

PENALTY

**Fined
not more than \$25,000 or
imprisoned for not more
than
five (5) years
or both**

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**1985 - TESTING SCOPE OF CONDUCT
PROHIBITED BY ANTI-KICKBACK STATUTE**


UNITED STATES V. GREBER
THE "ONE PURPOSE" RULE

If one purpose of the remuneration is to induce referrals, the statute is violated, even if the payment was also intended to compensate for professional services.

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WHAT IS REMUNERATION?

- Extremely Broad Scope, whether in cash or in kind, and whether made directly or indirectly, including:
 - Kickbacks;
 - Bribes;
 - Rebates;
 - Gifts;
 - Above or below market rent or lease payments;
 - Discounts;
 - Furnishing of supplies, services or equipment either free, above or below market;
 - Above or below market credit arrangements; and
 - Waivers of payments due.



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SAFE HARBOR PROVISIONS
42 C.F.R. 1001.952

- If entity/person satisfies requirements of one or more of the following safe harbor provisions, otherwise suspect payment practices are **NOT** subject to criminal prosecution –
 - Investment interests for publicly traded companies and smaller entities;
 - Space and equipment rental agreements;
 - Personal services and management contracts;
 - Sale of a medical practice;
 - Employees;
 - Group purchasing organizations and Discounts;
 - Waiver of beneficiary co-insurance and deductible amounts;
 - Warranties; and
 - Health Plan/Managed care.

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SAFE HARBOR PROVISIONS
42 C.F.R. 1001

- Investments in Ambulatory Surgical Centers (ASCs)
- Joint Ventures in Underserved Areas
- Practitioner Recruitment in Underserved Areas
- Sales of Physician Practices to Hospitals in Underserved Areas
- Subsidies for Obstetrical Malpractice Insurance in Underserved Areas
- Investments in Group Practices
- Specialty Referral Arrangements Between Providers
- Cooperative Hospital Services Organization

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SAFE HARBOR EXAMPLE: PERSONAL SERVICES AND MANAGEMENT CONTRACTS

- Written agreement signed by parties.
- Term of at least one year.
- Agreement must specify *aggregate payment* and such payment must be set in *advance*.
- Compensation must be *reasonable, fair market value* and determined through *arm's length negotiations*.
- Must set exact services required to be performed.
- Compensation must not be determined in manner that takes into account volume or value of referrals.
- All arrangements must be in ONE contract. Cannot have multiple overlapping contracts to circumvent the one-year rule.
- The arrangement must serve a commercially reasonable business purpose.

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**PERSONAL SERVICES AND
MANAGEMENT CONTRACTS**

If Agreement does not contemplate full-time services, it must also specify:

- > The *exact* schedule of intervals;
- > Their *precise* length; and
- > The *exact* charge for such intervals.

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Stark Act
42 U.S.C. 1395nn

- The Stark II Act prohibits a physician from making a **Referral**
 - > to an **Entity**
 - > for the furnishing of a **Designated Health Service**
 - > for which payment may be made under Medicare or Medicaid
 - > if the physician (or an immediate family member)
 - > has a **Financial Relationship** with the entity

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**Proof of
Intent is *Not*
Required**

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Penalty

Denial of payment or refund; civil money penalties (up to \$100,000) and exclusions from federal and state programs for improper claims or schemes

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Captain IntegritySM

Doctor Williams, I believe we can get around the Stark Act by contracting with your wife.

Doesn't the Stark Act apply to family members as well?

A physician cannot refer a patient for designated health services to an entity in which they have a financial interest. Under the Stark Act, "physician" includes family members such as Dr. Williams' wife.

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What is a Referral?

A referral includes:



- Request for an item or a service by a physician
- Request by physician for consultation with another physician, and any tests or procedures the other physician orders, performs or supervises
- Request for or establishment of plan of care that includes provision of designated health services

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What is a Referral?

