HEALTH CARE COMPLIANCE ASSOCIATION
DESERT SOUTHWEST REGION CONFERENCE
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The Year in Review: Fraud and Abuse Update

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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.

“HIPAA” 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

**AFFORDABLE CARE ACT REFORMS**

- Dramatically increased funding for health care fraud enforcement – HEAT Program, FBI and OIG, State Medicaid Fraud Control Units, private contractors for Medicare and Medicaid program integrity
- Foreign Corrupt Practices Act Enforcement
- Food, Drug and Cosmetic Act Enforcement.
AFFORDABLE CARE ACT REFORMS
(Cont’d.)

- Violation of Anti-Kickback Statute does not require proof that defendant knew that the statute prohibited the conduct forming the basis of the alleged violation of the law
- Reverses Ninth Circuit ruling in Hanlester Network v. Shalala
- Ignorance of the law is not a defense to anti-kickback charge.

AFFORDABLE CARE ACT REFORMS
(Cont’d.)

- Knowing and willful standard does not require proof of actual knowledge of health care fraud statute or specific intent to violate the statute (i.e. similar to Anti-Kickback Statute).

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 and culpability can be established without a showing of specific intent to violate the statutory prohibitions

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
FINES AND PENALTIES (Cont’d.)

- Civilly:
  - A violation of the Anti-Kickback Statute constitutes a false or fraudulent claim under the Civil False Claims Act
  - 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?
ANTI-KICKBACK STATUTE SAFE HARBORS

- Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Sale of Practice
- Referral Services
- Warranties
- Discounts
- Employees
- Group Purchasing
- Waiver of Beneficiary Coinsurance and Deductible Amounts
- Increased Coverage, Reduced Cost-Sharing Amounts or Reduced Premium Amounts Offered by Health Plans
- Price Reductions Offered to Health Plans
- Practitioner Recruitment
- Obstetrical Malpractice Insurance Subsidies
- Investments in Group Practices
- Cooperative Hospital Service Organizations
- Ambulatory Surgical Centers
- Referral Agreements for Specialty Services
- Price Reductions Offered to Eligible Managed Care Organizations
- Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations.

THE ANTI-KICKBACK STATUTE

- Criminal conviction under the Anti-Kickback Statute requires proof of criminal intent or scienter
- The United States Supreme court has held that, in the context of the Firearms Owners’ Protection Act, one acts willfully when one acts with a bad purpose, with knowledge that his conduct is unlawful. *Bryan v. United States.* See also *U.S. v. Starks,* 157 F.3d 833 (11th Circuit)

AFFORDABLE CARE ACT

- Linkage to False Claims Act – Many courts have held under an express or implied certification theory that a violation of AKS is actionable under the False Claims Act
  - Allows for significant penalties
  - Allows for whistleblowers to bring actions
- ACA Section 6402(f) adds language on this issue –
  "in addition to the penalties provided for in this section... a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the False Claims Act," § 1128B9g (Emphasis added)
United States ex rel. Kosenske v. Carlisle HMC, Inc., 554 F.3d 88 (3rd Cir. 2009)

- Anesthesiologist brought *qui tam* action under FCA, alleging hospital and owners submitted outpatient hospital claims to Medicare and other Federal healthcare programs that falsely certified AKS and Stark Compliance
- 3rd Circuit reversed summary judgment in defendants' favor and found that exclusive service arrangement for pain management services between Relator’s former practice (Blue Mountain Anesthesia Associates) and defendants (1) triggered Stark and AKS; and (2) did not meet the personal service exception to either statute.
- In 1992, Hospital and BMAA entered Anesthesiology Services Agreement:
  - Hospital would provide space, equipment and supplies at no charge and allow only BMAA physicians to provide anesthesia or pain management services at Hospital;
  - BMAA would provide anesthesia coverage for hospital patients 24/7 and use personnel, space, equipment and supplies provided by Hospital solely for practice of anesthesiology and pain management for Hospital’s patients; and
  - BMAA physicians would not practice anesthesia or pain management at any other location other than the Hospital or other facilities/locations operated by Hospital et al.
In 1998, Hospital opened a pain management clinic and BMAA began providing pain management services to its patients. Hospital did not charge BMAA rent for the space or equipment, or a fee for support personnel provided by Hospital. Parties did not execute a new agreement.

Lessons

- **Have (and update as necessary) a written agreement.** The only written agreement between parties was executed in 1992 and did not address pain management services later provided at a facility opened after the Agreement was signed. Nor did it address the free hospital space, staff or facilities provided to BMAA.

Beware non-monetary remuneration. The exclusive right to provide services and in-kind remuneration can also trigger AKS.

