2013 Healthcare Fraud and Abuse Bootcamp Webinar Series, Part V: Compliance

This bootcamp webinar series is brought to you by the Fraud and Abuse (Fraud) Practice Group and is co-sponsored by the Healthcare Liability and Litigation (HLL); Hospitals and Health Systems (HHS); In-House Counsel (In-House); Labor and Employment (Labor); Long Term Care, Senior Housing, In-Home Care, and Rehabilitation (LTC-SIR); Life Sciences (LS); Medical Staff, Credentialing, and Peer Review (MSCPR); Payors, Plans, and Managed Care (PPMC); Physician Organizations (Physicians); Regulation, Accreditation, and Payment (RAP); and Teaching Hospitals and Academic Medical Centers (THAMC) Practice Groups.

Wednesday, June 5, 2012 • 12:00-1:30 pm Eastern

Presenters

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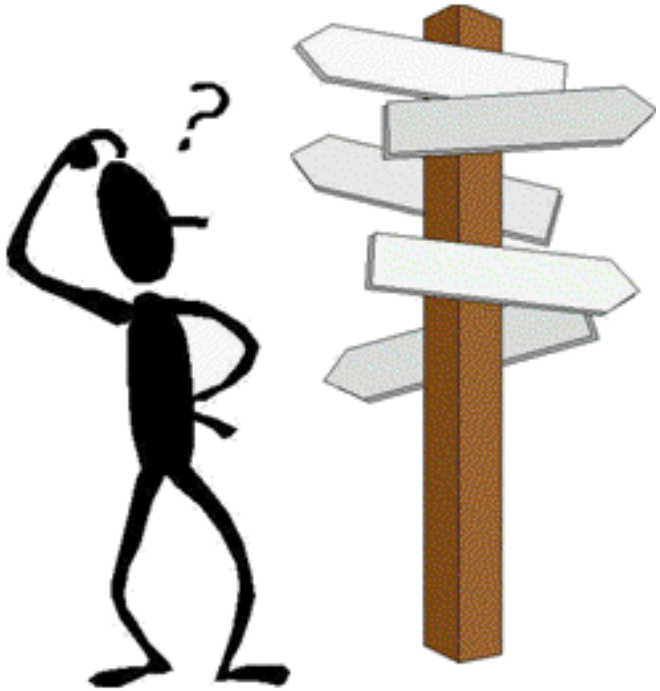
Agenda

- Why Develop a Compliance Plan?
- Elements of an Effective Compliance Program
- Self-Disclosure and the 60-Day Rule
- Compliance Concerns Surrounding Standard Transactions

WHY DEVELOP A COMPLIANCE PLAN?

Bill Mathias

Medicare and Medicaid Regulations Remain Incredibly Complex



"There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of matters addressed merely a passing phase."

— Chief Judge Ervin
United States Court of Appeals for the fourth Circuit in *Rehabilitation Association of Virginia v. Kozlowski*, 42 F. 3d 1444, 1450 (4th Circuit 1994)

Have You Seen OIG's Website Lately?

AMERICAN HEALTH LAWYERS ASSOCIATION

OIG

MOST WANTED FUGITIVES

REPORT FRAUD

Aggressive Enforcement

- Joint DOJ/OIG website www.stopmedicarefraud.gov
  - "A joint effort by HHS and the Department of Justice recovered a record $4 billion from fraudsters in FY2010."

Health Care Enforcement Climate

- DOJ False Claims Act Recoveries FY 2012
  - $4.9 billion in civil settlements and judgments in cases under the False Claims Act
- Health care fraud recoveries
  - $3 billion out of $4.9 billion total

Fighting Fraud is a Good Investment for the Government

- Government continues to view Fraud, Waste, and Abuse as a significant source of revenue
- The return-on-investment (ROI) for Health Care Fraud and Abuse Control (HCFAC) program
  - For the life of the program (since 1997), $5.4 returned for every $1.0 expended.
  - 3-year average (2010-2012), $7.9 returned for every $1.0 expended

Why Develop a Compliance Program?

- Federal Sentencing Guidelines
  - Must be an effective program to prevent and detect violations of the law.
- OIG Compliance Guidance
  - Started in 1998
  - Various provider types (hospital, home health, lab, billing company, DME, hospice, nursing facility, physicians, pharma manufacturers, etc.)
  - Voluntary guidance

Why Develop a Compliance Program?

- Federal and state certifications re compliance
- Expected by financial auditors, managed care payors, contracting providers, etc.

Why Develop a Compliance Program?

- Affordable Care Act (§ 6401)
  - Compliance plans to become mandatory as a condition of participation in Medicare and Medicaid
  - . . . but only after CMS promulgates implementing regulations to establish the core elements for mandatory compliance programs

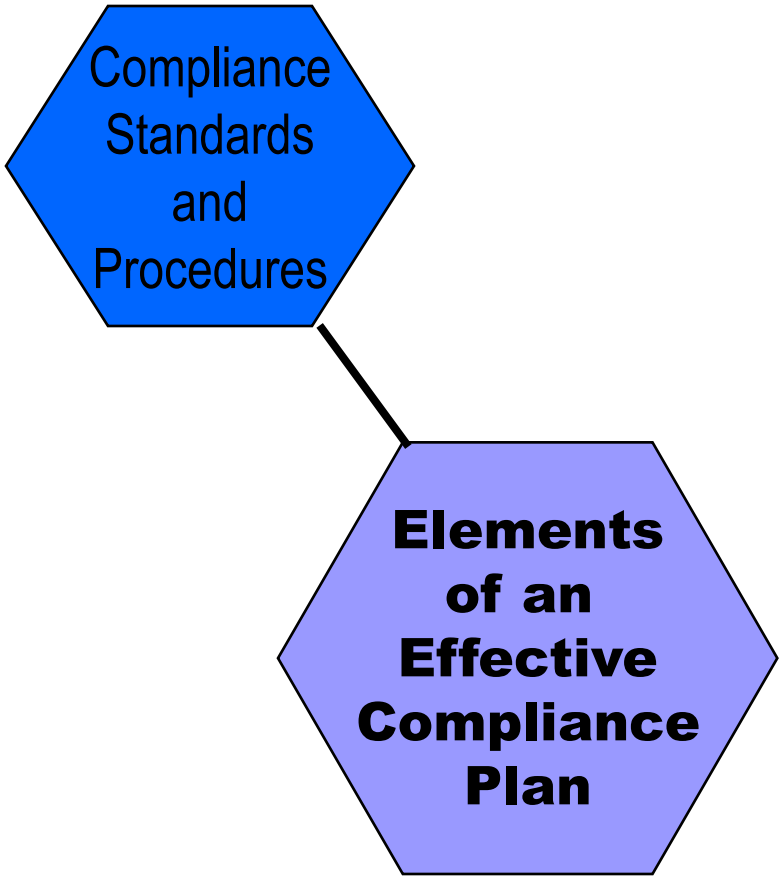
Why Develop a Compliance Program?