- A **referral** is not a DHS personally performed by a physician
- A referral does not include a request by:
 - **Pathologists** for clinical diagnostic laboratory tests and pathological examination services
 - **Radiologists** for diagnostic radiology services (professional and technical)
 - **Radiation Oncologists** for Radiation Therapy
- If the request for such additional services results from a consultation initiated by another physician


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Designated Health Services



- **Designated Health Services** include:
 - Clinical laboratory services;
 - Physical therapy and occupational therapy services;
 - Radiology or other diagnostic services (including MRI, CAT scans);
 - Radiation therapy services;
 - Durable medical equipment;
 - Parental and enteral nutrients, equipment and supplies;
 - Prosthetics, orthotics and prosthetic devices;
 - Home health services;
 - Outpatient prescription drugs; and
 - Inpatient and outpatient hospital services (encompassing almost every type of medical procedure).
- **Note:** Ambulatory Surgery Centers services are **not DHS!**


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What is a DHS Entity?

- Entity that *bill for DHS service*
- Entity that *performs service that is billed as DHS*
 - “Perform” is given common meaning


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What Is a Financial Relationship?

- A **Financial Relationship** includes:
 - **Ownership** interests
 - Through equity, debt , compensation or other means; and
 - **Compensation** arrangements
 - Includes virtually any form of direct or indirect **remuneration** (i.e., personal service contracts, medical directorships, lease agreements, consulting arrangements, medical service provider arrangements)

What Is a Financial Relationship?

Remuneration is defined (42 CFR§ 411.351) as “any payment **or other benefit** made directly or indirectly, overtly or covertly, in cash or **in kind**”





Nature of Exceptions

If Financial Relationship exists with an Entity, and patients are being Referred for Designated Health Service, then activity must either comply with an exception or the activity is illegal





Exceptions

- Permitted **Ownership** and Compensation Arrangements:
 - Physician Services
 - In-office Ancillary Services
 - Services to Members of Prepaid Health Plans
 - Academic Medical Centers
 - Implants Furnished by ASC
 - Dialysis-related Drugs Furnished by End Stage Renal Disease Facility
 - Preventative Screening Tests, Immunizations and Vaccines
 - Eyeglasses and Contact Lenses Following Cataract Surgery
 - Intra-family Rural Referrals


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Exceptions

- Permitted **Ownership** Interests:
 - Publicly-traded securities
 - Mutual Fund Investment
 - Rural Provider (75% of DHS to Rural Residents)
 - Hospitals in Puerto Rico
 - Hospital Ownership (whole, not department or floor)


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Exceptions



- Permitted **Compensation** Arrangements:
 - Rental of Office Space
 - Rental of Equipment
 - Employment Relationships
 - Personal Service Arrangement
 - Physician Recruitment
 - Isolated Transactions
 - Services Unrelated to Provision of Designated Health Services
 - Hospital-affiliated Group Practice Arrangements
 - Fair Market Value Payments Made by Physicians for Items and Services (i.e., clinical laboratory services)


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Exceptions



- Permitted **Compensation** Arrangements:
 - Charitable Donations by Physician
 - Non-monetary Compensation (Benefits) up to \$407 Per Year
 - Fair Market Value Compensation
 - Medical Staff Incidental Benefits
 - Risk-sharing Arrangements (i.e., withholds, bonuses, risk pools)
 - Compliance Training
 - Indirect Compensation Arrangements
 - Referral Services


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Exceptions



- Permitted **Compensation** Arrangements:
 - Obstetrical Malpractice Insurance Subsidies
 - Professional Courtesy
 - Retention Payments in Underserved Areas
 - Community-wide Health Information Systems
 - Electronic Prescribing Items and Services
 - Electronic Health Records Items and Services

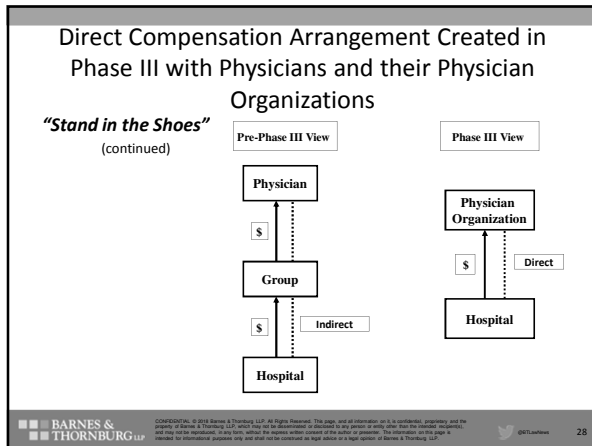



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Direct Compensation Arrangement Created in Phase III with Physicians and their Physician Organizations

