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HEALTH CARE | GENERAL COUNSEL INSTITUTE

Foundations in Fraud and Abuse

Building Blocks of Health Law

Presented by: Sarah E. Swank and Catherine A. Martin

Welcome

- Housekeeping
- Today's speakers
- Overview of the topic
- Discussion
- Questions

Welcome

- Download the slides for today's program by clicking the PDF link in the upper left corner of your screen.

- Also on the left is a Q&A box where you may type your questions. We'll look at those questions at the end of the program and answer as many as we can.

- At the end of the program, you'll receive an email with a link to a survey. Please take a moment to fill that out and give us your feedback.

Meet Today's Speakers

Sarah E. Swank
Principal, Ober|Kaler
seswank@ober.com
202.326.5003

Catherine A. Martin
Principal, Ober|Kaler
camartin@ober.com
410.347.7320

Sarah is cofounder of the Ober|Kaler Health Care General Counsel Institute.

Join us on LinkedIn: Ober|Kaler Health Care General Counsel Institute Group

Coming Soon

Watch your inbox for details on the next Ober|Kaler Health Care General Counsel Institute webinar

September 12, 2013
Topic: Drug Diversion

Foundations

- The Ober|Kaler Health Care General Counsel Institute is pleased to introduce its *Foundations* series, a collection of programs designed to equip in house counsel with a solid foundation in the cornerstones of health law. The series is for in house counsel who are:
  - beginning their careers
  - experienced counsel working outside of health law
  - experienced in health law and want to get up to speed in areas outside of their niches
  - experienced health law counsel who would like refreshers on current law and developing trends

Overview

- Introduction
- Overview of the Fraud & Abuse Laws
- OIG Guidance and Other Government Resources
- Recent Enforcement Trends
- Self-Disclosure Protocols
- Hot Topics
- Compliance Concerns and Practical Challenges for In House Counsel
- Questions

It Is Not As Easy As It Looks

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

Chief Judge Ervin, *Rehabilitation Association of Virginia v. Kozlowski*, 42 F. 3d 1444, 1450 (4th Circuit 1994)