The District Court heard the case on remand and denied the parties’ renewed cross-motions for summary judgment, finding numerous disputed issues of fact. *(United States ex rel. Kosenske v. Carlisle HMA Inc., 2010 U.S. Dist. LEXIS 31619 (W.D. Pa. 2010).*

A FCA qui tam case, in which the Relator argued, in part, that defendants caused physicians to submit false claims by certifying compliance with AKS.

In addition to allegations of typical AKS violations, Relators present a novel theory of AKS violation: “overfill kickback scheme” in which Defendants provided overfill of anemia drug Aranesp vials to dialysis providers and encouraged them to profit by improperly billing Medicare for the “overfill.” Relator alleged:

- Amgen gave excess (overfill) Aranesp to providers for which they did not pay;
Amgen advocated that providers bill Medicare for the free doses;
- Medicare does not pay for overfill;
- Amgen induced providers to purchase the drug and make false certifications of compliance with AKS

Defendants argue overfill is “part and parcel” of the product and cannot be remuneration
- District Court found that Relator adequately plead this count to survive MTD.

Cited Bay State, 874 F.2d at 29 (“The gravamen of Medicare fraud is inducement. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.”)
- Affirmed on other grounds, 2011 U.S. App. Lexis 15036 (1st Cir. 2001)

Defendants accused of violating the Anti-Kickback Statute, False Claims Act and related state statutes by providing rebates and other payments to Omnicare in connection with its purchases of Defendants’ drugs (and other arrangements).
- Defendants’ Motion to Dismiss was denied in part
United States v. Borrasi
639 F.3d 774 (7th Cir. 2011)

- Seventh Circuit Court of Appeals upheld Dr. Roland Borrasi’s conviction for violations of the Anti-Kickback Statute and joined other circuits in adopting the “one purpose” test.
- “One purpose” test: a payment or offer of remuneration violates AKS so long as part of the purpose of a payment to a physician or other referral source by a provider or supplier is an inducement for past or future referrals.
- Administrators of an inpatient psychiatric hospital (Rock Creek Center, L.P.) paid Dr. Borrasi and colleagues bribes to refer Medicare patients. Between 1999 and 2002, Dr. Borrasi, et al received $647,204 in potential bribes. In 2001 alone, they referred 484 Medicare patients to Rock Creek.

United States v. Borrasi
(Cont’d.)

- Dr. Borrasi, et al were placed on the Rock Creek payroll, received false titles and job descriptions, and submitted false time sheets. They were not expected to perform any of the duties listed in their job descriptions and attended very few meetings at Rock Creek.
- Dr. Borrasi and certain Rock Creek administrators were charged with conspiracy to defraud the U.S. Government and Medicare-related bribery. Dr. Borrasi was found guilty and sentenced to 72 months in prison, two years of supervised release and $497,204 in restitution.

United States v. Borrasi
(Cont’d.)

- He appealed his conviction, arguing that AKS exempts “any amount paid by an employer to an employee (who has bona fide employment relationship with such employer) for employment in the provision of covered items or services.”
- He urged the Court to adopt a “primary motivation” doctrine: if, upon examining the defendants’ intent, the trier of fact found the primary motivation behind the remuneration was to compensate for bona fide services provided, the defendants would not be guilty.
- The Court declined, adopted the “one purpose” test and held that “[b]ecause at least part of the payments to Borrasi was ‘intended to induce’ him to refer patients to Rock Creek, the statute was violated, even if the payments were also intended to compensate for professional services.”
**United States v. Borrasi**

*Cont’d.*

- What does Borrasi mean for interpreting the employment exception and Safe Harbor?
- Will Borrasi limit the protections of the employment exception and Safe Harbor?

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**RELATORS CHRIS RIEDEL & HUNTER LABORATORIES CASES**

- In 2005 Relators filed compliant alleging that several laboratories systematically overcharged the state’s Medi-Cal program for more than 15 years by giving illegal discounts to doctors, hospitals and clinics for private pay testing in return for referrals of Medi-Cal patients.
  - June 2011, Quest Diagnostics entered a settlement agreement with the State of California for $241 million relating to state False Claims Act violations. This was the largest recovery in the history of California’s False Claims Act.

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**RELATORS CHRIS RIEDEL & HUNTER LABORATORIES CASES (Cont’d.)**

- A similar suit was filed in S.D.N.Y in 2005, in which the government declined to intervene.
- August 2011, Laboratory Corporation of America entered into a similar settlement with state of California for $49.5 million.
- Other cases pending
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

FOREIGN CORRUPT PRACTICES ACT

- Offers of payment of a bribe to a foreign government official to obtain a business advantage
- Pharmaceutical and medical device manufacturers
- Others who do business in foreign countries (i.e. hospitals).
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 regulations have gone into effect in phases (I, II and III) in 2002 and 2004, 2008 and 2009, 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 time 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

CLOSER LOOK AT STARK EXCEPTIONS

- In Office Ancillary Services (an exception that applies to both ownership and compensation)
- The Physician Services Exception (an exception that applies to both ownership/investment interests and compensation)
- The Rural Provider exception (an exception that applies to only ownership/investment interests)
- The Rental of Office Space and Equipment exception (a compensation only exception)
- The Personal Services Arrangements exception (a compensation only exception).
OTHER STARK EXCEPTIONS (Cont’d.)