- In NYS, compliance programs are already mandatory for Medicaid providers claiming over $500,000 per year.

ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

Lynn Stansel


Compliance Standards and Procedures
Response and Prevention
Oversight Responsibilities
Elements of an Effective Compliance Plan
Enforcement and Discipline
Education and Training
Open Lines of Communication
Monitoring and Auditing


Compliance Standards and Procedures
Elements of an Effective Compliance Plan

Compliance Standards and Procedures (OIG)

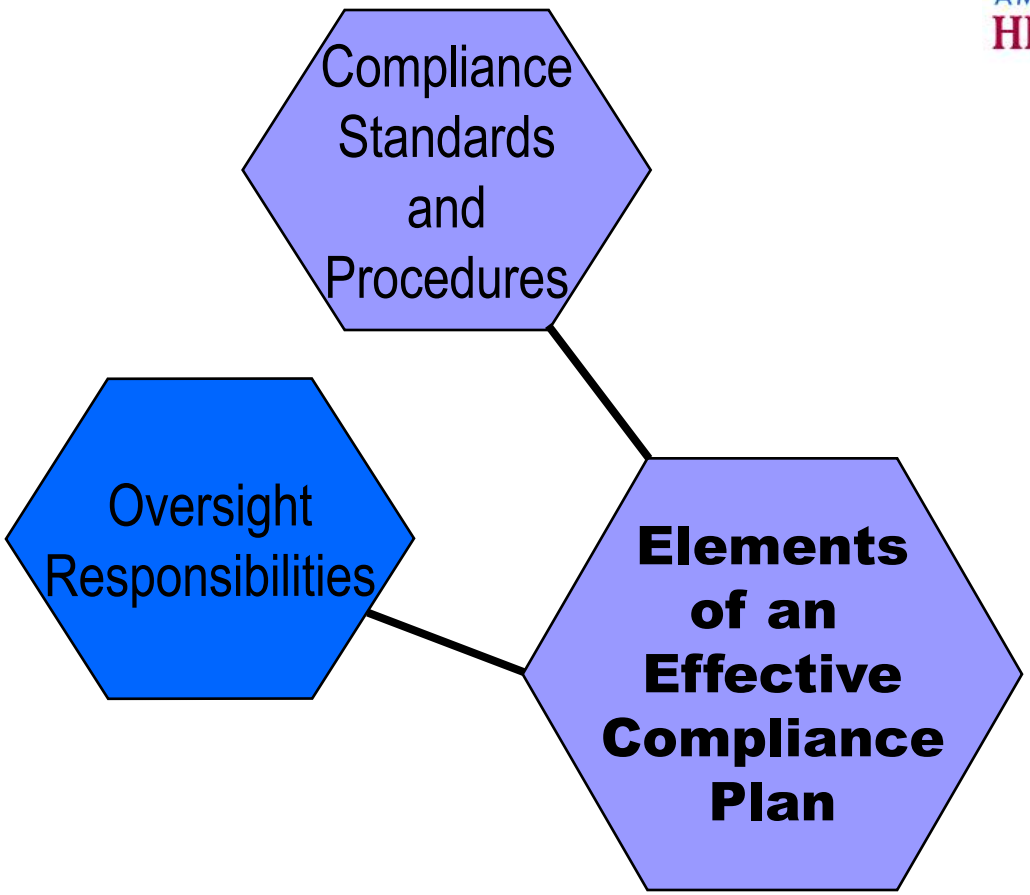
- Establish compliance standards and procedures that are reasonably capable of reducing the prospect of erroneous claims and fraudulent activity, while identifying any aberrant billing practices.
- Effective compliance standards will identify the organization's risk areas and establish internal controls to contain those risks.

Code of Conduct

- Concise summary of expected behaviors and commitment to ethical practices.
- Outline areas of focus. Examples: quality, HIPAA, conflicts of interest, billing integrity, HR, safeguarding assets, environmental safety, false claims.
- Specifically require employees to report concerns; tie into performance evaluations.

Other Documentation

- Develop compliance program charter.
  - Approved by governing body
  - Establish authority of compliance officer and describe reporting and communication lines
- Develop comprehensive manual of compliance-related policies
  - Ensure accessibility, internally and externally
  - Leverage all pertinent policies/processes in program


Compliance Standards and Procedures
Oversight Responsibilities
Elements of an Effective Compliance Plan

Oversight Responsibilities (OIG)

- The organization must designate one or more high-level individuals to oversee compliance activities, with access to senior leadership and the governing board.
- The organization must use due care not to put individuals who have demonstrated a propensity for violating the law into positions of substantial discretionary authority.