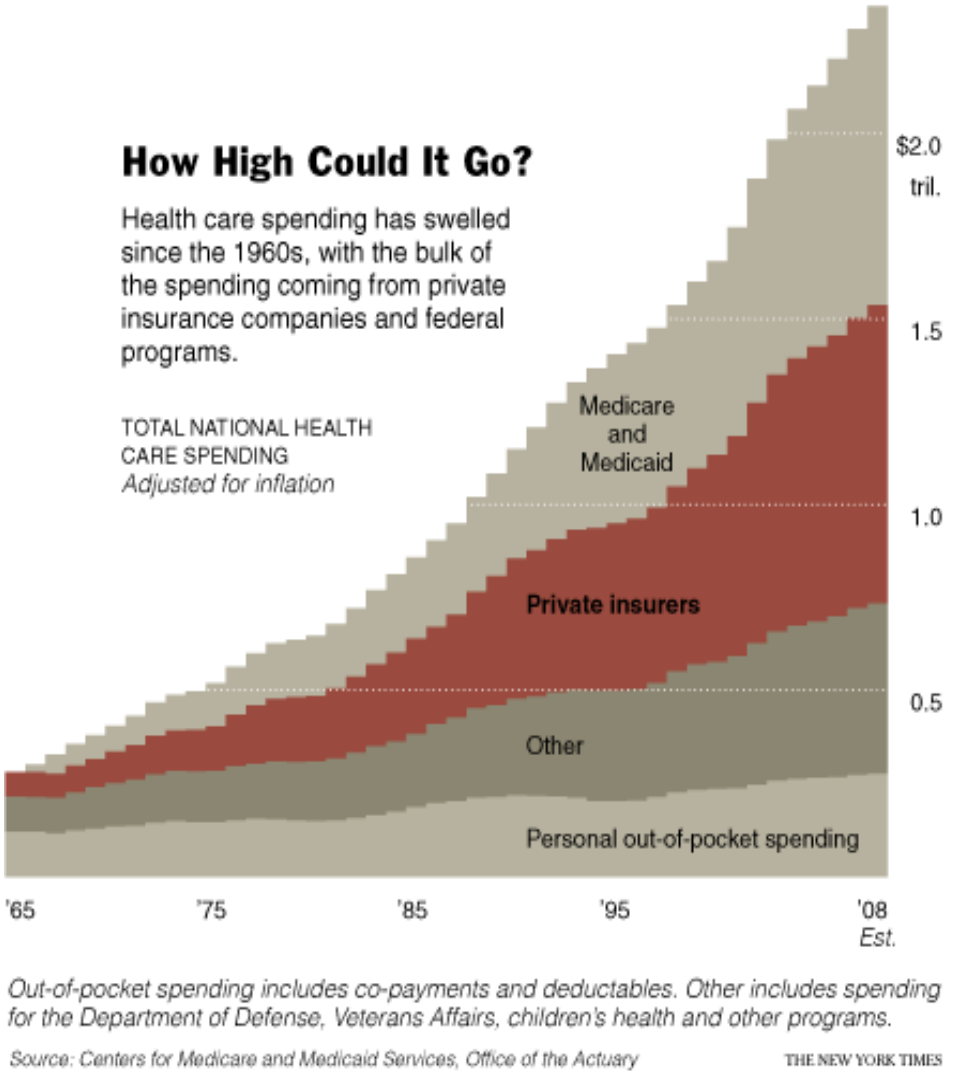
The Cost of Medicare

Each working day	• **Medicare pays over 4.4 million claims** • **To 1.5 million providers** • **Worth $1.1 billion**
Each month	• **Medicare receives almost 19,000 provider enrollment applications**
Each year	• **Medicare pays over $430 billion for more than 45 million beneficiaries**

Annual Health Care Spending in U.S.

- Health care spending in 2020 is projected to reach $4.64 trillion, accounting for 19.8% of GDP.

- Lost to fraud: 3% - 10% ($69 billion - $230 billion).



Fighting Fraud is a Good Investment

- OIG Reports $6.9 Billion in expected recoveries among FY 2012 accomplishments
  - $923.8 million in audit receivables
  - $6 billion in investigative receivables
- $8.5 billion in estimated savings resulting from legislative, regulatory, or administrative actions that were supported by our recommendations
- Excluded 3,131 individuals and entities in FY 2012
- 778 criminal actions against individuals or entities
- 367 civil actions

Fighting Fraud is a Good Investment

- Government continues to view Fraud, Waste, and Abuse as a significant source of revenue
- The return-on-investment (ROI) for Health Care Fraud and Abuse Control (HCFAC) program
  - For the life of the program (since 1997) $5.40 returned for every $1.00 expended.
  - 3-year average (2010-2012), $7.80 returned to every $1.00 expended

Fraud and Abuse

- Fraud: theft by deception
  - Claiming payment for a service you did not deliver or delivered knowing it to be unnecessary
- Abuse: “gaming the system”
  - Unbundling necessary services

Perpetrators of Fraud and Abuse

- Health care professionals
- Suppliers of equipment and drugs
- Corporate officers and administrative personnel
- Billing and coding personnel
- Marketing and sales representatives
- Organized crime

The Office of the Inspector General

- **Mission:** Overseeing and ensuring efficiency and integrity of 300+ programs of the Department of Health and Human Services and the beneficiaries of those programs
- **Significant Focus:** Medicare and Medicaid
- **Fraud and Abuse:** Top Priority of the OIG

Major Fraud and Abuse Laws

- False Claims Act
- Federal Anti-kickback Statute
- Physician Self-Referral Law
- Civil Monetary Penalty Law

Government Concerns

- Over-utilization
- Increased program costs
- Corruption of medical decision-making
- Unfair competition

False Claims Act

- **31 U.S.C. §§ 3729-3731**
  - Civil War vintage (1863) – known as "informer's Act" or "Lincoln Laws"
  - Initially directed at procurement fraud and price gouging
  - Became popular tool for combating fraud in 1986 when its scope greatly increased via statutory amendments
  - Since 1986 over $178 recovered in health care cases

