OVERVIEW OF HEALTH CARE FRAUD ENFORCEMENT

- Criminal Statutes Specifically Relating to Health Care Fraud (established by HIPAA)
  - Health Care Fraud [18 U.S.C. § 1347]
  - Theft or Embezzlement in Connection with Health Care [18 U.S.C. § 669]
“HIPAA” CRIME FOR HEALTH CARE FRAUD
18 U.S.C. § 1347

- Whoever knowingly and willfully executes, or attempts to execute a scheme or artifice —
  1) to defraud any health care benefit program; or
  2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program.

- In connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both.

ADDITIONAL “HIPAA” CRIME OF THEFT OR EMBEZZLEMENT IN CONNECTION WITH HEALTH CARE SERVICES
18 U.S.C. § 669

Whoever knowingly and willfully embezzles, steals, or otherwise without authority converts to the use of any person other than the rightful owner, or intentionally misapplies any of the moneys, funds, securities, premiums, credits, property, or other assets of a health care benefit program, shall be fined under this title or imprisoned not more than 10 years, or both.
"HIPPA" CRIME FOR SUBMITTING FALSE STATEMENTS RELATING TO HEALTH CARE MATTERS 18 U.S.C. § 1035

- Whoever, in any matter involving a health care benefit program, knowingly and willfully –
  1) Falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or
  2) Make any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 5 years or both.

- Court ruled that falsity through concealment exists where disclosure of the concealed information is required by statute, regulation or government forms for reimbursement.

OBSTRUCTION OF CRIMINAL INVESTIGATION OF HEALTH CARE OFFENSE 18 U.S.C. § 1518

a) Whoever willfully prevents, obstructs, misleads, delays or attempts to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a Federal health care offense to a criminal investigator shall be fined under this title or imprisoned not more than 5 years; or both.

b) As used in this section the term "criminal investigator" means any individual duly authorized by a department, agency, or armed force of the United States to conduct or engage in investigations for prosecutions for violations of health care offenses.
CONSPIRACY
18 U.S.C. § 371

- A Conspiracy or Agreement to Commit an Illegal Act is a Separate Crime
- Two or More, Conspired (agreed) to Commit An Offense and One or More Individuals Committed An Act to Advance the Object of the Conspiracy
- Agreement to Commit a Crime Can Be Inferred From Circumstantial Evidence and One Act Furthering Conspiracy is Sufficient for Culpability

AIDING AND ABETTING
18 U.S.C. § 2

- Anyone (i.e. consultant) who aids, abets, counsels, commands, induces or procures the commission of a Federal offense is culpable as if he or she directly committed the crime
- Aiding and abetting can be established if an individual associates with a venture, participates to bring it about and seeks by actions to make the venture succeed
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

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
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)

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

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
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).

Approximately $3 billion in health care FCA recoveries in FY '05 were from whistleblowers.

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.

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**I. THE ANTI-KICKBACK STATUTE**

- 42 USC § 1320a-7b(b)(2)
  
  It is unlawful to knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person - -

  a) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

  b) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.
THE ANTI-KICKBACK STATUTE

- What it all means? – Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal health care program

- 42 states and D.C. have enacted their own anti-kickback statutes

ELEMENTS

- Remuneration
  - Offered, paid, solicited, or received
  - Knowingly and willfully
  - To induce or in exchange for Federal program referrals
REMUNERATION

- Anything of value
- “In-cash or in-kind”
- Paid directly or indirectly
- Examples: cash, free goods or services, discounts, below market rent, relief of financial obligations

OFFERED, PAID, SOLICITED, OR RECEIVED

- Different perspectives – payors and payees
- “It takes two to tango”
- Old focus: payors subject to prosecution
- New focus: payors and payees (usually doctors)
TO INDUCE FEDERAL PROGRAM REFERRALS

- Any Federal health care program
- A nexus between payments and referrals
- Covers any act that is intended to influence and cause referrals to a Federal health care program
- One purpose test

FINES AND PENALTIES

- The Government may elect to proceed:
  
  **Criminally:**
  - Felony, imprisonment up to 5 years and a fine up to $25,000 or both
  - Mandatory exclusion from participating in Federal health care programs
  - Brought by the DOJ

  **Civilly:**
  - Violation is based on express or implied certification of compliance with violations of the Anti-Kickback and Stark Statutes
  - Penalties are same as under False Claims Act (more later)
  - Controversial, yet expanding use of the FCA
FINES AND PENALTIES (Cont’d.)