- The exception for Electronic Health Records (a compensation only exception).
- The exception for Electronic Prescribing (a compensation only exception)
- The exception for Technology Provided as part of a Community-wide Information System (a compensation only exception)
- There are also a number of other Stark Law exceptions. Each of the Stark Law exceptions has specific and technical requirements that must be met.

OVERVIEW OF RECENT STARK CHANGES AND AFFORDABLE CARE ACT PROVISIONS

OVERVIEW OF STARK CHANGES

- Anti-markup Provisions - location and reimbursement restrictions
- Prohibits “per click” and percentage payment arrangements for space and equipment leases – previously not explicitly prohibited
- Effectively prohibits non-rural, physician-owned “under arrangements” companies from providing turn-key services to the Hospital (i.e., ASCs, Cath Labs) by defining DHS entity as billing or performing entity – previously only billing entity
- Provides that physicians who hold an ownership interest or investment interest in their practice “stand-in-the-shoes” of the practice for purposes of determining whether any compensation arrangement between the practice and the Hospital satisfies a direct compensation exception
OVERVIEW OF STARK CHANGES (Cont’d.)

- Requires the Department of Health and Human Services (HHS) to create and implement a new Stark Act self-disclosure protocol, which was published on September 23, 2010, which allows health care entities to self-report Stark Act violations to the government. The Secretary of HHS has implemented this self-referral protocol through The Center for Medicare and Medicaid Services (“CMS”) and does have the authority to reduce repayments and penalties for Stark violations, depending on provider cooperation and the timeliness of the self-disclosure and other factors.
  - Vehicle to resolve technical violations of Stark law without extraordinary financial liability
  - CMS has discretion to resolve Stark violations
- Physician ownership of hospitals is prohibited with some exceptions – previously allowed by ownership in “whole hospital” exception.

PART I: THE FALSE CLAIMS ACT

- 31 USC § 3729 – The False Claims Act ("FCA") sets forth seven bases for liability. The most common ones are:
  1. Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment
  2. Knowingly making, using, or causing to be made or used, a false record or statement material to get a false or fraudulent claim paid
  3. Conspiring to commit a violation of the False Claims Act
  4. Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government
- Obligation defined as an established duty, whether or not fixed, arising…from retention of any overpayment

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
  - acted in “deliberate ignorance” of the truth or falsity of the information; or
  - acted in “reckless disregard” of the truth or falsity of the information.

**PENALTIES**

- Civil penalty of no less than $5,500 and no more than $11,000 per false claim
- Three times the amount of damages which the Government sustained.

**DEPARTMENT OF JUSTICE INVESTIGATIVE GUIDELINES**

- Were false claims submitted by a provider with knowledge of their falsity?
  - Was there actual or constructive notice of the rule or policy on which a potential case would be based?
  - Was the rule or policy clear?
  - Does the size of the false claim support inference of knowledge or inference of mistake?
  - What plans did the provider make to adhere to the rules?
  - Are there any past remedial efforts?
  - Did the provider receive guidance by program agents on the issue?
  - Have there been previous audits to the provider of same or similar billing errors?
QUI TAM ACTIONS & GOVERNMENT INTERVENTION

- A private person ("Relator") may bring a False Claims Act action under the *qui tam* provisions of the FCA – The Whistleblower
- Government may intervene in a suit brought by Relator
- The relationship between Relator and Government

FCA STATISTICS

- If the Government intervenes and obtains recovery, the Relator receives between 15% and 25% of the proceeds
- Since 1986, of all of the *qui tam* actions filed, the average yearly intervention rate has been about 20-25%
- Approximately $3 billion in health care FCA recoveries in FY 2010; a 25% increase from 2009
- Recoveries have increased (higher penalties and greater publicity); $6.8 billion since 2009 and $27 billion ($18.5 billion in health care) overall since 1986
- Highest number of False Claims Act filings during 2011 (in excess of 600 new cases)
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including investigation, initiation, testimony for, or assistance in the action (Anti-Retaliation Provision and Cause of Action)

AFFORDABLE CARE ACT FALSE CLAIMS ACT AMENDMENTS

- Liability for overpayments and failure to return a known overpayment within 60 days from identification-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
- Materiality requirement for False Claims Act liability
AFFORDABLE CARE ACT FALSE CLAIMS ACT AMENDMENTS (Cont’d.)