False Claims Act

- Most potent of weapons against health care fraud and abuse:
  - Severe penalties
  - Bounty-hunter rewards (*qui tam* provisions)
  - Broad scope

Federal False Claims Act-Prohibitions

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

Federal False Claims Act – Penalties/Consequences

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

Federal False Claims Act – Practical Tips

- Two significant concerns for facilities
  - The completeness and accuracy of the medical record
  - Accurate coding of services provided
- Both are compliance issues that can be addressed through education, auditing and monitoring
- Education, auditing and monitoring are all parts of an effective compliance plan

The Anti-Kickback Statute

- 42 U.S.C. § 1320a-7b(b)
- Prohibits purposeful payments to get federal health care program business
- Criminal statute - intent matters

The Anti-Kickback Statute

- Case-by-case approach
- Elements:
  - Remuneration
  - Offered, paid, solicited, received
  - To induce or reward referrals of Federal health care program business
  - Knowingly and willfully
- One purpose test

The Anti-Kickback Statute

- Jail, criminal fines, or both
- Civil Monetary Penalties - $50,000 per kickback plus 3x the remuneration
- Exclusion
- False Claims Act liability

Anti-Kickback Analysis – What To Look For

- Financial arrangement or non-cash inducement between party that has referrals and party that wants them
- Remuneration
- Follow the money and the referrals

The Anti-Kickback Statute

- **Statutory Exceptions**
  - Discounts
  - Bona fide employment relationships
  - GPO fees
  - Certain co-payment waivers
- **Certain managed care arrangements**

The Anti-Kickback Statute

- **Regulatory Safe Harbors**
  - 42 C.F.R. § 1001.952
  - Voluntary
  - Must fit squarely
  - Common features: written agreement, signed by the parties, one year term, compensation set in advance, services set forth in agreement
  - Benchmark: Fair market value

Safe Harbors - Examples

- Personal Services and Management Contracts
- Discounts
- Investment Interests
- Space Rental
- Ambulatory Surgical Centers Joint Ventures
- Electronic Prescribing and Electronic Health Records

The Anti-Kickback Statute – Practical Tips

- Concerned about relationships for the AKS
- Hospital – Physician relationships are prime source of AKS problems
- Control over contracting process for these relationships
  - Policy governing how contracts between facilities and physicians must be processed
  - Checklists for business purpose, FMV, etc.

Physician Self-Referral Law: Stark

General Prohibition:

"... If a physician (or an immediate family member of such physician) has a financial relationship with an entity ..., then the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made" under Medicare (also applicable to Medicaid).

Stark: Penalties

- **Strict liability statute**
- **Penalties include:**
  - Denial of payment for services provided
  - Refunds of amounts collected
  - Civil monetary penalties (up to $15,000 for each prohibited referral; up to $100,000 for a circumvention scheme)
  - Exclusion from Medicare/Medicaid
- **Potential FCA liability**

Three Questions

- Is there a referral by a physician for a designated health service payable by Medicare?
- Does the physician have a financial relationship with the entity furnishing the DHS?
- Does the financial relationship fit in an exception?

If not, there's a violation

What is a “Referral”?

- A request for, or the ordering of, or the certifying or recertifying of the need for, a DHS
- Establishment of a plan of care including DHS
- A request for a consultation with another physician and any test or procedure ordered by the physician-consultant

What is NOT a "Referral"?

- Service personally performed by the referring physician

- Services requested by a pathologist, radiologist or radiation oncologist pursuant to a consultation

Who are "Physicians" and "Immediate Family Members"?

- **Physicians:**
  - M.D., D.O.
  - Dentist, Podiatrist, Optometrist, Chiropractor
- **Immediate Family Members:**
  - Husband or wife
  - Birth or adoptive parent, child, sibling
  - Step-parent, step-child, step-brother or step-sister
  - Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law
  - Grandparent or grandchild
  - Spouse of a grandparent or grandchild

What are "Designated Health Services"?