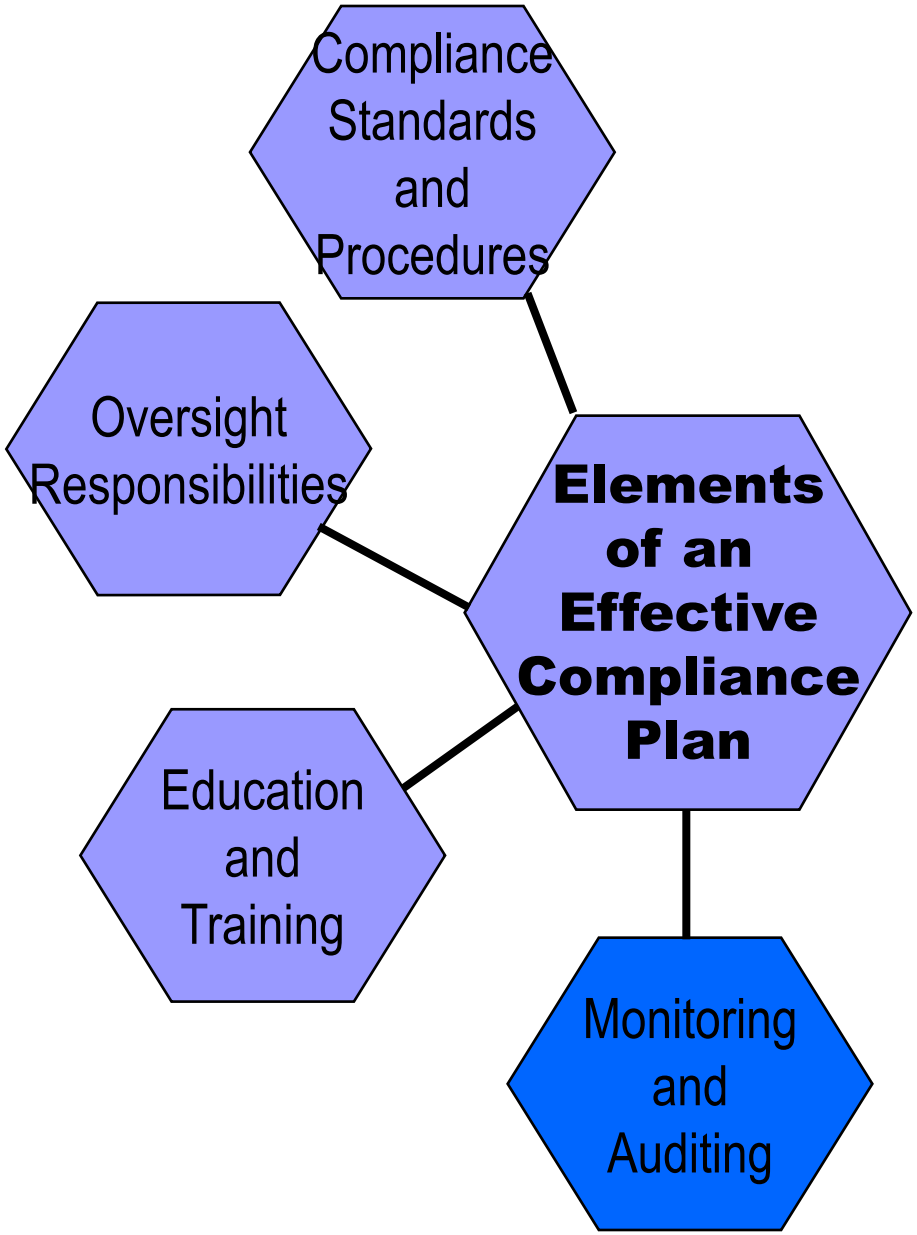
Effective Oversight Standards

- The compliance program should be adequately resourced and function effectively.
- Senior leadership and the governing board must exercise reasonable oversight of the program.
- Due diligence required in delegating authority and responsibility and in contracting.
- Federal and state Medicare/Medicaid exclusion list checks regularly performed.


Compliance Standards and Procedures
Oversight Responsibilities
Elements of an Effective Compliance Plan
Education and Training

Education and Training (OIG)

- The organization must communicate its standards and procedures to all employees, professional staff, and physicians in a meaningful and effective manner by implementing an effective training program that explains the requirements of the compliance program and applicable laws.
- Compliance training may include a variety of methodologies.[Training must meet Deficit Reduction Act (DRA) requirements re false claims/whistleblowing.]


Compliance Standards and Procedures
Oversight Responsibilities
Elements of an Effective Compliance Plan
Education and Training
Monitoring and Auditing

Monitoring and Auditing (OIG)

- The organization must evaluate the effectiveness of its compliance program on an ongoing basis by monitoring compliance with its standards and procedures and by reviewing its standards and procedures to ensure they are current and complete.
- A review of pending claims not yet submitted can establish a benchmark that will be used in ongoing reviews to chart the success of the organization's compliance efforts.

Monitoring/auditing Standards

- Develop detailed compliance work plan, based on risk assessments.
- Include consideration of federal and state oversight agency activities, especially the Office of Inspector General (OIG) workplan.
- Develop protocols re voluntary reporting and when to utilize attorney/client privilege.

Maintaining an “Effective” Program

- Organization should review compliance program periodically, since benefits dependent on whether deemed ‘effective”.
- Expectations for programs continue to rise; scalable to organization’s size and complexity, but cost beneficial to strive for “best practice” program.


Compliance Standards and Procedures
Oversight Responsibilities
Elements of an Effective Compliance Plan
Education and Training
Open Lines of Communication
Monitoring and Auditing

Open Lines of Communication(OIG)

- The organization must put in place an accessible system for reporting inappropriate activities and for communicating compliance questions and concerns.
- Standards and procedures must emphasize that failure to report erroneous or fraudulent conduct is a violation of the compliance program.
- Standards and procedures also must stress that no retaliation may be taken against individuals who in good faith report what reasonably appears to be misconduct or a violation of the compliance program.

Communications Standards

- Typically establish “helpline/hotline”. Important to document investigation and outcome, and develop metric reporting.
- Multiple laws address retaliation. Essential to conform policies and educate.
- If effective, significantly reduces whistleblower risk.