- Public disclosure ban no longer jurisdictional and does not require dismissal of a case if the government opposes dismissal.
- State proceedings and private litigation do not qualify as public disclosure, but Federal proceedings and news media reports do qualify for public disclosure.
- Original source no longer requires "direct and independent knowledge", but only independent of previously publicly disclosed information that materially adds to publicly disclosed information.

APPLICATION OF FRAUD AND ABUSE LAWS TO PRIVATE EXCHANGE INSURERS

- Authority to implement any measure or procedure appropriate to eliminate fraud or abuse.
- Federal payments to private insurance exchanges subject to False Claims Act.

ROLE OF THE OIG IN FCA CASES

- May assist in the investigation.
  - Settles as client agency on behalf of HHS.
  - Permissive exclusion authority.
  - May waiver exclusion authority in exchange for Corporate Integrity Agreement.
    - Monitoring and annual reports.
    - Successor liability.
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

TYPES OF FCA CASES

- Unbundling (billing single service as if one service)
- Services not rendered but claimed
- Billing for items or services that are not covered
- Upcoding
- Duplicate billing
- Submitting false or inflated cost reports or charges
TYPES OF FCA CASES (Cont'd.)

- Quality of Care ("standard of care claims" or "worthless claims")
- Research grant and clinical trial fraud
- Actions under the Food, Drug & Cosmetic Act
  - Misbranding and adulteration of drugs and promotion of off-label use
- False Claims Act cases based on violations of the Stark Law and/or the Anti-Kickback Statute ("Tainted Claims").

FALSE CLAIMS ACT ENFORCEMENT ACTIONS

- U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc. (D.S.C)
  - Physician contracts exceeding fair market value, not commercially reasonable and based on volume and value of referrals
  - Trial by jury and award to Plaintiff
  - FCA liability for damages and penalties in excess of $200 million
- U.S. ex rel. Baklid-Konz v. Halifax Medical Center (M.D. Fla.)
  - Hospital/Physician Compensation Arrangements
  - Employment exception challenging FMV + Volume/Value of referral prohibition.
  - Incentive pool equal to 15% of the "operating margin" for the hospital's medical oncology program does not comply with employment exception.
  - FCA liability for damages and penalties in excess of $85 million, plus attorney fees and costs
  - Case still pending on site of service allegations

U.S. EX REL. SINGH V. BRADFORD REGIONAL MEDICAL CENTER (W.D. PA.)

- Alleged violation of Stark Law/physician-hospital arrangement
- Hospital agreed to sublease a Nuclear Imaging Camera from a physician group
- FCA and kickback violation to induce physicians to continue referrals to Hospital for imaging services
- Interest issue going to jury
ST. JOSEPH’S MEDICAL CENTER SETTLEMENT FOR $22 MILLION

- FCA and AKS and Stark violations
- Professional Service Agreements with cardiology group in return for referrals to Hospital-cardiac surgical procedures
- Payments above fair market value for physician services not commercially reasonable
- One purpose for Professional Service Agreements was to induce referrals
- Sham Professional Services Agreements led to unnecessary cardiac stent procedures and resulting Corporate Integrity Agreement with Quality of Care Monitor – more to come

PHARMACEUTICAL AND MEDICAL DEVICE SETTLEMENTS-MISBRANDING AND PROMOTION OF OFF-LABEL USE

- More than $1.3 billion recovered in 2010 came from 18 pharmaceutical and medical device manufacturers
- Allergan Settlement – criminal and civil – off-label use, promotion of submission of false claims and payment of kickbacks to doctors
- Norvartis Settlement – off-label marketing of unapproved use and kickbacks
- AstraZeneca, KV Pharmaceutical, Mylan Pharmaceuticals, Forest Laboratories

SETTLEMENT TRENDS – Pharma/Device

- Big Pharma settlements continue, but fewer
  - Johnson & Johnson paid $2.2B (off-label, sales conduct)
  - Par Pharmaceuticals paid $45M (off-label)
  - Amgen paid $24.9 (sales conduct, alleged drug switching)
  - Ranbaxy Labs paid 500M (substandard generic & FDA issues)
- Device manufacturer settlements continue (small increase)
  - Guidant (Boston Scientific) paid $30M (defective cardiac devices)
  - C.R. Bard paid $48.3M (sales conduct)
  - Genzyme paid $22M (off-label sales of surgical device)
  - Abbott Labs paid $5.5M (sales conduct)
PHARMACEUTICAL AND MEDICAL DEVICE SETTLEMENTS (cont'd)

- Boston Scientific/Guidant Corporation Settlement
- Kickbacks in the form of post-market studies to implant pacemakers and defibrillators manufactured by Guidant
- Spectranetics Corporation $5 million settlement-illegal importation of unapproved devices and promotion of unapproved uses
- Atricure, Inc. $3.7 million settlement-payment of kickbacks and promotion of unapproved uses
- But see decision in U.S. v. Caronia (2nd Cir.): Promotion of Off-Label Use protected by First Amendment (“Free Speech”).