- Clinical laboratory services
- Therapy services (PT/OT/SLP)
- Radiology & certain other imaging services
- Radiation therapy services
- DME
- Home health
- Parenteral and enteral nutrients & supplies
- Prosthetics, orthotics, prosthetic devices
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

What is a DHS "Entity"?

- A person or entity that "furnishes DHS" by
  - Billing Medicare for the DHS, or
  - Performing services billed as DHS (eff. 10/1/2009)
- Effectively prohibits (except in rural areas) referrals from physician ownership of entities that provide services to hospitals "under arrangements"
- Physician-owned entity becomes a DHS entity and must meet an ownership exception
  - No grandfathering; existing relationships had to be restructured or unwound

What is a Financial Relationship?

- **Ownership or Investment Interests**
  - Direct or indirect
  - Includes equity/stock, LLC membership interests, debt, loans
- **Compensation Arrangements**
  - Direct or indirect
  - Includes employment agreements, independent contractor relationships, leases, medical director agreements, other service agreements with physicians
  - Look for any remuneration -- in cash or in kind

Exceptions to the Stark Law

- **Generally, there are three types of exceptions:**
  - Ownership/investment interests (§411.356)
  - Compensation arrangements (§411.357)
  - "Services" (applicable to both ownership/investment interests and compensation arrangements)(§411.355)

- **Other "exceptions" (§411.353)**
  - "Knowledge" exception for payments made to an entity that did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the prohibited referral for DHS
  - Temporary noncompliance

Stark – Practical Tips

- Again, a relationship-based problem
- Practical solutions much the same as with the AKS
- Control over the contracting process through appropriate policy and checklists
- Control over Accounts Payable to ensure that checks are cut only when there is appropriate documentation

CMP - Beneficiary Inducements

- Unlawful to offer or give remuneration
  - To a Medicare/Medicaid beneficiary
  - If, know or should know, likely to influence beneficiaries to choose a particular provider, practitioner, or supplier
  - For a Medicare/Medicaid covered service
- Examples: waivers of co-payments; free gym memberships; coupons for local stores
- $10,000 civil penalty

CMP- Beneficiary Inducements

- Exceptions
  - Financial hardship waivers
  - Coinsurance differentials
  - Preventive care incentives
  - Anti-kickback safe harbor

CMP – Practical Tips

- Hot area related to care coordination and readmission issue
- Some relief around inducement issue under the ACO waivers

Self-Disclosure Protocol
OIG HHS & SRDP

What Gets Disclosed Where?

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

OIG Self-Disclosure Protocol

- Voluntary process to disclose self-discovered evidence of potential fraud (63 Fed. Reg. 58,399)
  - Provides detailed instructions for making a self-disclosure
  - Requires internal investigation and damages calculation
  - Requires full description of conduct
- Avoid costs and disruption of government directed investigation
- Lower settlement amounts
- Corporate Integrity Agreement not required

