

**Weathering the Storm:
Critical Legal &
Operational Issues
Shaping Healthcare in 2010**

Pre-Seminar Workshop

The Anti-Kickback Statute

Sarah Downs

History and Purpose

- Enacted to prohibit practices that were already considered unethical
- Intended to prohibit payment for referrals
- First anti-kickback provisions were enacted in 1972
- 1977 amendments broadened the language and strengthened the penalties
- Three necessary elements
 - Intentional act
 - Direct or indirect payment of remuneration
 - Intent to induce the referral of patients or business
- Severe penalties: \$25,000 fine, imprisonment for not more than five years, and exclusion

Implications

- Broad definition of remuneration
- Common safe harbors
 - Personal services and management contracts
 - Space and equipment rental
 - Investment interests
 - Employees
- Not strict liability
 - Fitting within a safe harbor means the arrangement does not violate the statute
 - Not fitting within a safe harbor does not necessarily mean the arrangement is illegal

Enforcement

- Can be enforced through statute or CMP
- Key areas of enforcement
 - Intent standard
 - Recent focus on individuals
- Common pitfalls
- States' anti-kickback statutes

Healthcare Reform

- According to the White House, a significant portion of healthcare reform will be paid for by cutting waste, fraud, and abuse in existing government health programs

The Stark Law

Megan C. Phillips

History and Purpose

- Originally enacted in 1989 and applied only to physician referrals for clinical laboratory services
- Expanded in 1993 and 1994 to cover 11 other “designated health services”
 - e.g., physical and occupational therapy, DME, outpatient prescription drugs, home health services, inpatient and outpatient hospital services

Overview

- Generally prohibits physicians from referring Medicare patients for DHS provided by an entity with which the physician has a “financial relationship”
- Financial relationship is defined very broadly
- If a financial relationship exists, then an exception to the Stark Law must be met

Key Elements of Exceptions

- Many different exceptions exist for different types of arrangements
- Common elements to exceptions:
 - Compensation must be fair market value
 - Compensation must not vary with the volume or value of referrals
 - Arrangement must be documented in a written agreement

Implications

- Stark is a “strict liability” statute
 - No bad intent necessary
 - Even “technical” errors may constitute a violation
 - No general *de minimis* exception
- Severe penalties
 - Refund of all amounts billed pursuant to a prohibited referral
 - Penalty of \$15,000 per claim
 - Penalty of up to \$100,000 for engaging in a circumvention scheme

Healthcare Reform

- OIG no longer accepts Stark Law disclosures without a “colorable” anti-kickback violation
- CMS must develop its own self-disclosure protocol within 6 months
- Under the protocol, CMS will have authority to negotiate settlements

The False Claims Act (FCA)

Cori Casey Turner

History and Purpose

- Enacted during the Civil War to combat defense procurement fraud
- Government and private individuals can file claims under the FCA
- Since 1986 amendments, recoveries exceed \$26 billion
- Nearly 80% of all cases involve healthcare fraud
- Many states have enacted false claims acts

Liability for FCA Violation

- Claims submitted to the government and entities administering government funds (Medicare and Medicaid managed care)
- Penalties – up to \$11,000 per false claim
- Damages – 3 times the payment amount
 - Timeframe for potential damage reduction – 30 days after “discovered”

FCA Intent Standards

- Historically: FCA liability limited to “knowingly” or “intentionally” inducing government payment through presentment of a false claim
- 2009 FERA amendments: Expands liability to retention of government overpayments where no false claim made
 - Claims submitted without knowledge of their falsity that result in an overpayment can become a “false claim” if discovered and not repaid

Healthcare Reform

- Obligation to repay “overpayments” within 60 days of “identification” (unless reconciled through cost report)
- What is an “overpayment”?
- When is an overpayment “identified”?

Implications

- Failure to repay incorrect claims or billing errors
 - coding errors
 - system processing errors
 - not supported by medical necessity
 - documentation issues
- Failure to repay claims submitted in violation of Stark

How to Implement an Effective Compliance Plan

Mary R. Daniel

What is “Compliance”?

- Meaning of “Compliance”
- Development of a plan vs. *implementation of effective* plan
- Education about plan vs. education about *compliant conduct*
- Today, entities need to establish a “culture of compliance” from the CEO to the billing clerk

7 Essential Elements

1. Written standards of conduct
2. Chief Compliance Officer
3. Education and training programs
4. Process for anonymous reporting and protection from whistleblower retaliation
5. Responsiveness to allegations, including disciplinary action
6. Auditing and monitoring
7. Investigation, remediation, and sanctioning responsible individuals

Effective Education and Training

- Personnel understand how compliance relates to job responsibilities
 - Contract negotiator
 - Billing clerk
- Not a one-size-fits-all approach
- Empower individuals to develop solutions to common problems

Effective Auditing and Monitoring

- Establish a process to determine whether healthcare services are legitimate and needed
- Review changes in law and update compliance plan on a periodic basis
- Establish a process to audit contracts

Healthcare Reform

- Secretary of HHS/OIG will require certain Providers and Suppliers to adopt compliance programs
- Changes promulgated through regulations
- What will compliance programs cover?
 - CIAs?
 - Existing OIG Compliance Guidance?
 - Penalties?

Contract Management

Kim Gibbens

Purpose of Contracts

- Describes arrangement between the parties
- Regulatory compliance
- Helps mitigate compliance risks

Contract Management

- No one size fits all
- Written contract review policy
- Keep key personnel in loop
 - Department Staff
 - Accounts Payable
 - Legal

Contract Management

- Audit/Monitor through tracking system
 - FMV
 - Contract signed by all parties
 - Term/Termination
 - Educate staff

Potential Problem Areas

- Description/amount of services
- Financial terms – reconciliation
- Expiration versus auto-renewal
- Signature
- Services before contract in place