ORANGE IS NOT YOUR COLOR
HOW TO STAY IN THE BLACK:

Recent enforcement activities related to fraud and abuse, HIPAA and antitrust, and their financial implications
OVERVIEW

• Fraud & Abuse Enforcement Activities
  • Scenarios
• HIPAA Enforcement Activities
  • Considerations
• Anti-trust Activities
  • Scenarios
• Questions

Fraud and Abuse Enforcement Activities
### Stark Law
- Physician referral
  - To an entity with which he has a financial relationship
  - DHS
  - Reimbursable by Medicare
- Unless Exception
- Strict Liability/Civil
- Penalties
  - Refund
  - $15k/violation
  - FCA liability
  - Exclusion

### Anti-Kickback Statute
- Referrals from anyone
  - Offering, paying, soliciting or receiving value to induce
  - Any items/services
  - Reimbursable by any federal healthcare program
- Unless Safe Harbor
- Intent based / Civil & Criminal
- Penalties
  - Criminal - $50k/violation
  - Prison term
  - Civil - $25k/violation
  - FCA liability
  - Exclusion

### False Claims Act
- Prohibits anyone who knowingly submits a false claim or knowingly uses false statements for payment of a claim by the federal government (e.g., Ordering unnecessary medical services or excessive charges)
- “Qui tam” provision that allows whistleblower lawsuits
- Civil Penalties
  - 3x actual damages
  - monetary penalties $5,500 - $11,000 per false claim
- Criminal Penalties
  - $25,000 in fines and/or 5 years prison

### State Law
- Mimic federal laws but broader application
- Generally compliant if meets a federal safe harbor
FEDERAL ENFORCEMENT

- Department of Justice (DOJ)
- Federal Bureau of Investigation (FBI)
- Department of Health and Human Services (DHHS)
- Department of Defense
- Department of Veteran Affairs
- Department of Labor
- United States Postal System
- Federal Trade Commission

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

- Office of Inspector General (OIG)
- Center for Program Integrity
- Administration on Aging
- Healthcare Integrity and Protection Data Bank
- Food and Drug Administration
- Program Integrity Contractors
MULTI-AGENCY FEDERAL ENFORCEMENT

- Healthcare Fraud and Abuse Prevention and Enforcement Action Team (HEAT)
  Composed of:
  - Federal and law enforcement agents, prosecutors, attorneys and auditors from both DOJ and DHHS
  - State officials from the Medicaid Fraud Control Units
  - Medicare Strike Force team composed of federal, state and local investigators who investigate through community policing and data analysis

STATE AND LOCAL ENFORCEMENT

- State Attorney General (AG)
- District Attorney (DA)
- Health & Human Services Commission (HHSC)
HIGHLIGHTS OF 2014 FRAUD AND ABUSE ENFORCEMENT

• $2.3 Billion in health care fraud recoveries
• Fifth straight year of the Justice Department recovering more than $2 Billion
• Justice Department has recovered $14.5 Billion in federal health care dollars between January 2009 through 2014
• Pharmaceutical, hospital, and home health services accounted for a significant portion of 2014 recoveries
• May 13, 2014 – Medicare Strike Force charged 90 individuals, including 27 doctors, nurses and other medical professionals, in six states with allegedly participating in Medicare fraud schemes involving $260 Million in false billings

FRAUD & ABUSE

Recent Enforcement Activities

Settlements:

• Johnson & Johnson, its subsidiaries, Janssen Pharmaceuticals, and Scios settlement for $1.1 Billion – claimed to have promoted prescription drugs for uses not approved as safe and effective by the FDA
• Omnicare settlement for $116 Million – claimed to have promoted facilities to use Omnicare as their pharmacy provider by inducing referrals through kickbacks
• Community Health Systems settlement for $98.15 Million – claimed to have billed services as inpatient rather than as outpatient
• Amedisys, Inc. settlement for $150 million – claimed to have billed for home health services that were medically unnecessary and for services to patients that were not home bound
Recent Enforcement Activities