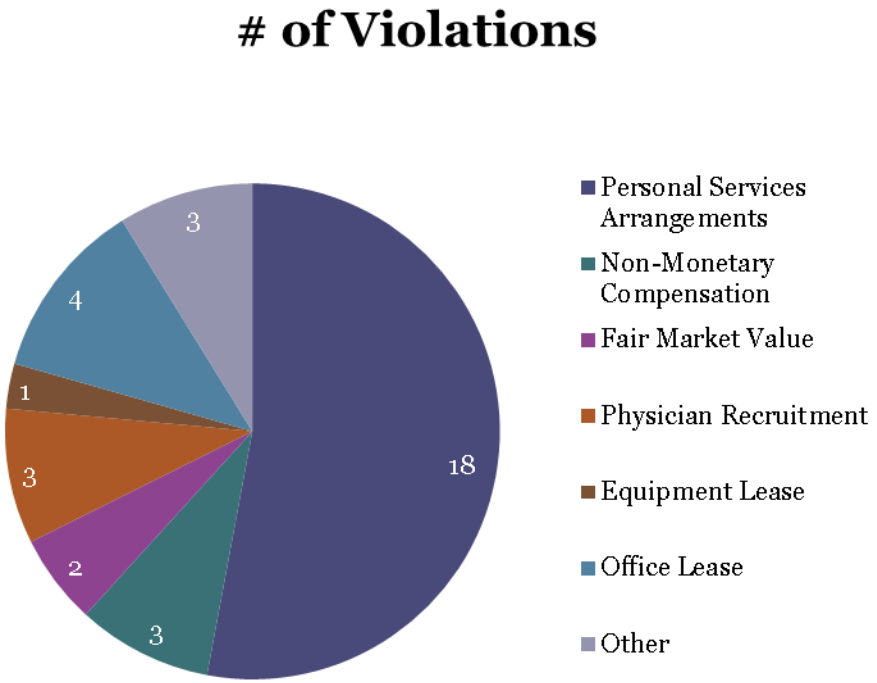
OIG Self-Disclosure Protocol

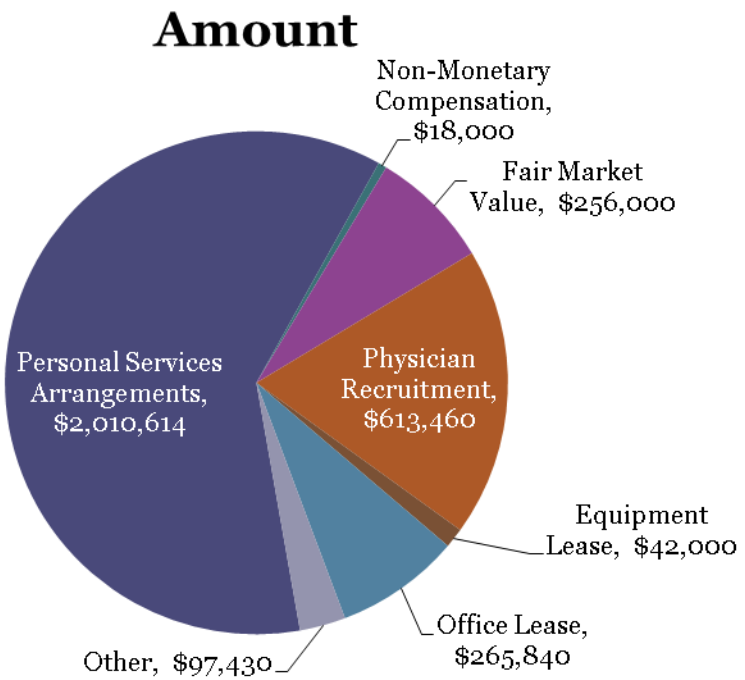
- March 24, 2009 Open Letter
  - Limited the scope of the OIG self-disclosure protocol regarding Stark - must include a colorable Anti-kickback violation
  - Minimum settlement amount of $50,000
- Monetary recoveries have exceeded $270 million
- Settlements posted on the OIG website
- http://oig.hhs.gov/fraud/selfdisclosure.asp
- Online submission process now available

Stark Self-Disclosure Protocol

- CMS statutory authority to compromise for amounts due and owing for only violations of Section 1877 of Soc. Sec. Act
- Estimated 300 disclosures; 29 published settlements
- "Look Back" Period
- Disclosures should be organized with complete legal and financial analysis and sufficient supporting information and documentation
- New practical tips on the Stark self-disclosure protocol put out by AHLA Public Interest www.healthlawyers.org/hlresources/PI/Documents/StarkSDP_4Pager_FINAL.pdf

CMS Settlements Under the Stark Self-Referral Disclosure Protocol February 2011 to June 2013





Hot Topics

Hot Topics: PODs

- Physicians moving into the distributor world
  - Largely confined to spinal and joint implant segments but Physician Owned Distributors (PODs) are spreading to other segments
- Sources of guidance:
  - OIG's 1989 Fraud Alert on Joint Venture Arrangements
  - 2006 correspondence between AdvaMed and OIG
  - 2008 OIG Congressional testimony
  - FY 2009 Stark Law annual regulatory process
  - Dec. 2011 Sunshine Act Proposed Rule includes PODs as distributors
- No clear legal boundaries – case-by-case analysis