- **“Stand in the Shoes”**
 - 42 CFR 411.354 (c) (ii) - A physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization. In such situations, for purposes of this section, the physician is deemed to stand in the shoes of the physician organization


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Personal Service Arrangement Exception

(Applies to *Compensation* Relationships)

- Remuneration paid under personal service arrangement is not prohibited compensation arrangement if:
 - Arrangement is set out in **writing**, signed by parties and specifies services covered by arrangement
 - Arrangement **covers all services** to be provided by physician to entity
 - This condition is met if contract:
 - References all other arrangements; or
 - References **master list** of contracts that is maintained with historical record of all arrangements
 - Term for at least **one year**

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Personal Service Arrangement Exception

(Applies To *Ownership* and *Compensation* Relationship)

- Services are **reasonable** and **necessary**;
- Compensation is set in **advance**, does not exceed **FMV**, is **reasonable** and determined through **arm's length negotiations**, and is not determined in manner which takes into account volume or value of referrals between parties

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**Personal Service
Arrangement Exception**
(Applies To *Ownership* and *Compensation* Relationship)

Hold over month-to-month following a term of at least one year, assuming all other provisions of the exception are met, continuing on a month-to-month basis for up to 6 months as long as the terms during the hold over period are fair market value will meet the personal service arrangement exception

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The Civil False Claims Act


31 U.S.C. § 3729, the False Claims Act (“FCA”) sets forth seven bases for liability. The most common ones are:

- Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment
- Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid

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The Civil False Claims Act

- Conspiring to defraud the Government by getting a false or fraudulent claim allowed or paid
- Knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government



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Elements of an FCA Offense

- The Defendant must:
 - Submit a claim (or cause a claim to be submitted)
 - To the Government
 - That is false or fraudulent
 - Knowing of its falsity
 - Seeking payment from the Federal treasury
 - Damages (maybe)
 - **Reverse False Claim:** Reimbursement received inappropriately and knowingly decide to keep reimbursement and do not repay or process claims

Knowing & Knowingly

- No proof or specific intent to defraud is required
- The Government need only show person:
 - Had **“actual knowledge of the information”**; or
 - Person acted in **“deliberate ignorance”** of the truth or falsity of the information; or
 - Person acted in **“reckless disregard”** of the truth or falsity of the information

PENALTIES

- Civil penalty from \$5,500 to \$11,500 per false claim
- Three times the amount of damages which the Government sustained (meaning 3x reimbursement received).

Qui Tam Actions & Government Intervention

- A private person (“Relator”) may bring a False Claim Act action under the *qui tam* provisions of the FCA – The Whistleblower
- Government may intervene in a suit brought by Relator
- Relationship between Relator and Government
 - Collaborators in recovery of money

Health Care Reform and False Claims Act Amendments

- Liability for overpayments and failure to return a known overpayment within 60 days from identification (after “reasonable inquiry” – meaning **reasonable diligence** and utilization of **reasonable resources**) – return of known overpayment an affirmative and express obligation.
- Claims for payment from government contractors, grantees or other recipients if money is spent on government’s behalf or to advance a government program or interest

FCA Statistics

- If the government intervenes and obtains recovery, the Relator receives between **15% and 25% of the proceeds**
- Since 1986, of all the *qui tam* actions filed, the average yearly intervention rate has been about 25% (approximately 300-400 cases)

FCA Statistics

- Recoveries have increased (higher penalties and publicity)
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including initiation, investigation, testimony for, or assistance in the action
- Separate cause of action under False Claims Act for “retaliation” against an individual engaged in “protected activity.”

Trends in Individual Liability

Historical case resolution model:

1. Corporation plea/False Claims Act settlement
2. Corporate integrity agreement with possible exclusion of an irrelevant subsidiary
3. No personal liability or exclusion.