Compliance Standards and Procedures
Oversight Responsibilities
Elements of an Effective Compliance Plan
Enforcement and Discipline
Education and Training
Open Lines of Communication
Monitoring and Auditing

Enforcement and Discipline (OIG)

- The organization must enforce its compliance standards through consistent and appropriate disciplinary action.
- Disciplinary procedures should include, as appropriate, discipline of individuals who should have detected an offense but failed to do so.

Enforcement/Discipline Standards

- Biggest challenge is ensuring consistency for all levels within an organization.
- Develop protocols around compliance-related violations. Example: privacy breaches, non-compliant physician billing.
- Consider that documentation created may be utilized in disciplinary hearings, as well as government investigations.


Compliance Standards and Procedures
Response and Prevention
Oversight Responsibilities
Elements of an Effective Compliance Plan
Enforcement and Discipline
Education and Training
Open Lines of Communication
Monitoring and Auditing

Response and Prevention (OIG)

- If an compliance violation is detected, the organization should take all reasonable steps to respond appropriately to the violation
  - Take corrective action to rectify any harm resulting from the current offense
  - Prevent similar offenses from occurring in the future.

Response/Prevention Standards

- Overpayments identified must be repaid.
- Develop corrective action plans and follow through on implementation of recommendations.
- Utilize consultants/attorneys when appropriate, especially on specialized issues and decisions re sensitive reviews.

SELF-DISCLOSURE AND THE 60-DAY RULE

Bill Mathias

Why are Internal Investigations Important?

- Increasing promotion of self-identification and self-disclosure
- 60-day repayment of overpayments & potential FCA liability
- Enforcement remains aggressive
  - Federal Level
  - State Level
- Government view Fraud, Waste, and Abuse as a significant source of revenue

When Must You Investigate?

- Any time there is:
  - An allegation of a violation of law.
  - A suggestion of improper conduct.
  - A potential for an overpayment by the government.
  - A potential for a significant overpayment by a commercial insurer or other third-party payor.
  - A potential for whistleblower activity.

How Much Must You Investigate?

- Depends on the facts.
- Initially, need to investigate enough to gauge the credibility of the allegation.
  - Believable on its face
  - Documentary evidence exists
- Dollar amount of potential exposure impacts practical decisions regarding scope, depth, and personnel involved in investigation.

Who Should Investigate?

- Depends on the type of issue:
  - Human resources issues (such as sexual harassment or discrimination) – investigated by HR Department and/or employment counsel.
  - Other general issues (non-criminal in nature, unlikely to result in substantial civil liability) – initially investigated in-house.
    - Consider whether attorney-client privilege may be important? If so, involve counsel (in house or outside).

Who Should Investigate?

- Criminal issues or issues likely to result in significant civil liability (whistleblower situations, high dollar overpayments, systemic problems) – shouldn't be investigated without legal counsel.
  - Attorney-client privilege important – may want outside counsel involved to strengthen argument supporting attorney-client privilege.

Conduct Your Investigation

Results of Your Investigation

- No problem ⇨ Done!!!

- Problem ⇨ Fix it???

Fix The Problem

- Take corrective action
- Assess existing compliance process and policies to identify shortfalls
- Discipline responsible employees, as appropriate
- Add policies, procedures, or reporting layers as necessary to prevent reoccurrence

Now What?

- Need to discuss with client:
  - Whether the past conduct needs to be reported
  - If so, to whom?

Drivers of Disclosure

- Legal obligation to disclose
  - False Claims Act
    - Covers retention of overpayment
  - 60-day Repayment Rule
    - Return and disclosure of “identified” overpayments

60-Day Repayment Requirement

- §6402 of ACA requires reporting and repayment of overpayments within 60 days of identification
  - Effective March 23, 2010
  - What's "identification"?
- Violations actionable under FCA
- Proposed regulations
  - 77 Fed. Reg. 9,179 (Feb. 16, 2012)
  - 10-year look-back
- Final regulations are expected

Drivers of Disclosure

- Potential to avoid criminal liability
- Potential to minimize civil exposure.
- Potential to avoid Corporate Integrity Agreements.
- Potential to neutralize *qui tam* suits

Drivers of Disclosure

- Invites detailed scrutiny
- May encourage government to require additional investigation
- May result in penalties for conduct that would have remained undiscovered

Disclosure Calculus

- Balance legal obligations and business risks
  - If available, disclosure generally offers protections too significant to pass up
  - Useful for substantial violations of law
  - Leaves as an open question more minor or isolated violations – time + expense + minimum settlement may make minor disclosures prohibitively costly
  - Continuing focus on compliance programs, good faith cooperation, and prompt disclosure