- Boston Scientific Corp. settlement for $30 Million – claimed that Guidant LLC, Guidant Sales LLC and Cardiac Pacemakers Inc. sold defective heart devices
- King’s Daughters, Medical Center settlement for $41 Million – claimed that King’s Daughters billed for unnecessary coronary stents and diagnostic catheterizations
- St. Joseph Health System settlement for $16 Million – claimed that St. Joseph performed numerous unnecessary invasive cardiac procedures

Other Settlements of Interest

- Infirmary Health System Inc., two IHS affiliated clinics and Diagnostic Physicians Group P.C. agreed to pay $24.5 Million for allegedly paying or receiving financial inducements in connection with the Medicare Program
- Daiichi Sankyo, Inc. agreed to pay a total of $39 Million for allegedly paying kickbacks to induce physicians to prescribe Daiichi drugs
- SelfRefind, PremierTox LLC and two physicians agreed to pay $15.75 million for allegedly submitting claims to Medicare and Medicaid for tests that were medically unnecessary
Other Settlements of Interest

- Memorial Hospital of Ohio agreed to pay $8.5 Million for allegedly creating sham joint ventures with physicians so that patients would be referred between the parties.
- EndoGastric Solutions Inc. agreed to pay $5.25 Million for allegedly misleading health care providers about how to bill federal health care programs for a procedure using a device manufactured by the company.

SCENARIOS

Scenario 1
Hospital and group of oncologists who referred patients to the Hospital had agreements that provided an incentive bonus that included the value of prescription drugs and tests the oncologists ordered in providing care to their patients.

Scenario 2
Rehab Company A purchases the contracts to provide therapy of Rehab Company B. Rehab Company A pays Rehab Company B $400,000 to $600,000 upfront payment and allowed Rehab Company B to retain a percentage of revenue generated by each referral.
SCENARIOS (con’t.)

Scenario 3
Hospital entered into exclusive part-time employment agreements with physicians to ensure they would not move their outpatient business out of Hospital’s ambulatory surgery center. The physicians were paid 131% of their net revenues collected in return for their services and a non-compete agreement.

Scenario 4
DME provider hires a marketing representative as an independent contractor and pays the individual a percentage of the revenue derived from those orders generated by the physicians he is to market to on behalf of the DME provider.

Health Insurance Portability & Accountability Act of 1996 (HIPAA)
Enforcement Activities
WHAT IS HIPAA?

- Health Insurance Portability & Accountability Act of 1996 (amended by HITECH Act)
- Sets Standards for Confidentiality and Privacy of Individually Identifiable Health Information
- Enforced by the Department of Health and Human Services (HHS), Office of Civil Rights (OCR)
- No Private Cause of Action under HIPAA

WHAT IS A BREACH?

- Unauthorized Use or Disclosure of PHI
- If More than a Low Probability the PHI Was Compromised – Reportable Breach
- Risk Analysis to Make Determination
  - Nature of the PHI involved
    - Account numbers, DOB, diagnosis, treatments, names, SSNs, credit card numbers
  - Unauthorized party that accessed the PHI
  - Whether the information was actually viewed
  - Extent to which the incident may be mitigated
  - Any other relevant factors
PENALTIES FOR VIOLATION

• Failure to Meet Privacy Standards
  • Civil Fine $100 - $50,000 per Violation
  • Not to exceed $1.5M per year

• Knowing Violation of HIPAA
  • Criminal fine of $50,000
  • Up to a year in prison

• Attempt to Sell PHI
  • Fine up to $250,000
  • Up to 10 years in prison

RISK OF BREACH – INVESTIGATION!

