the DHS entity and a physician?

The financial relationship may be direct or indirect. The financial relationship may also involve either an ownership interest in the entity or a compensation arrangement with the entity

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Stark Law—Overview

- Three critical issues in deciding whether a particular arrangement or agreement violates the Stark Law:

3. Finally, if there is a referral of patients by the physician to the DHS entity for the provision of a DHS and a financial relationship between the physician and the entity, does the arrangement or agreement satisfy the requirements of an **exception**?

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Stark Law—Overview

- If there is a referral of patients by the physician to the entity for the provision of a DHS and a financial relationship between the physician and the entity and the proposed agreement or arrangement does not satisfy the requirements of a particular exception, then the arrangement will be deemed to violate the Stark Law.

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Stark Law--Exceptions

- Stark Law exceptions exist for both ownership interests and compensation arrangements
- Compensation arrangement exceptions include:
 - Rental of Office Space and Equipment
 - Personal Service Arrangements

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Stark Law--Exceptions

- Common components
 - Written agreements
 - Minimum term of 1-year
 - Rental charge is set in advance, consistent with FMV in an arms-length transaction and not determined in a manner that takes into account the volume or value of referrals
 - Space and equipment to be leased is what is necessary to accomplish commercially reasonable business purpose
- Compare with AKS Safe Harbor
 - Rental charge versus **aggregate** rental charge

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Stark Law—Enforcement

- Violations of the Stark Law, including unintended violations, will result in **nonpayment** (or a required refund) for the referred service. This could be a substantial financial consequence.
- In addition, willful violations of the Stark Law could result in the imposition of **civil fines** of fifteen thousand dollars (\$15,000) per referral.

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BASIC Healthcare Contracting Checklist



- ✓ Identification of parties
- ✓ Effective Date
- ✓ Recitals/Background
- ✓ Definitions
- ✓ Subject Matter of the Agreement (Goods, Services, Personnel)
- ✓ Consideration
- ✓ Representations and Warranties
 - ✓ No exclusion or debarment
- ✓ Term and Termination

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BASIC Healthcare Contracting Checklist

- ✓ Insurance and Indemnification
- ✓ Confidentiality
- ✓ Exclusivity?
- ✓ Restrictive Covenants (Non-competes, Non-Solicitation, Proprietary Information)?
- ✓ Regulatory Issues/Concerns
 - ✓ HIPAA, AKS, Stark Law, tax exempt concerns, FDA, state law (fee splitting, prohibition of the corporate practice of medicine), CIA obligations
- ✓ Intellectual Property Rights?

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BASIC Healthcare Contracting Checklist

- ✓ Adherence to Ethical & Religious Directives
- ✓ Adherence to Compliance Program
- ✓ ADR/Arbitration?
- ✓ Change in Law?
- ✓ Miscellaneous
 - ✓ Assignment rights, relationship among the parties, notices, amendment, governing law,

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Practical Application—Medical Director Agreement



- AMCs likely have Medical Director Agreements with Physicians/Physician Groups
- Issues/Considerations
 - Who will provide medical director services?
 - Ability of Group to appoint, assign replacement?
 - Joinder Agreement?
 - Performance standards/qualifications

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Practical Application—Medical Director Agreement

- Issues/Considerations
 - Duties and obligations commensurate with compensation.
 - **AKS and Stark Law** compliance concerns—FMV payment for commercially reasonable
 - Documentation requirements
 - Use of provider resources
 - HIPAA
 - Business associate or workforce member?
 - Compliance program covenants and obligations
 - Non-Exclusion/debarment representations
 - Indemnification
 - Confidential Information/Trade Secrets
 - Non-competition/non-solicitation

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Practical Application—Clinical Trial Agreement

- AMCs often enter into CTAs with research Sponsors.
 - Often times, the Principal Investigator is employed by the AMC or an affiliate (Faculty Practice Plan)
 - Often times, the study subject is a federal health care program beneficiary
- Issues/Considerations
 - Medicare Coverage Analysis
 - What does the Study budget/protocol require?
 - What does the Study budget/protocol cover?
 - Does the PI have a financial relationship with Sponsor?
 - Conflict of interest?
 - PhRMA and AdvaMed Codes

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Practical Application—Clinical Trial Agreement

- Issues/Considerations
 - Proprietary rights?
 - Publication rights?
 - Risk allocation/subject injury

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Practical Application—Data Agreements

- AMCs have access to significant amounts of valuable clinical data and information
- AMCs also seek access to clinical information data bases and repositories
- Issues/Considerations
 - Data elements
 - HIPAA concerns/considerations
 - PHI
 - LDS of PHI
 - De-identified health information
 - Data transfer/acquisition
 - License?
 - Sale?



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Practical Application—Data Agreements

- Issues/Considerations
 - Consideration commensurate with FMV
 - Permitted Uses and Disclosures of Data

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Practical Application—Products Purchase Agreement



- Universities/AMCs purchase health care products from commercial vendors
- Issues/Considerations
 - Product recall obligations
 - Representations and warranties
 - Manufacture, stored and distributed in accordance with all applicable laws
 - License and permits

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Practical Application—Products Purchase Agreement

- Universities/AMCs purchase health care products from commercial vendors
- Issues/Considerations
 - Indemnification
 - Failure to supply obligations
 - Discounts, rebates and incentives
 - AKS concerns
 - Vendor access and support issues
 - HIPAA

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Takeaways

- Contracts management function within the Life Sciences function of a University involves special regulatory concerns
- Use of forms/templates is recommended
- Proper identification of parties and affiliates is important
 - Referral sources?
 - Conflicts of Interest?
- Contracts tracking tool/management system/checklist is beneficial
- Legal and compliance review is required

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