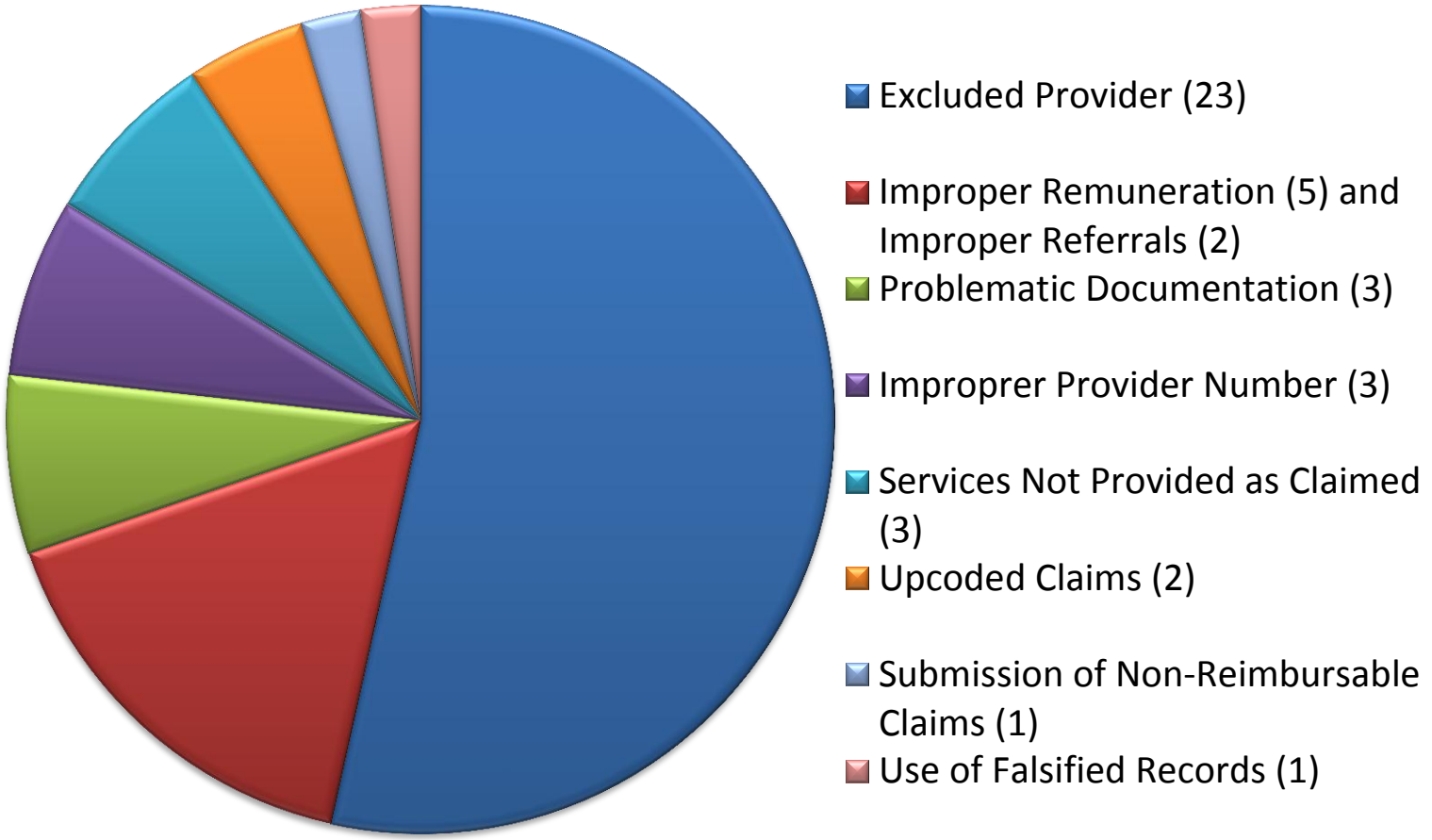
What Gets Disclosed Where?

- To OIG – only "potential fraud against the Federal health care programs, rather than merely an overpayment."
  - "Potential fraud" does not include Stark only violations – must be at least a "colorable" AKS violation
- To CMS – Stark only violation
- To Contractor – "merely an overpayment"
- To U.S. Attorney's Officer – depends
- To State – depends on state laws