Office of Civil Rights (OCR) Automatically Opens Investigation if Breach > 500 people

A Complaint to the OCR Opens the Organization to an Audit

Either May Lead to Requirement of Remedial Action by the Organization and/or a Penalty
## STATISTICS

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### Resolutions by Year and Type

Resolutions by Year and Type from April 14, 2003 through December 31, 2013.
GENERAL CAUSES OF BREACH

- Theft
- Cyber Attacks
- Bad Actors
- Disposal of Patient Information

**Common Theme**
Failure to Follow Policies, Lack of Security Policies, Failure to Conduct Vulnerability Assessments

**Recent Enforcement Activities**
THEFT

• Adult & Pediatric Dermatology, PC
  • Theft of unencrypted thumbdrive from employee’s vehicle containing PHI of 2,200 individuals
  • Lack of security management process and policies as well as workforce training policies
  • Settlement $150,000 and Corrective Action Plan (CAP)

• BC/BS of TN
  • Theft of 57 unencrypted hard drives containing names, SSNs, DOB, diagnoses of 1M individuals
  • Settlement $1M and CAP

• Aspire Indiana
  • 11/2014 theft of unencrypted laptops from office containing medical information and SSNs of > 45,000 individuals.
  • Findings and penalty TBD

CYBER SECURITY

• Anthem
  • Victim of cyber attack gaining access to SSNs, DOBs, addresses, and employment information of 80M individuals
  • Vulnerability due to failure to encrypt internal databases that did NOT contain medical information
  • Settlement TBD (breach announced 1/2015)

• Community Health Services
  • Cyber attack over a 90 day period allowing access to patient names, DOB, addresses and SSNs of 4.5M individuals
  • Settlement TBD (breach announced 8/2014)
  • Offered identity theft protection to all (cost ~ $110/ind/yr)
  • Class action suit filed in Alabama
VULNERABILITY

• New York Presbyterian & Columbia University
  • Joint breach report after physician hired to develop applications for the entities deactivated a personal server on the network causing ePHI of 6,800 patients to become available on internet
  • Failure to conduct thorough risk analysis, failure to establish appropriate P&Ps, failure to follow P&Ps in place
  • Settlement $4.8M and CAP

• Lone Star Circle of Care (Federally Qualified Community Health Clinic)
  • A back-up file containing names, DOBs, addresses, etc. of 8,700 individuals improperly placed on Lone Star’s website by a company that designed, maintained and secured website
  • Findings and Penalty TBD
  • How do you protect your organization from acts of a Business Associate?

DISPOSAL

• Affinity Health Plan
  • Returned leased copiers without removing ePHI of ~345,000 individuals from the hard drives
  • Failed to incorporate this type of ePHI into its security risk/vulnerability assessments
  • Settlement $1.2MM, CAP and retrieve hard drives

• Midwest Women’s HealthCare Specialists
  • Disposed of patient records in public dumpster. Neighbor told staff that papers were blowing out of dumpster but dismissed him
  • Contacted media
  • Class action suit filed
    • Breach of fiduciary duty under HIPAA
    • Violation of Missouri common law prohibiting disposal in public dumpsters
BAD ACTORS

• Parkland Memorial Hospital
  • Employee used position in registration at hospital to assess over 2,000 patient records, including claims/financial information, to contact individuals who were potential clients of his home health business
  • Took confidential information for financial benefit
  • Faces 5 years in federal prison and $250,000 fine

• Walgreen Company
  • Indiana pharmacist divulged patient prescription information to patient’s partner to be used in a custody battle
  • $1.4M jury verdict against Walgreen for privacy breach under Respondeat Superior (employer responsible for acts of employee)
  • HIPAA was used as a standard of care for private cause of action

BAD ACTORS (con’t.)