Trends in Individual Liability

- The Department of Justice in October, 2010, announced intention to pursue individuals.
- Lew Morris, from the Office of Inspector General, in February 2, 2011, Congressional testimony:
 - Notes large providers may consider settlement “cost of doing business”
- Wants to “alter the cost-benefit calculus” of corporate executives who run companies that settle
- Express intention to increase individual exclusions

Trends in Individual Liability

- Synthes/Norian: October 2010 Corporate plea to felony off-label marketing/improper clinical trials
 - \$23.5 million settlement amount
 - Divestiture required
 - Corporate Integrity Agreement
 - Four executives plead guilty to misdemeanor's with jail sentences

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Trends in Individual Liability

- Stryker Biotech, LLC settlement January 30, 2012:
 - Corporate misdemeanor plea with \$15 million fine
 - Charges still pending against Chief Executive Officer, dropped against other individuals
- Wellcare Indictment:
 - Indictment of five former executives of Medicaid HMO, including former CEO, CFO and GC

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Trends in Individual Liability


- United States vs. Borrasi (Eleventh Cir, May 4, 2011)
 - Alleged conspiracy between physician and two executives of inpatient psychiatric hospital to compensate Dr. Borrasi and his group in exchange for increase Medicare referrals.
 - Defense was that payments were for part-time employment relationships for administrative services.
 - Testimony at trial included "false titles," "faux job descriptions," "false time sheets." Physicians did not perform any of the administrative duties.
 - Criminal conviction of physician and CEO with 72 month jail sentence.


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Compliance Program Recommendations

- **Benefits of compliance program:**
 - Establish effective controls
 - Ethical environmental
 - Identify and Prevent Illegal and Unethical Conduct
 - React quickly to employees' compliance concerns
 - Improve quality, efficiency, and consistency of patient care
 - Centralized distribution of healthcare statutes, regulations and other program directives
 - Encourage employees to report potential problems internally
 - Minimize risk under Anti-Kickback Statute and False Claims Act








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Seven Elements

- 1) Written standard of conduct and policies and procedures
- 2) Designation of compliance officer and compliance committee
- 3) Regular and effective education and training programs
- 4) Creation of reporting system, including hotline
- 5) Audit and monitoring
- 6) Development of appropriate disciplinary actions to enforce standards and policies and procedures
- 7) Establish policies that direct prompt and proper response to detected offenses, including initiation of appropriate corrective actions






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1. Written Policies and Procedures

A) Standard of Conduct

- Articulate organizations commitment to comply with all federal, state and private insurer standards
- Establish clear expectations for business conduct
- Easy to understand (including Spanish, if applicable)
- Distributed to all employees and contractors





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1. Written Policies and Procedures

B) Risk Areas

- Unlawful, Unethical or Unprofessional Conduct
- Underutilization
- Falsified medical records or plans of care
- Untimely and/or forged physician certifications
- Inadequate or incomplete services rendered by the Interdisciplinary Group
- Providing incentives to actual or potential referral sources (i.e., physicians, and patients)
- Improper relinquishment of core services to others including, volunteers and privately paid professionals
- Billing for higher level of care than reasonable and necessary



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1. Written Policies and Procedures

B) Risk Areas (Cont.)

- Knowingly billing for inadequate or substandard care
- False dating of amendments to medical records
- Improper patient solicitation such as “patient charting”
- Improper billing through misuse of provider certification numbers
- Failure to adhere to licensing requirements and Medicare Conditions of Participation
- Failure to repay known overpayments
- Financial arrangements with referral sources (i.e., physicians)
- Real Estate



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1. Written Policies and Procedures

C) Anti-Kickback Statute/Self Referral (Stark)

- All financial arrangements between organization and referral sources (physicians, hospitals and nursing homes) should be evaluated to ensure that all payments made are **fair market value** and not intended to induce referrals.
- Organization should not offer gifts, free services or other incentives to patients and other referral sources for the purpose of inducing referrals (gifts to beneficiaries that are valued \$10 or less per gift not to exceed \$50 annually should be acceptable). *OIG Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries, August 2002.*

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1. Written Policies and Procedures

C) Anti-Kickback Statute/Self Referral (Stark) *(Cont.)*

- Establish approval process for all financial arrangements with referral sources.
- Non-Monetary Compensation (\$407 annually [CY 2018])
- Medical Staff Incidental Benefits (\$34 per benefit [CY 2018])

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Captain IntegritySM

Dr. Jones, I have ten Super Bowl tickets for you!