Administratively:

- Monetary penalty of $50,000 per violation and assessment of up to three times the remuneration involved
- Discretionary exclusion from participating in Federal health care programs
- Brought by the OIG

EXCEPTIONS AND SAFE HARBORS

- Many harmless business arrangements may be subject to the statute
- Approximately 24 exceptions (“Safe Harbors”) have been created by the OIG
- Compliance is voluntary
- Must meet all conditions to qualify for Safe Harbor protection
- Is substantial compliance enough?
GUIDANCE ON THE ANTI-KICKBACK STATUTE

- Advisory Opinions from the OIG
  - A party may request advice on the law, concerning (1) remuneration within the meaning of the law, (2) whether they are meeting one of the law’s exceptions or safe harbors, or whether their arrangement warrants the imposition of a sanction
  - Recent Advisory Opinions on gainsharing arrangements in hospitals

GUIDANCE ON THE ANTI-KICKBACK STATUTE (Cont’d.)

- Fraud Alerts and Special Advisory Bulletins
- Preamble to the Safe Harbor Regulations
- Compliance Program Guidance’s
- www.oig.hhs.gov
THE STARK LAW

- Section 1877 of the Social Security Act, 42 U.S.C. 1395nn
- The law is complicated and consists of the original statute (Stark I in 1989) and the amended provisions (Stark II in 1996)
- Stark II regulations have gone into effect in phases in 2002 and 2004, but some are still pending

THE STARK LAW

- A prohibition on physician self-referrals
- If a physician (or immediate family member) has a direct or indirect financial relationship (ownership or compensation) with an entity that provides designated health services ("DHS"), the physician cannot refer the patient to the entity for DHS and the entity cannot submit a claim for the DHS, unless the financial relationship fits an exception
PENALTIES

- Nonpayment of claims to entity submitting claims
- Civil Money Penalties of $15,000 for each service rendered plus an assessment of three times the amount claims
- Penalty of up to $100,000 for “circumvention scheme”
- FCA liability for submission of false claims resulting from Stark prohibited referral.

DIFFERENCE BETWEEN ANTI-KICKBACK STATUTE AND THE STARK LAW

- Physician referrals only
- No “knowingly and willfully standard” – strict liability
- Involves Designated Health Services (“DHS”)
TYPES OF DESIGNATED HEALTH CARE SERVICE ("DHS")

- Clinical laboratory
- Physical therapy
- Occupational therapy
- Radiology and Imaging Services (MRI, CAT, scan, ultrasound)
- 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
- Inpatient and outpatient hospital services

WHAT IS A FINANCIAL RELATIONSHIP?

- Nearly any type of investment or compensation agreement between the referring physician and the DHS entity will qualify as a financial arrangement under the Stark law.
- Examples:
  - Stock ownership
  - Partnership interest
  - Rental contract
  - Personal service contract
  - Salary
- Compensation agreements can be direct or indirect.
  - Exceptions for certain indirect compensation arrangements.
EXCEPTIONS

- Compliance is mandatory
- Types of exceptions:
  - In-office ancillary services
  - Personal physician services by member of group practice
  - Pre-paid health plan
  - Certain publicly traded securities
  - Rural provider (investment interests)
  - Hospital ownership (must be in the “whole” and not “specialty” hospital)
  - Rental of office space and equipment
  - Bona fide employment
  - Personal services arrangement
  - Physician recruitment