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.
  - Does not include private contractor actions, such as pre-payment and post-payment audit of claims and demands for overpayments and/or revocation of enrollment status

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. See 42 U.S.C. § 1395y; 42 U.S.C. § 1396(b)(1)(D); 42 C.F.R. § 405.370(a).
- 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. 42 C.F.R. § 405.370(a).
- 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. 42 C.F.R. § 405.370(a).
SUSPENSION, OFFSET AND RECOUPEMENT OF PAYMENTS TO PROVIDERS (Cont'd.)

- Administrative remedies for challenging suspension, offset or recoupment are limited
- Notice and opportunity to submit rebuttal statement
- If no rebuttal statement received, offset or recoupment automatically effective
- Applies until debt is liquidated or satisfied by other payment arrangements

SUSPENSION, OFFSET AND RECOUPEMENT OF PAYMENTS TO PROVIDERS (Cont'd.)

- Suspension of payments 42 C.F.R. § 405.371 et seq
- CMS or Medicare contractor impose suspension of payments
- Possession of reliable information of existence of overpayment or that payments to be made are incorrect, although additional information may be necessary for a conclusive determination
- Cases of suspected fraud, after consultation with OIG and/or DOJ, unless there is good cause not to suspend payment.

SUSPENSION, OFFSET AND RECOUPEMENT OF PAYMENTS TO PROVIDERS (Cont'd.)

- Lasting a minimum of 180 days, but may be extended indefinitely by CMS, OIG and/or DOJ
- Suspension procedure set out at 42 C.F.R. § 405.372, 374, 375, et seq, including notice and opportunity for rebuttal and basis for extended period of suspension
- Suspension determination not appealable at 42 C.F.R. § 405.375(c)
- Section 6402(h)(2) of Affordable Care Act provides that Federal financial participation in Medicaid program shall not be made when state should have suspended Medicaid payments. See also, 42 C.F.R. § 455.2.
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 or ordered by an excluded party. See generally authority for exclusion at 42 C.F.R. Part 1001 et seq.

EXCLUSION (Cont’d.)

- Unless and until an individual or entity is reinstated, 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.
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.

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.

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.

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.)

- A mandatory exclusion based on an initial program-related crime must be imposed for at least five (5) years. Those convicted of three health care-related crimes must be permanently excluded from any Federal health care program. Individuals convicted of two health care-related crimes are subject to a mandatory minimum 10-year exclusion.

- There are numerous provisions authorizing exclusion actions on a discretionary basis by the OIG

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. 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

- The submission of false and fraudulent claims

- Payments to induce reduction or limitation of services

- Illegal remuneration under the Stark and Anti-Kickback Statutes
RECENT AMENDMENTS TO CIVIL MONEY PENALTY LAW

- Failure to grant timely access, upon reasonable request, to the OIG/HHS for audits, investigations, evaluations or for other statutory functions. See 42 U.S.C. § 1320a-7(a).
- Expansion of Center for Medicare and Medicaid Services ("CMS") Civil Money Penalty Authority for improper ordering and prescribing, false statements or fraudulent claims related to program reimbursement or contract bids and retention of a known overpayment. Id.
- Civil Money Penalties for program beneficiaries who knowingly participate in a Federal health care fraud offense. See 42 U.S.C. § 1301
- Amendment to Beneficiary Inducement Prohibition allowing for remuneration which promotes access to care and poses low risk of harm to patients and/or Federal health programs. See 42 U.S.C. § 1320a-7(a)(6)

CORPORATE INTEGRITY AGREEMENTS ("CIA'S")

- The OIG imposes compliance obligations on health care providers as part of settlements of Federal enforcement actions arising under a variety of health care fraud statutes.
- The option for a health care provider to agree to corporate integrity obligations is in return for the OIG’s agreement to not seek program exclusion.

CORPORATE INTEGRITY AGREEMENTS ("CIA'S") (Cont'd.)