Hot Topics: PODs

- **March 26, 2013: Special Fraud Alert "Physician-Owned Entities**
  - Addresses AKS concerns related to physicians holding ownership interests in companies that make money from the sales of implantable medical devices utilized by the physician-owners for their patients
  - Arrangements described as "inherently suspect" under the AKS
  - Reminders that the AKS applies to both parties involved in an impermissible kickback and "one purpose test"
- OIG identifies four major concerns with PODs: (i) corruption of medical judgment; (ii) over-utilization; (iii) increased costs to federal health care programs and beneficiaries; and (iv) unfair competition
- Lawfulness of a POD under AKS turns on the intent of the parties, which may be evidenced by a POD's characteristics, including its structure, operational safeguards, and actual conduct of the individuals involved

Hot Topics: PODs

List of Concerning Characteristics

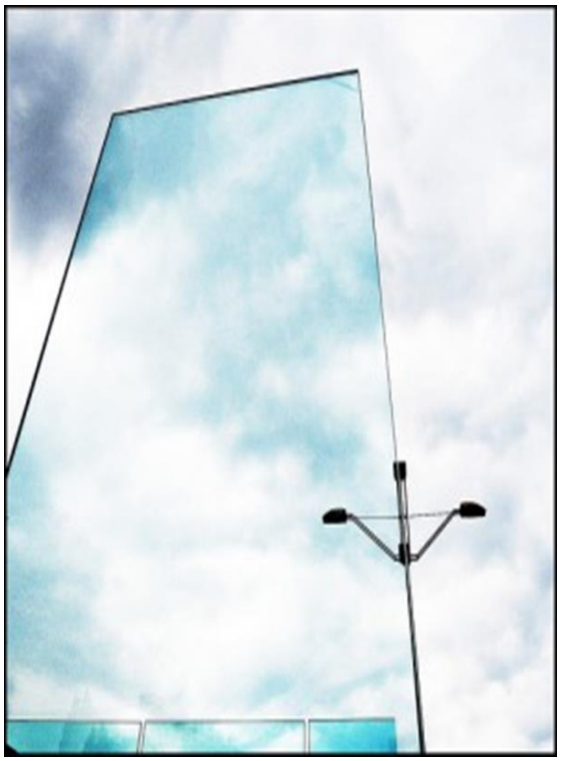
- Size of physician's investment varies with expected or actual volume or value of devices used by the physician
- Distributions are not in proportion to ownership interest
- Physician-owners condition their referrals to hospitals or ASCs on the purchase of the POD's devices through coercion or promises
- Physician-owners are required, encouraged or pressured to refer or arrange for the purchase of the devices sold by the POD
- The POD retains the right to repurchase a physician-owner's interest for failure to refer or arrange for purchase of the POD's devices
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain sufficient inventory, or employ necessary personnel
- The POD does not maintain continuous oversight of all distribution functions
- Hospital or ASC requires physicians to disclose conflicts of interest and the POD's physician-owners either fail to inform or actively conceal their ownership interest in the POD

Hot Topics: 60-Day Repayment Rule

- Affordable Care Act – amendments to the False Claims Act
  - 60-day deadline to report/return "identified" overpayments
  - Failure to do so – false claim liability
- "Identified"– knows or acts in "reckless disregard"
- Inquiries with "all deliberate speed"