ADDITIONAL EXCEPTIONS
ADDED IN JANUARY 2002

- Fair Market Value compensation arrangements
- Academic medical center arrangements
- Implants provided in an ASC (implants are DHS, but are not included in the bundled Medicare ASC payment)
- EPO and other dialysis-related drugs furnished in or by an ESRD facility
- Preventing screening tests, immunizations, and vaccines
- Eyeglasses and contact lenses following cataract surgery
- Non-monetary compensation up to $300
- Medical staff incidental benefits provided by a hospital
- Risk sharing arrangements
- Compliance training
- Indirect compensation arrangements

- Stand in Shoes Doctrine
- Anti-Markup Provisions – Location and Reimbursement Restrictions
- Physician in Group Practice must Have an Individual Contract Directory with Group
- Strong Comment Regarding Shared Ancillary Services and Block Lease Requirements
- Other Clarifying Amendments.

ADMINISTRATIVE SANCTIONS

- Introduction

The term “sanctions” represents the full range of administrative remedies and actions available to the Federal and state governments to deal with questionable, improper or abusive actions of health care providers under Federal health programs.
SUSPENSION, OFFSET AND RECOUPEMENT OF PAYMENTS TO PROVIDERS

- Suspension of payment is the withholding of payment by an intermediary or carrier from the provider of an already approved Medicare payment amount before a final determination is made as to the amount of any overpayment that exists.

- Offset is the recovery by the Medicare program of a non-Medicare debt (i.e. Medicaid) by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

- Recoupment is the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

EXCLUSION
42 U.S.C. § 1320A-7

- When an exclusion is imposed, no payment is made to anyone for any item or service furnished, ordered, or prescribed by an excluded party under Medicare, Medicaid, or any other Federal Health Program. In addition, no payment is made to any business or facility – e.g., a hospital that submits bills for payment of items or services provided by an excluded party.
EXCLUSION (Cont’d.)

• Unless and until an individual or entity is re-instated, no payment will be made by Medicare, Medicaid, or any other Federal Health Program for any item or service furnished by an excluded individual or entity, or at the medical direction of, or on the prescription of, a physician or other authorized individual who is excluded.

EXCLUSION (Cont’d.)

• It is important to note that a provider may not submit claims to Medicare automatically upon the expiration of the period of exclusion. Excluded health care providers must petition for reinstatement, and be reinstated by the Department of Health and Human Services: Office of Inspector General (“OIG”), before they can lawfully submit claims to Federal Health Programs. An excluded individual or entity submitting, or causing the submission of, claims for items or services furnished during an exclusion period is subject to at least a civil monetary penalty, potential criminal liability, or both.
EXCLUSION (Cont’d.)

• The Secretary of Health and Human Services (the “Secretary”) must exclude individuals and entities from Medicare, Medicaid, and other Federal Health Programs when they are convicted of certain offenses. The grounds for mandatory exclusion were expanded as part of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

• First, if an individual or entity has been convicted of a criminal offense relating to the delivery of an item or service under Medicare or under any state health care program, (i.e. Medicaid) exclusion is mandatory.

EXCLUSION (Cont’d.)

• Second, if an individual or entity has been convicted under federal or state law of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service, exclusion is mandatory. This is true even when such patients are not program beneficiaries.

• Third, exclusion is required for individual or entities that have been convicted, under federal or state law, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.
EXCLUSION (Cont’d.)

- Finally, if an individual or entity has been convicted, under Federal or state law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, exclusion must be imposed.

EXCLUSION (Cont’d.)

- These exclusions may apply to those individuals or entities that (a) are or have been health care practitioners or providers, (b) hold or have held a direct or indirect ownership or control interest in a health care entity, (c) are or have been officers, directors, agents, or managing employees of the entity, or (d) are or have been employed in any capacity in the health care industry.
EXCLUSION (cont’d.)

The Secretary may, but is not required to, exclude an individual or entity when, among other circumstances:

- An individual or entity has been convicted, under Federal or state law:
  - Of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of any health care item or service or with respect to any act or omission in a program operated by or financed in whole or in part by any Federal, state or local government agency; or
  - Of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program (other than a Federal Health Program) operated by or financed in part by any Federal, state or local government agency.

EXCLUSION (cont’d.)