- A part of global criminal and/or civil settlements
- May represent OIG’s opinion on the effectiveness of the organization’s compliance program
- CIA’s adhere to the essential elements of an effective compliance program in the United States Sentencing Guidelines for Organizations
### Legacy of Organizational Accountability

Deemed insufficient to curtail fraudulent and abusive practices
- Congressional and Executive Branch officials concerned that organizations are considering fines and penalties and Deferred Prosecution and Corporate Integrity Agreements as the cost of doing business and not deterring fraudulent and abusive conduct.
- Consequently recent enforcement actions target organization executives for criminal, civil and administrative liability based on organizational misconduct.
  - Assumption is that organizational misconduct cannot occur without individual involvement
  - What individuals are responsible for organizational misconduct?
  - Responsible Corporate Officer Doctrine

### Responsible Corporate Officer Doctrine

- U.S. v. Dotterweich and U.S. v. Park (1975) originally established Responsible Corporate Officer Doctrine
- Corporate misconduct and violations of law can result in conviction of organization executives without individual involvement in wrongdoing or even knowledge that wrongdoing was taking place.
  - Recent application in cases involving violations of law which protects the health and safety of Medicare and Medicaid Program beneficiaries (i.e. Purdue Frederick, Inc. – promotion of “off-label” use of Oxycontin).

### Responsible Corporate Officer Doctrine (Cont’d.)

- Individual criminal (i.e. plea to misdemeanor conviction), civil (i.e. individual multi million dollar fines) and administrative (Federal health program exclusion) liability for CEO, GC and CMO.
- Individual criminal, civil and administrative liability against Purdue executives not based on personal involvement or even knowledge of organization wrongdoing.
- Based on Responsible Corporate Officer doctrine whereby each executive had “responsibility and authority to prevent or to promptly correct the organizational misconduct.”
RESPONSIBLE CORPORATE OFFICER
DOCTRINE AND PROGRAM EXCLUSION

- Responsible Corporate Officer Doctrine – Strict liability application without need for establishing personal involvement in wrongful conduct (criminal and administrative liability, misdemeanor and exclusion).
- Pharma and Medical Device Industry for violations of Food, Drug & Cosmetics Act (Purdue Frederick and Synthes, Inc.).
- Exposure for health care organization and Board Members and upper level management.
  - Responsibility for and authority to prevent or correct non-compliant activity.

PHARMA AND MEDICAL DEVICE INDUSTRY
Exposure for health care organization and Board Members and upper level management.

RESPONSIBLE CORPORATE OFFICER
DOCTRINE AND PROGRAM EXCLUSION (Cont’d.)

- Federal Health Care Program Exclusion also based on Responsible Corporate Officer Doctrine
  - No knowledge of or participation in core activity
- Board Members – knew or should have known; Managers – strict liability

RESPONSIBLE CORPORATE OFFICER
DOCTRINE AND PROGRAM EXCLUSION (Cont’d.)

- Sufficient nexus and common sense connection to misconduct
- Individual exclusion liability based solely on position in organizational hierarchy
- See Guidance for Implementing Permissive Exclusion Authority under Section 1128(b)(15) of the Social Security Act; available at http://oig.hhs.gov/fraud/exclusions/asp.
BROAD APPLICATION AND ADDITIONAL ACTIONS AGAINST INDIVIDUALS

- Criminal, civil and administrative liability based on Responsible Office Doctrine can be applied for organizational violations of the Anti-Kickback and Self-Referral laws and/or the submission of false and fraudulent claims.
- Corporate Integrity Agreements have already required individual responsibility and accountability for management officials, business unit managers and Chief Compliance Officers (i.e. Pfizer and Astra Zeneca).

BROAD APPLICATION AND ADDITIONAL ACTIONS AGAINST INDIVIDUALS (CONT’D.)

- Individual liability under the False Claims Act and Civil Money Penalty and Exclusion authorities
  - U.S. v. Sulzbach (i.e. General Counsel and Compliance Officer)
  - OIG v. Montijo (i.e. physician arrangements with medical device companies)
  - OIG v. Baskt (i.e. Stark law violations by CEO of Hospital)
- Recent actions against individuals
  - U.S. v. Lauren Stevens (i.e. criminal prosecution of General Counsel at Glaxo Smith-Kline)
  - Denkel v. OIG (i.e. exclusion of owner of diagnostic imaging company)

QUALITY OF CARE MEDICAL NECESSITY AND REASONABLENESS OF SERVICES

- 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.
SETTLEMENT TRENDS – Medical Necessity

- Fairfax Nursing Center paid $700K (unnecessary speech therapy)
- Ensin Group (NF chain) paid $48M (unnecessary speech and physical therapy and failure to discharge SNF patients who no longer required SNF level care)
- Grace Healthcare paid $2.7M (unnecessary therapy)
- Williston Rescue paid $800K (unnecessary ambulance transports)
- Lynch Ambulance paid $3M (unnecessary ambulance transports)
- EMH Regional and N. Ohio Heart Center paid $4.4M (unnecessary angioplasty and stent cases)
- Jackson Cardiology paid $4M (unnecessary cardiac procedures)
- Dr. Korban (cardiologist) paid $1.15M (unnecessary cardiac procedures)