Hot Topics: Data Use

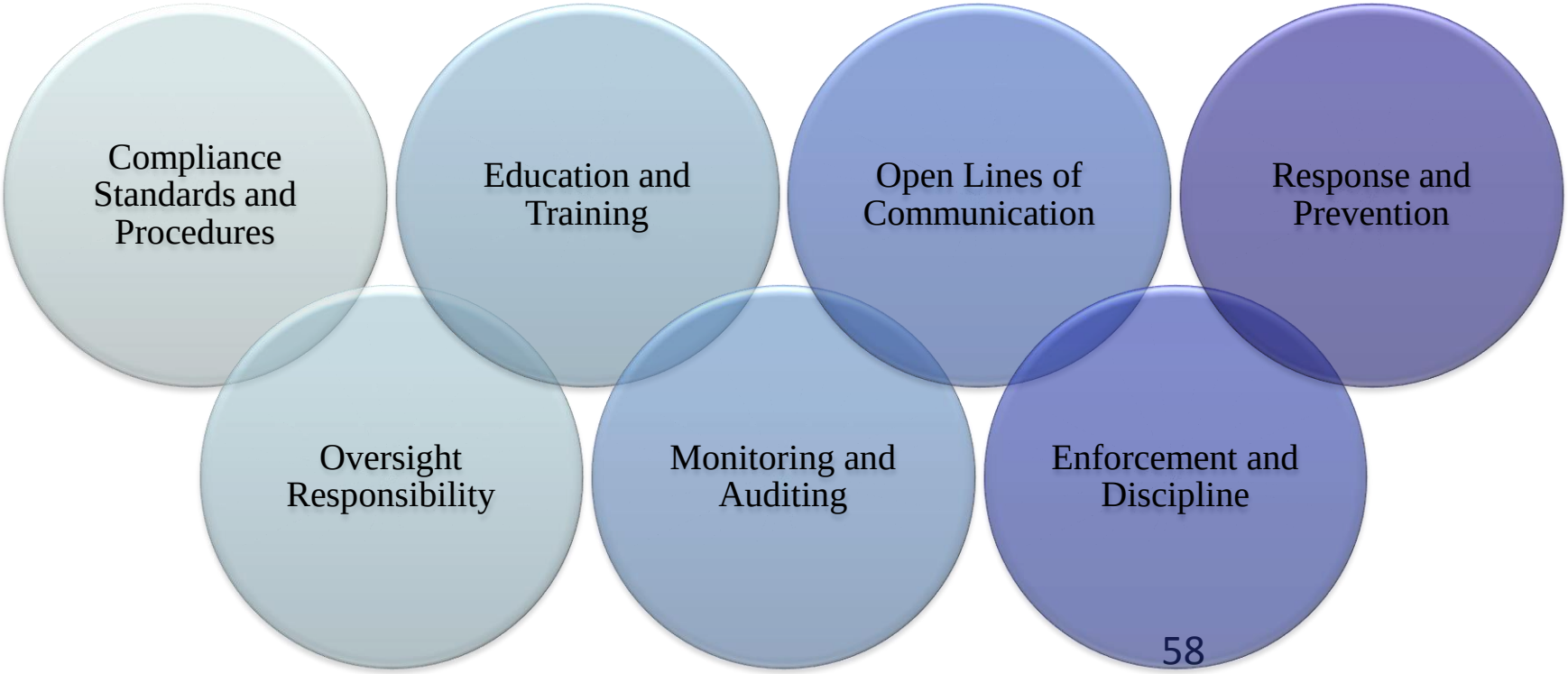
- Expanded Access to and Use of Data for Oversight and Enforcement
  - Data sharing agreements
  - Real-time data
- CMS Center for Program Integrity
- Impact of More Data
  - Transparency
  - Quality of Care
  - Accountability
- Volume metrics in transactional and operational decision making



Hot Topics: Compliance

- Benchmarking:
  - What is it?
  - How to do it?
  - Does it matter?
- What are the REAL measures of a strong compliance program?
- How does US DOJ view compliance?
- How do compliance programs influence charging decisions and resolutions?