- An individual or entity has been convicted under Federal or state law in connection with the interference or obstruction of any investigation into any criminal offense pertaining to program-related crimes.
- An individual or entity has been convicted under Federal or state law of a criminal offense which is a misdemeanor relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance.
- An individual or entity whose license to provide health care has been revoked or suspended by any state licensing authority or who otherwise has lost such license or right to apply for or renew such license for reasons bearing on the individual’s or entity’s professional competence, professional performance, or financial integrity.
EXCLUSION (cont’d.)

- An individual or entity has been suspended or excluded from participation or otherwise sanctioned under any Federal Health Program or state health program for reasons bearing on the individual’s or entity’s professional competence, professional performance, or financial integrity.

- An individual or entity has submitted a false or improper claim, regardless of whether a civil monetary penalty or assessment has been imposed.

- An individual or entity has been determined by the Secretary to have committed an act involving fraud, a kickback, or other prohibited activities.

EXCLUSION (cont’d.)

- An entity with respect to which the Secretary determines that a person who has been previously sanctioned has a controlling interest.

- An entity is controlled by a family member or a member of the household of a sanctioned individual if the transfer of ownership or control interest in an entity was made to such person “in anticipation of, or following, a conviction, assessment, or exclusion”.

- An individual or entity fails to grant immediate access upon reasonable request to the Secretary, a state agency performing reviews and surveys for the Secretary, the OIG or a state Medicaid Fraud Control Unit.
EXCLUSION (cont’d.)

- An individual has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know (under the definition relating to CMPs) of the action constituting the basis for the sanction described below or is an officer or managing employee of such an entity. A “sanctioned entity” is an entity that has been convicted of any offense giving rise to a mandatory exclusion or of fraud, obstructing an investigation, or a misdemeanor offense relating to controlled substances or that has been excluded from participation under the Medicare Program or under a state health care program.

- The length of a permissive exclusion ranges from one to three years and may be adjusted based on mitigating or aggravating factors as set forth in the governing regulations.

EXCLUSION (cont’d.)

- The OIG will also attempt to exclude “indirect participants” in the Medicare program by prohibiting Medicare providers from doing business with the “indirect participant” and refusing to reimburse providers for the costs of any items or services purchased from the “indirect participant.” The authority of the OIG to impose such an exclusion on “indirect participants” is questionable and has not been addressed directly by the courts. However, the OIG maintains that such power derives from Section 1862(3) of the Social Security Act, which denies payment for services furnished at the medical direction or on the prescription of an excluded physician. According to the OIG, this language demonstrated Congressional intent that the government not pay, directly or indirectly, for the services of “untrustworthy individuals and entities.”
EXCLUSION (cont’d.)

- The remedy of exclusion has been upheld against challenges on the basis of a violation of the Double Jeopardy and Ex Post Facto clauses of the United States Constitution.

EXCLUSION (cont’d.)

- It has been held that an administrative delay in reviewing and affirming a providers’ appealed exclusion does not, in itself, constitute a denial of due process.

- The exclusion period may commence long after the underlying basis (i.e. conviction of program related crime) for the exclusion action.
CIVIL MONEY PENALTY LAW

- Civil Monetary Penalties Law
  - Since 1981, HHS has had the authority to levy administrative penalties and assessments against providers as punishment for filing false or improper claims or as a collateral consequence of prior bad acts. Social Security Act § 1128 and 1128a. 42 U.S.C. § 1320a-7 and 1320a-7a. Since then, the statute has been amended regularly to apply to other Federal programs and agencies and to apply to a broader range of acts and omissions.
  - Treble damages and penalties

HOT TOPICS

- Medical Directorships
- Physician Recruitment
- Joint Ventures
- Pharma and Medical Device Marketing
- Clinical Research
QUALITY OF CARE

- Hospital/physician services
  - Cardiac catheterization procedures
  - Hospital/medical staff responsibility
- Quality of care in nursing homes
  - Services not provided
  - “Deficient” services vs. “worthless” services
- Physician services
- Deficient services versus “worthless” services – medically unnecessary and unreasonable.