SETTLEMENT TRENDS - Other

- FCA settlements based upon physician financial relationships continue
  - Cooper Hospital paid $12.6M (Stark allegations)
  - Intermountain Health Care paid $25.5M (Stark allegations)
  - St. Vincent Healthcare paid $3.95M (Stark issues with 86 employed physicians)
  - White Memorial paid $14M (below FMV rent and above FMV compensation for teaching services)
  - St. James Healthcare paid $3.85M (real estate JV issues)
- Inpatient vs. Outpatient Cases continue
  - St. Joseph (Maryland) paid $4.9M
  - Shands HealthCare paid $26M
  - Beth Israel Deaconess paid $5.3M

NOTEWORTHY CASES

- Potential application of the Stark Law to Medicaid claims through the FCA
- Violations of enrollment rules not basis for FCA claims
  - U.S. ex rel. Hobbs v. MedQuest Associates (CHOW deficiencies not basis for FCA claims)
  - U.S. ex rel. Hansen v. Deming Hospital (CLIA noncompliance not basis for FCA claim).
NOTEWORTHY CASES

- Violation of CIA could be basis for qui tam claim

- Failure to conduct follow-up on coding internal review basis for FCA claims
  U.S. ex rel. Keltner v. Lakeshore Med. Clinic (weak E&M audit process as basis for reverse FCA)

- AKS applies to more than just doctors
  U.S. v. Vernon (11th Cir) (conviction of pharmacy owners upheld)

- FCA Liability of a related entity requires that the affiliate entity be affirmatively involved in the FCA scheme
  U.S. ex rel. Lista v. Par Pharmaceuticals

- Claims against qui tam relators possible
  U.S. ex rel. Wildhirt v. AARS Forever (employment agreement included provision not to file FCA suit, and defendant's counterclaims partially survive)

- Access to CIA documents under FOIA is limited
  Public Citizen v. HHS (HHS withholdings under FOIA for Pfizer and Purdue Pharma CIA materials largely upheld)

- In-house lawyers cannot become whistleblowers
  U.S. ex rel. Fair Laboratory Practices v. Quest Diagnostics (2nd Cir) (Former general counsel violated NY ethics rules by filing a qui tam action and qui tam action dismissed).

- OIG prevails in exclusion litigation
  Salko v. Sebelius (false progress note adequate basis for 5 year exclusion)
  Harkone v. Sebelius (exclusion of CEO of Immune upheld)

- U.S. ex rel Drakeford v. Tuomey Health Care System
- United States ex rel. Baklid-Kunz v. Halifax Hospital
  Compliance Review and Voluntary Disclosure
United States ex rel. Tyson and State of Illinois vs. Amerigroup Illinois, Inc. and AmeriGroup Corporation

Fraud and Abuse of Managed Care Organizations (“MCO”)

- AmeriGroup Corporation: Medicaid HMO servicing Illinois Medicaid recipients through Managed Care Capitated Payment Plan
- Allegations of Whistleblower Complaint
  - Submission of false or fraudulent certifications to State of Illinois for Medicaid payment
  - False and fraudulent representations to induce State of Illinois to enter into contracts with MCO
  - Failure to provide State of Illinois with information which would be critical to purchasing decision
  - Implied certification that AmeriGroup Corporation was in compliance with applicable law and regulations

CONTRACT WITH STATE OF ILLINOIS

- Managed Care Contracts with State of Illinois require Medicaid HMO to service both healthy and unhealthy Medicaid recipients
- Alleged scheme was for AmeriGrup to enroll as many healthy members and eliminate unhealthy members thereby increasing profit because of capitated payment arrangement
- Discrimination based on health status
**SCHEME TO DEFRAUD**

- Avoid enrollment of pregnant women
- Avoid enrollment of individuals with substance and abuse problems
- Avoid enrollment of individuals with HIV or cancer
- Avoid enrollment of individuals who have specialist needs or any out-of-network care

**OUTCOME OF CASE**

- State of Illinois joined case and collaborated with Federal government and Relators in presenting case
- AmeriGroup agrees to multi-million dollar settlement

**SETTLEMENT TRENDS – HIPAA and HITECH**

- Increase in cases and settlement amounts
  - Hospice of No. Idaho paid $50K (lost laptop; OCR claims 1st settlement based upon security rule affecting less than 500 individuals)
  - Idaho State Univ. paid $400K (data breach involving 17,500 records)
  - Affinity Health Plan paid $1.2M (photocopier hard drive with 344K individuals’ records)
  - Dermatology group paid $150K (lost thumb drive with 2200 individuals’ data; OCR claims 1st settlement based upon CE’s failure to have P&Ps)
  - Shasta Regional Med Center paid $275K (privacy breach; PHI shared with reporters)
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