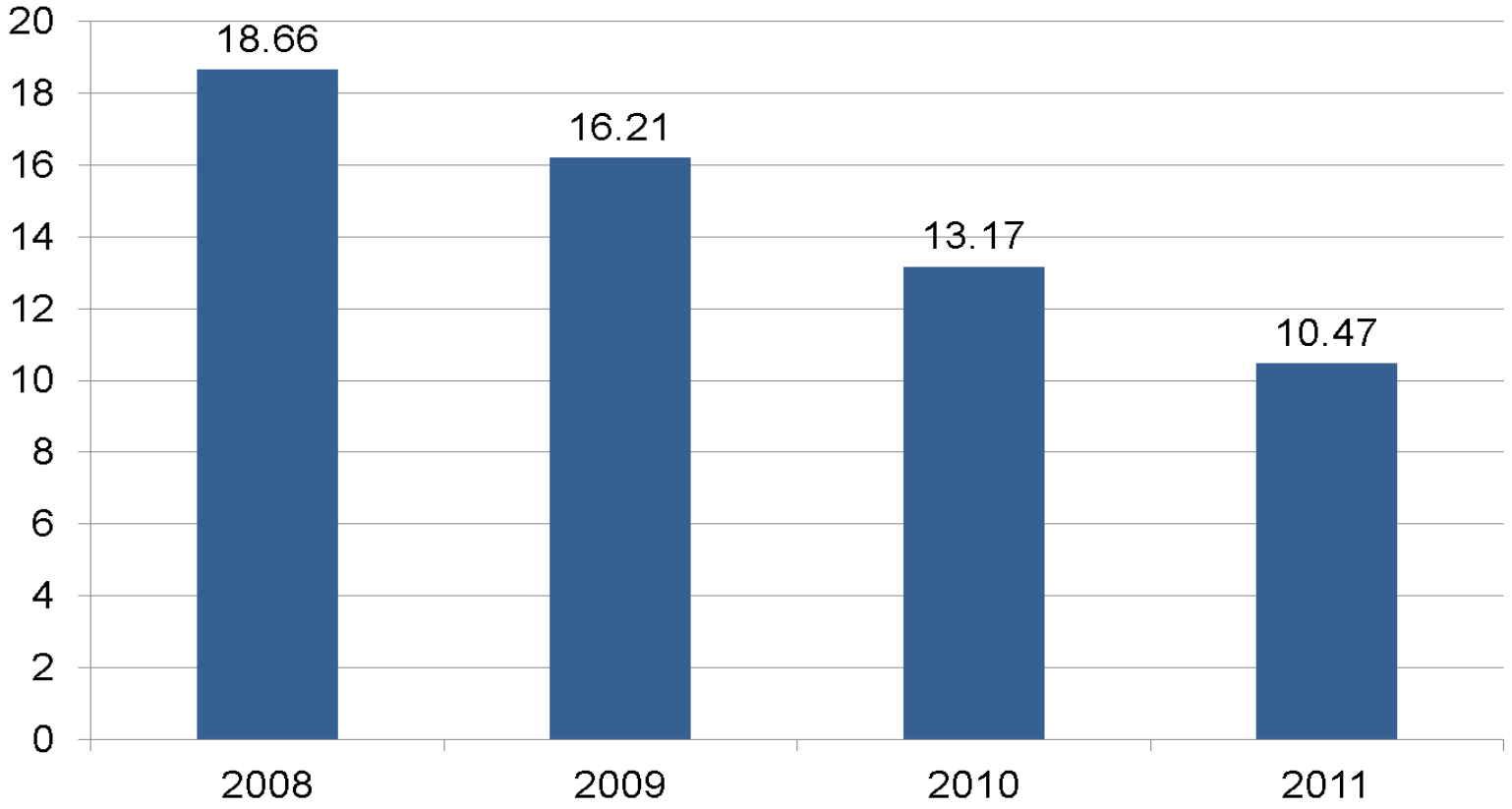
OIG Provider Self-Disclosure Protocol

- Updated April 17, 2013
- Replaces 1998 Self-Disclosure Protocol (SDP) and 3 Open Letters
- Establishes a process for health care providers to voluntarily identify, disclose, and resolve violations subject to OIG's civil money penalty (CMP) authority

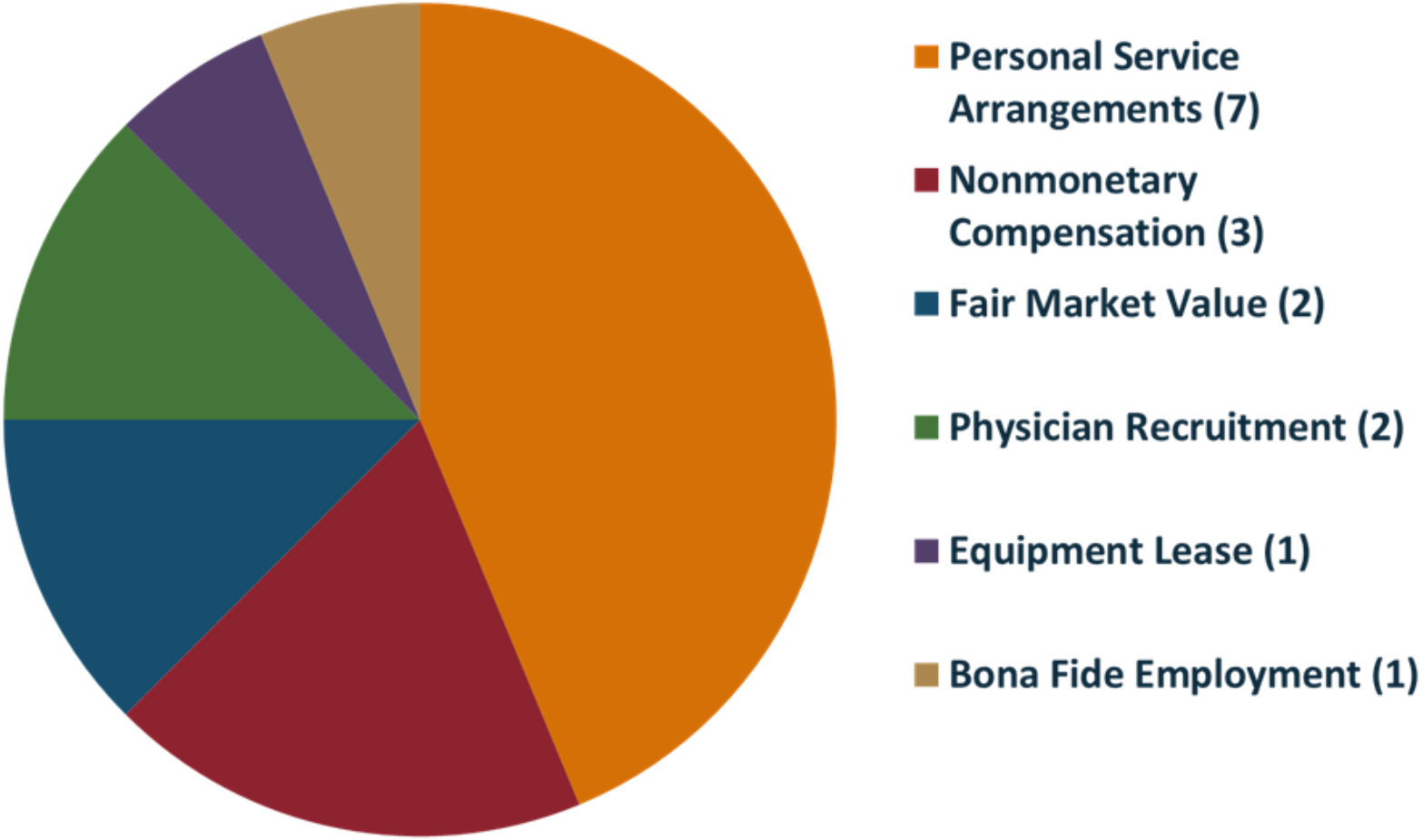
Breakdown of OIG Self-Disclosure Resolution



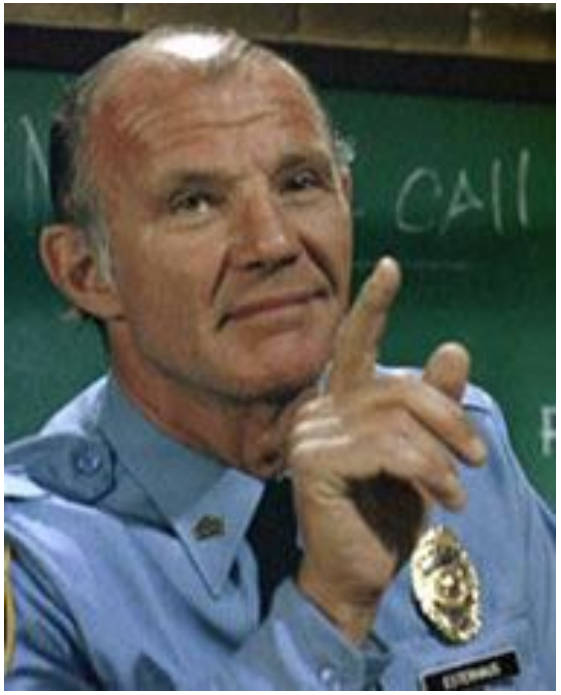
Average Length of Time in OIG Self-Disclosure Protocol (In Months)