OFFICE OF INSPECTOR GENERAL
WORK PLAN
2007
**OIG WORK PLANS**

- Articulates areas of high compliance risk
- Priorities for enforcement activity
- Identify Federal health program vulnerabilities
- Road map for compliance program effectiveness and auditing and monitoring agenda for health care organizations
- Work plan assists in identification and focus for compliance efforts for health care organizations

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**OFFICE OF INSPECTOR GENERAL (“OIG”)**

**OFFICE OF INVESTIGATIONS (“OI”)**

- OI conducts investigations of fraud and misconduct and health care fraud
- Identifies systematic weaknesses in vulnerable program areas and recommends management, regulatory and legislative corrective action
- Provides investigative assistance in criminal and civil false claims, civil money penalty and exclusion cases
- Responds to thousands of complaints of health care fraud from various sources, including “whistleblowers”
- Provider self-disclosure program
- False claims and anti-kickback violations
OFFICE OF INSPECTOR GENERAL
OFFICE OF LEGAL COUNSEL ("OCIG")

- Resolution of Civil False Claims Act cases and negotiation of Corporate Integrity Agreements ("CIA")
- Provider Compliance with Corporate Integrity Agreements
- Industry Guidance: Advisory Opinions, Fraud Alerts and Compliance Program Guidances
- Development of regulations, including safe harbors to the anti-kickback statute
- Enforcement of civil money penalty and exclusion statutes
- Enforcement of the patient anti-dumping statute

PRIVATE PAYOR FRAUD

- What is private payor insurance fraud?
  - Fraud against those who pay for private health insurance coverage
FEDERAL STATUTES PROHIBITING PRIVATE PAYOR INSURANCE FRAUD

- Mail fraud
- Wire fraud
- Fraud against health care benefit plans
- Conspiracy to commit fraud through false claims and false statements
- Fraud under the RICO statute

CORPORATE LIABILITY, COMPLIANCE AND GOVERNANCE

- HIPPA ’96 and Corporate Scandals
- The New Era of Corporate Responsibility
- Sarbanes-Oxley Act of 2002
- Department of Justice Principles of Federal Prosecution of Business Organizations of 2003
- United States Sentencing Guideline Amendments of 2004
CORPORATE LIABILITY, GOVERNANCE AND COMPLIANCE

- Eliminate conflicts of interest and promote independent decision-making in the best interests of the business organization
- Self governance, self reporting and acceptance of responsibility are building blocks of the organizational culture expected from reordered enforcement priorities

SARBANES-OXLEY AND THE SENTINEL EFFECT ON BUSINESS ORGANIZATIONS

- Public companies – governance and integrity of financial information
- Private companies – fiduciary obligations of Board of Directors and shareholder derivative liability
- Not-for-profit organizations – fiduciary obligations and Attorney General oversight
- Caremark Decision – all organizations
  - Duty of compliance oversight enters the Boardroom – fiduciary obligation of individual Board members
CAREMARK DECISION (cont’d.)

- Oversight and responsibility for compliance by the Board of Directors and high level personnel of the organization
- Board knowledge about the content and operation of the organization’s compliance program to prevent and detect violations of the law
- Board exercises reasonable oversight with respect to implementation and effectiveness of the compliance program.

SARBANES-OXLEY ACT (cont’d.)

- Corporate scandals resulted in quick legislative action in 2002
- Attempt to foster change in the way business organizations act and assign greater responsibility to executives for failures in the accuracy of financial statements
SARBANES-OXLEY ACT (cont’d.)

- Increased accountability of corporate executives and board members and improved self governance
- Accuracy and full disclosure of corporate financial information
- Elimination of internal and external conflicts of interest
- Foster compliant corporate culture by protecting reports of misconduct.

DEPARTMENT OF JUSTICE PRINCIPLES OF FEDERAL PROSECUTION OF BUSINESS ORGANIZATIONS “THOMPSON/McNULTY MEMO”

- Voluntary disclosure and self-reporting as quasi mandatory function of cooperation
- Cooperation in investigating business organizations own wrongdoing
- Affects charging decision against business organization
- Affects sentence under sentencing guidelines
- Business organization’s cannot run the risk of failing to have an effective compliance program
- Failure to detect and prevent wrongful conduct will result in consequences for any business organization in current enforcement environment.
  - Deferred Prosecution Agreements and Corporate Integrity Agreements
WHAT CHANGED?