FEDERAL PROSECUTIONS INVOLVING FRAUD AGAINST PRIVATE PERSONS

- Examples
  - US v. Individual Chiropractor
    - Health care fraud: 18 U.S.C. § 1347; Conspiracy: 18 U.S.C. § 371 – for claims for services in accordance with a standard treatment protocol lasting approximately three months regardless of the patient injuries or the medical necessity of the treatment protocol, and for submission of claims for medical, chiropractic and therapeutic services which were not performed during the treatment protocol and/or never occurred

EXAMPLES OF PRIVATE PAYOR POSITIONS IN CIVIL LITIGATION

- Violations of federal or state false claims statutes
- Violations of federal or state Anti-Kickback and self-referral laws
- Violations of state law governing insurance and provider relationships
- Submission of claims which are allegedly medically unnecessary and/or unreasonable
**DEPARTMENT OF JUSTICE PRINCIPLES OF FEDERAL PROSECUTION OF BUSINESS ORGANIZATIONS**

*THOMPSON/MCNULTY/FILIP 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 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.

**“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/Filip Memos
  - Disclosure in a timely and complete manner before facts become stale and to better enable recovery of losses
  - 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, but the United States Sentencing Commission, the Courts and Congress responded to 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
  - U.S. v. Wakemed Health and Hospitals (E.D. N.C.) DPA rejected by the court for lack of severity and individual accountability.

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.
TYPES OF CRIMINAL AND CIVIL HEALTH CARE FRAUD CASES

- Hospital/physician relationships (Stark and Anti-Kickback Statutes)
  - Medical Directorships
  - Physician Recruitment
  - Employment Arrangements
- Joint Ventures
- Pharma and Medical Device Marketing and Kickback Arrangements
- Research Grant and Clinical Trial Fraud
- Actions Based on Violations of Food Drug & Cosmetics Act
  - Misbranding and adulteration of drugs and promotion of off-label use

TYPES OF CRIMINAL AND CIVIL HEALTH CARE FRAUD CASES (Cont'd.)

- Quality of Care/Medical Necessity and Reasonableness of Services
- Effective Compliance Programs
- Anti-Kickback and Stark Compliance
- False Claims Act liability-overpayments
  - Failure to return known overpayments within 60 days of identification
  - Improper Site of Service (inpatient/outpatient)

TYPES OF CRIMINAL AND CIVIL HEALTH CARE FRAUD CASES (Cont'd.)

- Improper Reimbursement Criteria (physician supervision requirements)
- Improper Billing and Coding (use of modifiers on claims)
- Cardiac Catheterization and Stent Procedures
- Discounts and Swapping Arrangements
TYPES OF CRIMINAL AND CIVIL CASES

- Claims for services not provided or not provided as claimed
- Claims "unbundled" and submitted as a single service, which is reimbursed as part of another service
- Claims for non-covered services (Implantable Cardiac Defibrillators)
- Claims for duplicate services
- Claims involving false or inflated cost reports

OIG DEVELOPMENTS

- Special Fraud Alert on physician owned entities
  - Physician-owned distributors ("PODs")
- Updated OIG Provider Disclosure Protocol
- Updated Special Advisory Bulletin on excluded persons
- OIG Civil Monetary Penalty actions
  - Only 3 cases of $1M+ (billing and AKS cases)
  - 83% of CMP resolutions based upon self-disclosures
  - 56% based upon employment of excluded individuals
  - Only 11 EMTALA settlements
- 19 Advisory Opinions.

OTHER DEVELOPMENTS

- CMS' Stark Law self-disclosure protocol (Sept. 2010)
  - As of 1/1/2014: 38 matters resolved (21 matters in 2013)
    - Average settlement amount: $105,800
    - Median settlement amount: $67,750
    - 4 settled for more than $250,000
    - 22 settled for less than $75,000
- Physician Payment Sunshine Act
  - Data collection began: 8/1/13
  - Manufacturers report to CMS: 3/31/14
  - CMS will publish data: 9/30/14
OTHER DEVELOPMENTS

- Premium support payments and exchanges: illegal beneficiary inducement or legitimate business activity?
  - Secretary of HHA states that Qualified Health Plans and other Exchange-related programs are not "federal health care programs" (Oct. 2013)
  - CMS issues subsequent FAQ (Nov. 2013) expressing "significant concerns" with such patient subsidies
  - IRS is silent to date on "private benefit" implications of premium support plan for tax exempt hospitals
  - Note: contributions to separate foundation which applies charity care guidelines are apparently permitted in any event.

THE END