Thanks, but I don't think I can accept.

Why, are you busy?

No. I think there will be a Stark Act issue if I accept gifts from hospitals.

Dr. Jones is right! Gifts have to be tracked and are limited to \$373* per physician.

* Increases each year

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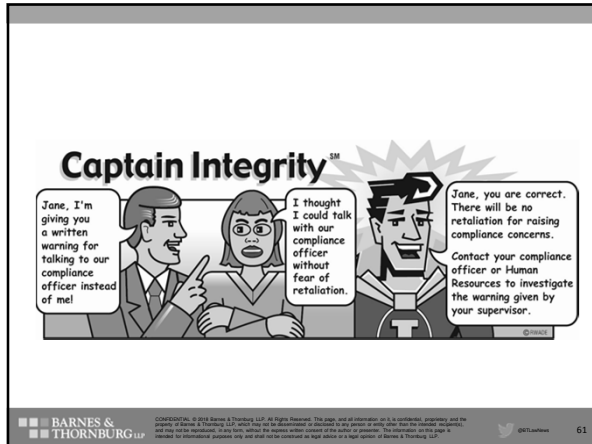
1. Written Policies and Procedures

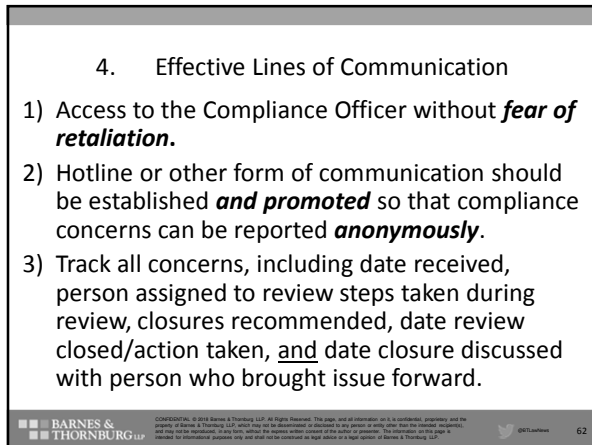
D) Retention of Records

- The organization's providers must retain, in compliance with all laws:
 - Medical records
 - Records necessary to protect the integrity of the organization's compliance process and the effectiveness of the Compliance Program

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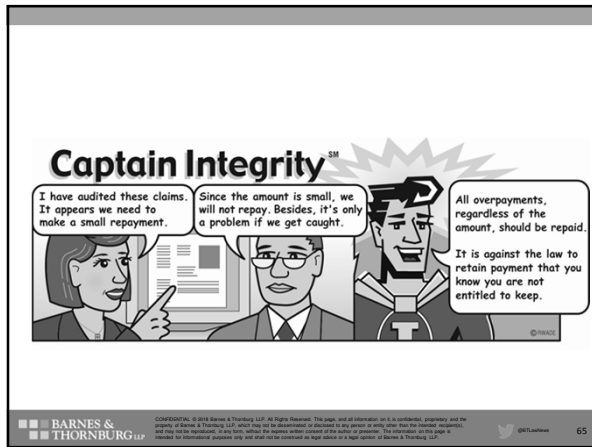




5. Auditing and Monitoring



- Organization should develop an annual auditing program. High risk areas should be reviewed.
- Monitoring includes periodic evaluation of safeguards implemented based upon prior audits and reviewing of high risk areas to determine if significant variations from the baseline exists.
- Auditing and monitoring activities could be conducted by either internal or external reviewers.



6. Enforcing Standards Through Disciplinary Guidelines

Disciplinary standards should be established for compliance infractions up to and including possible termination. Disciplinary guidelines should be enforced equally regardless where the employee is in the entities organizational chart.