- More consistent, nationwide law enforcement response to corporate fraud
- Proactive approach and faster prosecutions encouraged
- Greater uniformity in case disposition with potentially grave consequences for business organizations.

WHAT CHANGED?

- New emphasis on completeness of cooperation
- Did business organization, while purporting to “cooperate”, engage in conduct that actually impeded investigation, e.g.:
  - Overly broad assertions of legal representation (organization and employees)
  - Directions not to meet/cooperate with government agents
  - Incomplete or delayed document production
  - Failure to promptly disclose illegal conduct known to corporation
  - Continued financial or other support of culpable employees: Modified by Impact of McNulty Memo
  - Joint defense agreements with culpable employees.
WHAT CHANGED?

- Complete cooperation includes full disclosure of key facts
- May require waiver of attorney-client and work product protections
- Substantially Modified by McNulty Memo
  - Limited to factual internal investigation
  - Routine requests for waiver has been controversial and subject to abuse by prosecutors.

WHAT DOES THE GOVERNMENT EXPECT FROM BUSINESS ORGANIZATIONS

- Partnership with Federal and State governments in detecting and preventing misconduct and promoting an ethical corporate culture
- Organizations which fail to ferret out wrongful conduct and non-compliant activity will likely suffer the consequences of not doing so
- Cooperation in investigating an organization's own wrongdoing.
SENTENCING GUIDELINE AMENDMENTS OF 2004

- Sentencing guidelines for organizations introduced concept of compliance program to reduce criminal culpability for business organizations in 1991
- Sarbanes-Oxley Act required United States Sentencing Commission to review and amend guidelines to enhance compliance program effectiveness
- Amendments encourage business organizations to partner with Federal government and promote self policing, reporting and cooperation in investigations of its own wrongdoing.

SENTENCING GUIDELINE AMENDMENTS OF 2004 (cont'd.)

THE UNITED STATES SENTENCING COMMISSION'S ORIGINAL ESSENTIAL ELEMENTS FOR A COMPLIANCE PROGRAM

- Standards of Conduct and Policies and Procedures
  - Developed and distributed to all employees to promote a commitment to compliance
- Compliance Officer
  - Focal point for compliance activities
- Education and Training
  - Continued education and training essential for an effective compliance program
- Monitoring and Auditing
  - Process for continuing evaluation for a successful compliance program
SENTENCING GUIDELINE AMENDMENTS
OF 2004 (cont’d.)
THE UNITED STATES SENTENCING
COMMISSION’S ORIGINAL ESSENTIAL ELEMENTS
FOR A COMPLIANCE PROGRAM

- Reporting and Investigation
  - Communication to detect and prevent misconduct with ability to investigate and implement corrective action
- Enforcement and Discipline
  - Discipline for failure to adhere to compliance standards and procedures
- Response and Prevention
  - Ability to respond to and correct non-compliant activity and conduct.

Amendments continue to emphasize prevention and detection of criminal conduct, but further emphasize promotion of organizational culture which encourages compliant and ethical conduct.

Amendments stress organizational responsibility, risk assessment and ethical behavior.

Strict legal compliance must be accompanied by a strong commitment to proactive governance and management of risk and ethical behavior.

Compliance with law, but also implement “best practices”
SENTENCING GUIDELINE AMENDMENTS (cont’d.)

- Amendments adopt “carrot and stick” approach regarding criminal penalties for business organizations
- Sustained effective compliance program can mean difference between survival and demise of business organizations

CONTENT OF SENTENCING GUIDELINE AMENDMENTS

- Establishment of compliance standards and procedures and creation of code of conduct reasonably capable of reducing misconduct and promoting ethical behavior
  - Focus on areas of high risk and adopt procedures to reduce non-compliant activity
- Assigning oversight and responsibility to high level personnel and governing authority for organizational compliance program
  - Knowledgeable about content and operation of compliance program
  - Ensure implementation and effectiveness of program
  - Compliance professionals provided with adequate resources and authority and reporting responsibility to governing authority.
CONTENT OF SENTENCING GUIDELINE
AMENDMENTS (Cont'd.)