Elements of An Effective Compliance Plan



OIG Work Plan

- Great place to start to set out your audit plan for the year

Hot Topics: Hospital Joint Ventures

- Increased Interest in Joint Ventures
  - Provides access to capital, expertise, and market growth
- Significant OIG Guidance on Joint Ventures
  - 1989 Special Fraud Alert on Joint Venture Arrangements
  - 2003 Special Advisory Bulletin on Contractual Joint Ventures
  - OIG Supplemental Compliance Program Guidance for Hospitals
  - OIG Advisory Opinions

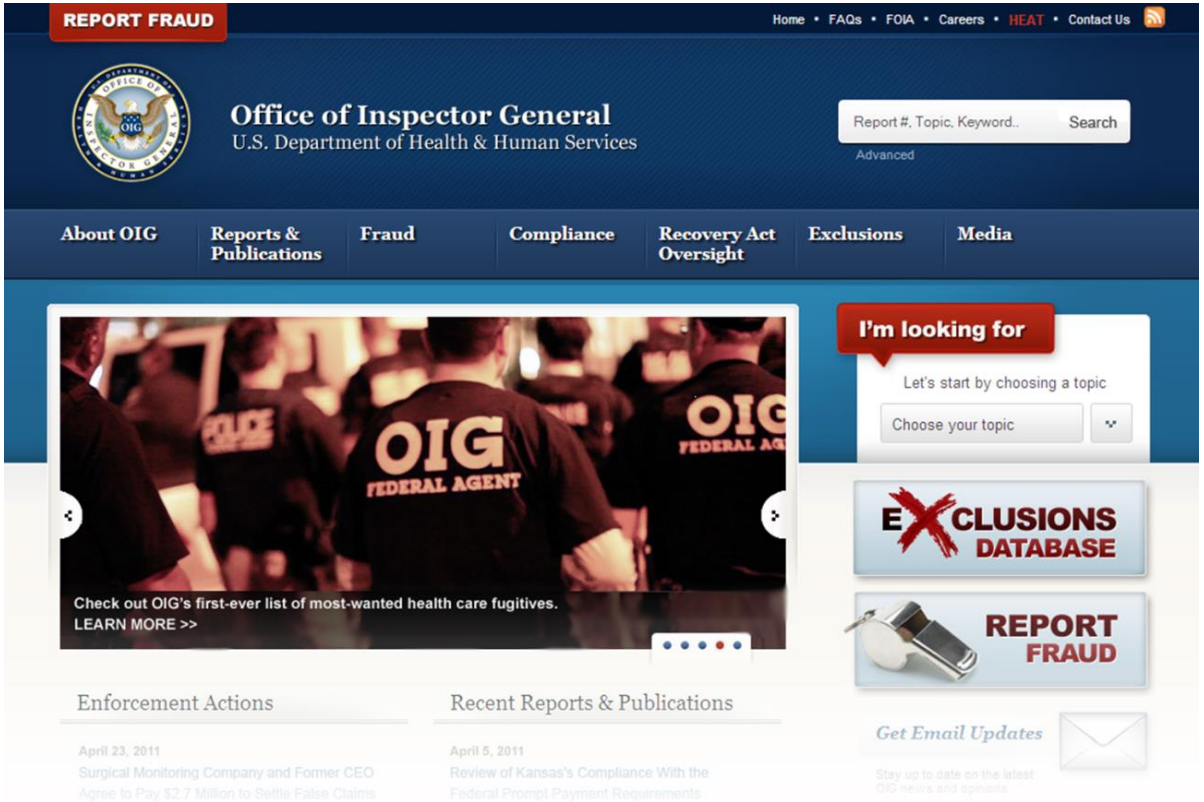
Hot Topics: Hospital Joint Ventures

- Review the applicable safe harbors:
  - Publicly Traded Entity Safe Harbor - 42 C.F.R. 1001.952(a)(1)
  - Small Entity Investment Safe Harbor - 42 C.F.R. 1001.952(a)(2)
  - Space Rental Safe Harbor - 42 C.F.R. 1001.952(b)
  - Equipment Rental Safe Harbor - 42 C.F.R. 1001.952(c)
  - Personal Services and Management Contracts Safe Harbor - 42 C.F.R. 1001.952(d)

Hot Topics: ACOs and CINs

- Accountable Care Organizations (ACOs) and Clinically Integrated Networks (CINs)
- ACOs include 5 waivers while CINs are in traditional fraud and abuse laws unless they are also an ACO that applies into the MSSP
- Will the waivers last?
- Are there more waivers to come?

Available Resources – www.oig.hhs.gov



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