Breakdown of CMS Settlement



Final Words of Advice



“Be careful out there”

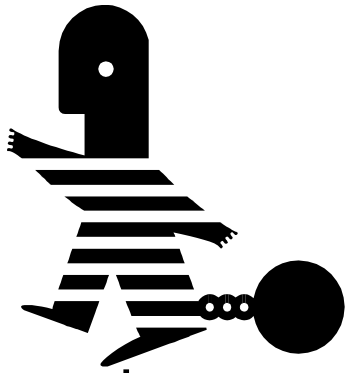
COMPLIANCE CONCERNS SURROUNDING STANDARD TRANSACTIONS

Matt Albers

Anti-Kick Back Statute (the “AKS”)

- Knowing and willful
- Solicitation, receipt, offer or payment
- Of remuneration
- Directly or indirectly, overtly or covertly, in cash or in kind
- In return for the referral of Federal health care program business, or
- To induce the referral of Federal health care program business

AKS - Penalties



- Violation of the AKS is a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both
- Conviction results in automatic exclusion from the Medicare and Medicaid programs
- Violations of the AKS are subject to Civil Monetary Penalties up to $50,000 and damages up to 3x the amount of the illegal kickback

Penalties

- HHS also exclusionary authority through administrative proceedings, without a criminal conviction
- Civil False Claims Act liability: Compliance with the AKS is a condition of payment under Medicare and other Federal health care programs
  - Mandatory penalties of between $5500 and $11,500 per claim
  - Mandatory treble damages; government takes the position that damages equal amount paid on “tainted claims”
  - Whistleblower *(qui tam)* actions

Elements of Stark Law Claim

- A physician;
- May not make a referral;
- Of a Designated Health Service (for which reimbursement from the federal government may be obtained);
- To an entity in which the physician (or a direct family member of the physician) has a financial interest;
- Unless the referral *or* the financial interest is "excepted" from the prohibition under the statute;
- **No Intent Requirement.**

Designated Health Services

- Clinical laboratory services;
- Physician therapy services;
- Occupational therapy services;
- Radiology services (including diagnostic nuclear medicine services and supplies, MRI, CAT Scans, and ultrasound);
- Radiation therapy services and supplies;
- Durable medical equipment and supplies;
- Parenteral and enteral nutrients, equipment and supplies;
- Prosthetics, orthotics, and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs; and
- Inpatient and outpatient hospital services.

Definition of "Referral" Under the Stark Law

- The request or establishment of a plan of care which includes the provision of DHS.
  - For services covered under Medicare Part B, the mere request by a physician for an item or service (including a consultation request) comprises a referral.
- Does not include services performed by the physician individually.

Financial Relationships – Two Types

- Ownership/Investment interests
  - Direct or indirect ownership or investment in an entity that provides DHS by a physician or an immediate family member of a physician.
- Compensation relationship
  - Any Any direct or indirect compensation relationship with a DHS provider, where there is an exchange of anything of value as compensation.

Stark Penalties

- Civil statute
  - $15,000 per violation
  - $100,000 per circumvention arrangement
  - $10,000 per day for failure to report financial relationships
  - Non-payment of item/service
  - Exclusion – minimum of five years
  - Potential loss of professional licensure/certification
- False Claims Act Crosswalk

Exceptions to the Stark Law

- Global
- Ownership Interest Exceptions
- Compensation Interest Exceptions
- Proposed Exceptions

Commonly-Used Stark Exceptions
42 C.F.R. §§411.350 – 411.361

- Office space and equipment leases
- Employment and independent contractor arrangements
- Physician recruitment (limits permissible non-compete and liquidated damages provisions) and retention
- Indirect compensation to physician
- Publicly-traded securities, mutual funds, and investment interests in specific types of providers
- E-prescribing and EHR items/services (hardware, software, and information technology and training services)

False Claims Act

- **31 U.S.C. §§ 3729-3731**
  - Civil War vintage (1863) – known as “Informer’s Act” or “Lincoln Laws”
  - Initially directed at procurement fraud and price gouging.
  - Became popular tool for combating fraud in 1986 when its scope greatly increased via statutory amendments.
  - Since 1986 over $17B recovered in health care cases.

False Claims Act Cont.

- Most potent of weapons against health care fraud and abuse.
  - Severe penalties
  - Bounty-hunter rewards
  - Broad scope

Federal False Claims Act – Prohibitions

- Prohibits the knowing submission of false claims or the use of a false record or statement for payment with government funds.
- Covers claims presented to any health care program funded in whole or in part by federal funds.
- “Knowing” includes actual knowledge, deliberate ignorance and reckless disregard for the truth or falsity of the information.
- Applies to individuals and corporate entities.

Federal False Claims Act – Penalties/Consequences

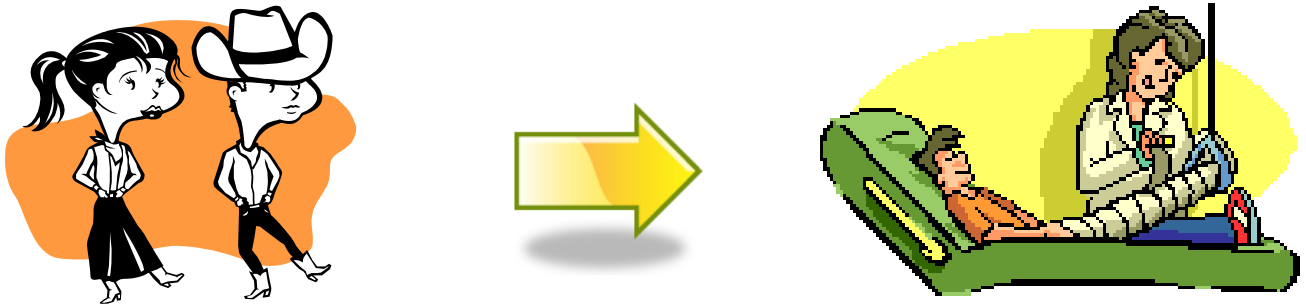
- Monetary penalties of between $5,500 and $11,000 **per claim,** plus 3 times the damages sustained by the government.
  - Possible exclusion of violators from participation in federal health care programs and from employment by entities receiving federal health care funds.
  - Professional license sanctions.
  - Loss of entity accreditation/certification.
- Example - $100,000 in reimbursement for 500 claims