- Compliance Responsibilities Should Not Be Delegated to Individuals Who Have Engaged in Misconduct
  - Organizational Screening Process Required for Hiring and Promotion
- Training of Upper Level Management and Employees and Agents Addressing Specific Risk Areas
- Auditing and Monitoring to Detect Violations of the Law
  - Procedures for Allowing Anonymous Reporting
  - Expanded Focus of Reporting to Include Potential Misconduct and Seeking Guidance on Compliance Matters.
- Expand Enforcement of Compliance Program by Disciplinary and Incentive Measures with Employees
- Responsiveness to Misconduct Through Investigation, Corrective Action and Possible Voluntary Disclosure.

ONGOING RISK ASSESSMENT OF LIKELY RISKS FOR BUSINESS ORGANIZATION

- Amendments expect more than creation of compliance program – compliance program must actually be effective in detecting and preventing misconduct
  - Offense by high level personnel creates rebuttable presumption of ineffectiveness
“COOPERATION” OR “UNCONDITIONAL SURRENDER”

- Cooperation taken into consideration in charging decisions by Department of Justice
  - Organization’s ability to make witnesses available
  - Disclosure of organization’s internal investigation, including waiver of attorney/client privilege when necessary, to identify individuals responsible and scope of conduct: Substantially Modified by McNulty Memo
  - Disclosure in a timely and complete manner before facts become stale and to better enable recovery of losses

“COOPERATION” OR “UNCONDITIONAL SURRENDER” (Cont’d.)

- Cooperation evaluated on case-by-case basis
- Deferred Prosecution Agreement – survival of business organization – Corporate Integrity Agreement with Department of Health and Human Services
- Circumstances literally coerce business organizations into cooperation and compromise of employee rights and protections and the United States Sentencing Commission and the Courts are taking notice of constitutional abuses.
“COOPERATION” OR “UNCONDITIONAL SURRENDER” (cont’d.)

- Powerful incentives involved in business organization’s decision to cooperate in investigation of own wrongdoing
- Department of Justice views self-reporting as a quasi mandatory function of cooperation
- Drives wedge between organization and its employees
  - Undermines fundamental employer/employee relationship.

DEFERRED PROSECUTION AGREEMENTS (“DPA”)

- Deferred Prosecution Agreement – creature of Department of Justice – consequence of enforcement of corporate culpability
  - Organization commits to “best practices” for effective governance and promotion of ethical culture of compliance
  - Chief Compliance Officer reporting directly to Board
  - Extensive training and education programs
  - Hotline reporting of non-compliant conduct
  - Appointment of monitor to oversee obligations under deferred prosecution agreement.
CORPORATE INTEGRITY AGREEMENTS ("CIA")

- Creature of Office of the Inspector General ("OIG") of the United States Department of Health and Human Services
  - Obligations in return for continued participation in Federal health programs
- A part of global criminal and/or civil settlement
- May represent OIG’s opinion on the organization’s compliance programs
- Adopts and adheres to seven essential elements of an effective compliance program, including:
  - Education and training
  - Focused audit and monitoring
  - Independence of compliance officer
- Reporting requirements to OIG.

INDEPENDENCE OF THE COMPLIANCE OFFICER

- Dual responsibility of compliance officers are suspect to the OIG at large organizations
- Concern with sufficient commitment of resources
- Reporting to Board of Directors/Trustee
- Independent COO
OIG EXPECTATIONS
COMPLIANCE TRAINING

- Broad based compliance program training
- Extensive and specific training for risk areas
- Document training
- Efforts made to train physicians
- Technology training
- Essential for effective compliance programs

BOARD OF DIRECTORS
DUTY OF CARE

- Duty of care involves determining whether the directors acted:
  - In good faith
  - With the level of care that an ordinarily prudent person would in like circumstances
  - In a manner that they reasonably believe is in the best interest of the corporation
DIRECTOR’S OBLIGATIONS

- Decision-making function
  - Applying duty of care principles to a specific decision or board action

- Oversight function
  - Applying duty of care principles with respect to the general activity in overseeing the day-to-day business activities of the corporation

WHY CORPORATE COMPLIANCE PROGRAMS?