• Rogue Employee Acting Outside Scope of Work
  • Organization’s fiduciary duty usually limited to reasonably foreseeable risk
  • May be liable for negligent hiring, supervision, failure to establish sufficient policies and procedures, failure to adequately train staff
HIPAA AS STANDARD OF CARE

- HIPAA Preempts **Conflicting** State Law
  - Conflicting state law, not all state law
  - Private right of action under state law

COMPONENTS TO THE COST OF A PRIVACY BREACH

- Fines Penalties
- Remediation
  - Administrative, IT, Legal Fees
- Identity Theft Protection/Credit Monitoring
- Defending Against Patient and/or Shareholder Lawsuits
- Reputation/Customer Confidence
- Insurance Fraud Stemming from Theft of SSNs
Antitrust Enforcement Activities

LEGAL BACKGROUND

The Increased Impact of the Federal Antitrust Laws in Health Care

The Patient Protection and Affordable Care Act of 2010 and the Health Care and Education Reconciliation Act of 2010, collectively referred to as the “Affordable Care Act” or the “ACA”, incentivizes health care providers to work together, either in different entities or through one entity, to increase quality while decreasing cost.

The Justice Department and the Federal Trade Commission have established guidance on how health care entities can work together within the confines of the antitrust laws.

With increased activities among the providers, federal and state authorities are being more proactive in pursuit of those arrangements and transactions impacting competition.

These investigations and prosecutions have resulted in Courts issuing a series of rulings favorable to the government limiting what providers may do in working together.
Section One of the Sherman Act – 15 U.S.C. §1

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.


Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.

Section Seven of the Clayton Act – 15 U.S.C. §18 (con’t.)

No person shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of one or more persons engaged in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition, of such stocks or assets, or of the use of such stock by the voting or granting of proxies or otherwise, may be substantially to lessen competition, or to tend to create a monopoly.
Section 5 of the FTC Act - 15 U.S.C. §45

Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

Recent Enforcement Activities

St. Luke’s Health System

- In 2012, St. Luke’s Health System attempted to acquire the Saltzer Medical Group
- In addressing the Federal Trade Commission’s concerns with how the acquisition could impact competition, St. Luke’s argued that the transaction would allow for better care through an integration of health care
- The FTC argued that such a consolidation would negatively impact competition within the marketplace
Recent Enforcement Activities

St. Luke’s Health System – (con’t.)

• The U.S. Ninth Circuit Court of Appeals ruled this past month that the consolidation creates a substantial risk of higher prices.

• It is not sufficient in overcoming the FTC’s actions to show that a merger would allow the health system to better serve patients. In fact, the Court of Appeals held that St. Luke’s did not need to acquire Saltzer to create a more integrated approach to the delivery of health care.

Recent Enforcement Activities

ProMedica Health System

• In 2010, ProMedica merged with St. Luke’s which the two accounted for half of the four hospitals in Lucas County, Ohio.

• Five months after the month, the FTC challenged the merger because of the size of market share that the merged entities captured.

• Post-merger ProMedica had achieved fifty percent (50%) of the market for primary and secondary services and eighty percent (80%) of the obstetrical market.
Recent Enforcement Activities
ProMedica Health System – (con’t.)

- The U.S. District Court ruled the merger adversely affected competition under Section 7 of the Clayton Act and stated “no court ... has found efficiencies sufficient to rescue an otherwise illegal merger.”
- ProMedica appealed the District Court ruling to the U.S. Sixth Circuit Court of Appeals taking the position the FTC had incorrectly judged the market
- The Sixth Circuit Court of Appeals upheld the District Court
- ProMedica has appealed to the U.S. Supreme Court

Scenario 1
Two urology practices merge and come under the scrutiny of the federal and state authorities that the merger had impacted the pricing and delivery of prostate cancer treatment. By having an impact on the marketplace for the delivery of this care, it allowed for the merged medical practice to have an uneven advantage in negotiating managed care contracts. What can be offered by the merged practice to the governmental authorities to ensure that it has not unfairly impacted the marketplace?
Scenario 2

Two cardiology practices merge in a given geographic area. There are other cardiologists in the area that may provide the same medical services but the merged practice accounts for a majority of the cardiology services provided in the area. The physicians of the merged medical practices had non-compete provisions in their employment agreements prior to the merger. What can be offered by the merged practice to the governmental authorities to ensure that the merged entity does not control the marketplace?