Touchstones of Compliance

- Fair Market Value
- Bona Fide Services/Goods
- Written Agreement
- Arms-Length Negotiation
- “Set-in-Advance”
- No reference to “volume or value”

Scenario 1 - Medical Directorship (Facts)

- 75-bed Hickory Medical Center
- Located in/serves community of Hickory
- Hickory residents LOVE country line dancing
- Noted increase in number of orthopedic cases



- Dr. Fancy Bones is orthopedic surgeon in Hickory
- Booming business, she sends patients to Hickory Medical Center for services

Scenario 1 - Medical Directorship (Proposal)

- President of Hickory Medical Center excited to “align” Dr. Bones
- President asks Dr. Bones to become “Medical Director of Dance Injuries”
- No duties yet established, “We’ll work it out later.”
- Compensation will be $75,000 / year

Scenario 1 – Medical Directorship

Issues:

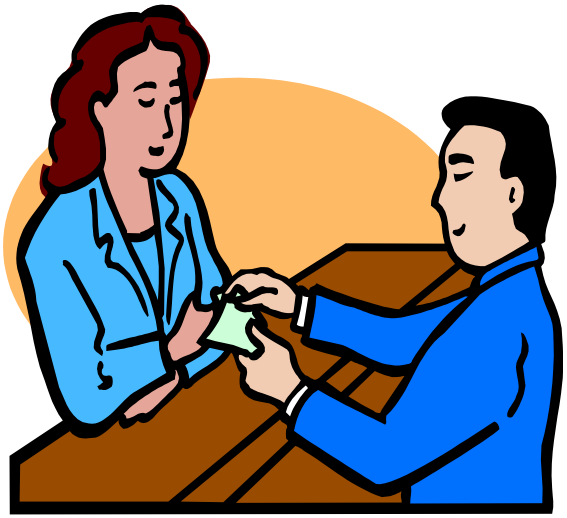
- Is the directorship bona fide?
- Stark Law applies
  (personal services exception)
- Anti-Kickback Law applies (intent of “alignment”)

Scenario 2 – Practice Acquisition (Facts)

- Academic Group wants to expand GI & Urology services
  - focus on surgical and oncology care
- Dr. Shome Colon & Dr. Ifix Bladder sole shareholders of 15-member "Private Group"
  - Specialize in Gastroenterology and Urology surg/onc care
  - "Major Presence" in Hickory area, offices near Aspen Medical Center (HMC's competitor)
  - Owns/leases equipment, space
  - Physicians privileged at Aspen

Scenario 2 – Practice Acquisition (Proposal)

- Private Group expects Academic Group to
  - Purchase / assume liabilities for equipment
  - Employ all Private Group physicians
  - Compensate Private Group for "good will value"



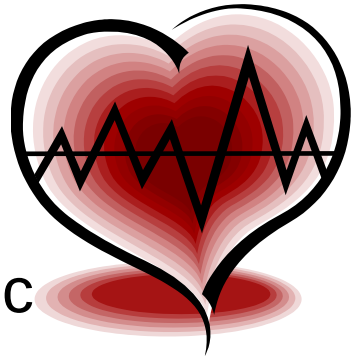
- Negotiations occur
  - Private Group's attorney (Mr. Nose Little) sets out purchase price
  - Mr. Little explains Private Group is expecting price to reflect *"value of increased procedural and patient volumes represented by acquisition"*

Scenario 2 – Practice Acquisition (Issues)

Fair Market Value:

- Can we pay for/assume the equipment contracts?
- Can we pay for/assume the space/office leases?
- Can we pay for “good will”?
- Can we recognize the “value” represented by their counsel?

Scenario 4 - Billing Issues (Facts)



- Physician Group employs Dr. Olive Echos
- Dr. Echos staffs hospital-based cardiology clinic (5 miles away from main hospital)
- Physician Group billing manager (Codezar Kool) participated in obtaining “provider-based” designation” for this hospital clinic
  - Hospital bills facility fee for patient at clinic
  - Physician Group bills professional fee for patient at clinic
- Dr. Olive Echos renders similar services at this hospital clinic and at her other physician office

Scenario 4 - Billing Issues (Situation)

- Medicare requires “place of service” (POS) code for Dr. Echos’ services
- POS 11 is for Physician’s office
  - Medicare reimburses medium-level visit with POS 11 at $57.96
- POS 22 is for Outpatient hospital site
  - Medicare reimburses medium-level visit with POS 22 at $41.31
- Codezar decides since services are similar, bill all services with POS 11
  - Submits 1,000 claims (HCPCS Code 99213) to Medicare
  - Each claim is for medically necessary services, performed by Dr. Echos in compliance with all other laws/regulations

Scenario 4 - Billing Issues (Getting Bad)

- Dr. Echos' services at hospital clinic should have been billed with POS 22
- Wrong POS resulted in $16.65 overpayment for each encounter ($57.96 - $41.31 = $16.65)
- Need refund and rebill with POS 22
- Net <u>reduction</u> in revenue is **$16,650**
  - Presumes all claims can be rebilled

Scenario 4 - Billing Issues (Much Worse)

- Codezar knew clinic is provider-based – wrong to bill as doctor office space
- False Claims Act – potential violation
  - 3 times amount billed for each claim
  - $57.96 x 3 x 1,000 = $173,880
- Fine of $11,000 per claim
- $11,000 x 1,000 = $11,000,000
- Total potential liability for Physician Group: **$11,173,880**

QUESTIONS?