- Risks associated with non-compliance have grown dramatically

- Board compliance program oversight responsibility is an ongoing element of the duty of care

- Compliance programs are designed to mitigate risks to health care organizations in a heavily regulated industry.
AUDIT AND COMPLIANCE COMMITTEES

Committee’s Compliance Functions
(as defined by Board Policy)

- Ensure that appropriate policies and procedures are in place to preserve and safeguard the System’s assets
- Ensure proper ethical and legal standards are present and maintained in meeting all applicable laws, rules and regulations
- Monitor compliance with applicable laws, rules and regulations.

COMMITTEE’S/BOARD’S FOCUS ON COMPLIANCE

Two Categories

- Structural – the Board’s understanding of the scope of compliance program
- Operational – the Board’s understanding of the operations of compliance program.
STRUCTURAL QUESTIONS

- How is Board structured to oversee compliance issues?
- How is the compliance program structured and who are the key employees responsible for its implementation and operation?
- How does the compliance reporting system work?
- How frequently does the Board receive reports about compliance issues?

(Cont’d.)

- What are the goals of the compliance program?
- Does the compliance program address the significant risks that may apply to our organization?
- How were those risks determined and how are new compliance risks identified and incorporated into the program?
- How has management determined the adequacy of the resources dedicated to implementing and sustaining the compliance program?
OPERATIONAL COMPONENTS OF COMPLIANCE PROGRAM

- CODE OF CONDUCT
- POLICIES AND PROCEDURES
- COMPLIANCE INFRASTRUCTURE
- MEASURES TO PREVENT VIOLATIONS
- MEASURES TO RESPOND TO VIOLATIONS

WHAT ARE THE GOALS OF THE COMPLIANCE PROGRAM?

- Develop annual auditing and monitoring work plans
- Effectively communicate regulatory changes to include accountability for implementation
- To create a culture that promotes
  - Integrity
  - Open Communication
  - Responsiveness to concerns
WHAT ARE THE GOALS OF THE COMPLIANCE PROGRAM? (Cont’d.)

- Develop annual auditing and monitoring work plans
- Effectively communicate regulatory changes to include accountability for implementation
- To create a culture that promotes
  - Integrity
  - Open communication
  - Responsiveness to concerns

ACCOUNTABILITY

- Directors and Managers are accountable for:
  - Failure to detect and report non-compliance issues
  - Any retaliation or retribution against individuals who report compliance concerns
  - Compliance as an element of our performance evaluations.
ACCOUNTABILITY (Cont’d.)

- Specifically for:
  - Charge Systems and Chargemaster
    - CPT Codes (current and accurate)
    - Application of appropriate modifier to charges
    - Patient charge procedures and coding
    - Final billing outcome
  - Quality of care
  - Adherence to JCAHO standards
  - Adherence to conditions of participation for health care services under Medicare and Medicaid Programs
  - Patient and associate
    - Safety
    - Privacy
    - Satisfaction
  - Internal controls
    - Rules and regulations specific to our department functions and activities
  - Identification and management of any potential risk areas
  - Proper documentation
    - Clinical
    - Non-clinical
DEFICIT REDUCTION ACT
(EFFECTIVE JANUARY 1, 2007)

- Impact on enforcement of the health care fraud and abuse laws under state law and under state Medicaid programs.
- Provisions:
  1. Required states to pass false claims statutes which are consistent with the Federal False Claims Statute, including a whistleblower provision and gives the states significant economic incentives to obtain recoveries under the statute.
  2. Medicaid provider who receives in excess of $5 million annually is required to implement compliance measures or face the prospect of denied reimbursement for Medicaid services.
THE END