7. Responding to Detected Offenses and Developing Corrective Action Initiatives

- **Billing Errors.** Use normal repayment channels if possible. Repayments should be made *within 60 days of determining* an overpayment exists.
- **Inappropriate Financial Inducements.** Discovered inappropriate financial inducements should be reported to the Centers for Medicare and Medicaid Services (Stark Act Anti-Referral), Department of Justice or the Office of Inspector General (Anti-Kickback Statute)

Compliance Effectiveness


- Organizations should periodically test the effectiveness of their Compliance Program. Outside consultants may be advisable so that review is independent and objective.
- It is ALL ABOUT THE CULTURE!

Effective Pointers

- Brand Identify Program – See “White Paper”
See: <http://captainintegrity.com/branding.php>
- Actively Promote Reporting Process
- C-Suite must be enthusiastic supporters
- “Iron fist” with “velvet glove” 
- Don't be “Chicken Little” 
- Control your tone and actions
- Sometimes issue can only be resolved effectively using outside resources (i.e., lawyer, consultant, auditor)
- Read industry periodicals (i.e., Report on Medicare Compliance)


Effective Pointers

- Attend educational conferences (in-person or webinars)
- Simplify issues as much as possible so people “get it”
- Back-up position with references/examples
- Review OIG Work Plan annually
- Assure people that the source of compliance problems usually stem from either i) Lack of Training/Education, or ii) Lack of Resources
- Understand the difference between i) Personal Ethics, and ii) Corporate Compliance/Ethics.
- Be operationally sensitive
- Use Compliance Committee and hold members accountable



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Effective Pointers

- Work collaboratively with all Departments, especially HR and Finance
- There is no such thing as a “Risk Free” healthcare operations
- Understand that Compliance is a stressful role
- Maintain files on all internal reviews and audits
- High risk compliants/internal reviews should be heavily documented
- Watch out for your personal reputation
- Know when to use legal counsel
- Watch for Conflicts of Interests
- Test compliance safeguards
- Fair Market Value is Paramount


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Recent Cases, Settlements, and Investigations


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Beth Israel Deaconess Medical Center

(Boston)
July 2013

- BIDMC paid \$5.3M to settle allegations by the federal government that it overcharged the Medicare program by admitting patients as inpatients who should have been treated as outpatients.
- BIDMC continues to defend the admissions as medically necessary and appropriate because physicians had concluded that the patients should be admitted as inpatients.

St. Vincent Healthcare

(Montana)
May 1, 2013

- ARRANGEMENTS BASED ON THE VALUE OR VOLUME OF REFERRALS
- St. Vincent Healthcare settled allegations related to physician incentive payments thought to have violated the Stark Law. St. Vincent Healthcare settled the matter for nearly \$4 million.
- The OIG alleged that two facilities in Montana paid physicians incentive compensation that took into account the value or volume of their referrals by including designated health services in the formula for calculating the physician incentive payments.

Imagimed LLC

August 2013

- False claim allegation based on lack of "direct" supervision for MRI scans performed with contrast dye.
- Additional allegations of violations of the fraud and abuse laws because the MRI center billed for services referred to it by physicians with whom it had improper financial relationships.
- Both Stark Law and Anti-kickback Statute violations were alleged.

Deming Hospital Corporation
November 2013

- Failure to comply with CLIA standards is a violation of a *condition of participation* and not a violation of a *condition of payment*.
- False Claims Act complaint dismissed.

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Intermountain Health Care
(Utah)

- NONCOMPLIANT EMPLOYMENT CONTACTS AND LEASE ARRANGEMENTS
- In April 2013, Intermountain settled allegations regarding noncompliant compensation arrangements, employment contracts, and lease arrangements which were alleged to have violated the Stark Law.
- Intermountain settled for \$25 million
- The alleged relationships included 209 physicians that were either employed or contracted with. In particular, the government alleged that employed physicians received bonuses based upon the value of their referrals. Also alleged was the improper lease arrangements with referring physicians.
- This settlement resulted from a self-disclosure to the government.

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Questions 

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