

CSI: OIG

**I. Voluntary Disclosure Panelists**

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**D. Session C. CSI: OIG, plus HEALTH REFORM  
DISCLOSURE/REPAYMENT MANDATES**

**II. Intermediate to Advanced Session**

- A. Discussion will be based on examples
- B. Panelists will review options and potential consequences
- C. Discussion will include references to laws and cases.
  - Readers will find a brief overview of new laws and recent settlements and cases at the end
- D. The focus is on strategic advice and analysis of the facts of a potential violation

**III. LAWS**

- A. Laws imposing the obligation to disclose –
  - Health Reform (Stark voluntary disclosure and 60 day Repayment Obligation)
  - FERA amendments
  - Criminal statutes
  - Federal Criminal Sentencing Guidelines

**IV. Rewards and Risks of Self-Disclosure**

- A. Can providers expect a timely and equitable resolution?

- B. How can a provider manage the risks of a self-disclosure?
- C. What are the rewards of self-disclosure?
- D. What is the risk if the provider does not self-disclose?

**V. A. Lease Example**

- Your system has hired a real estate management company to administer the real property assets of the system. The new manager comes to you with a problem.
- She has compared revenue from the leases in the Medical Square Professional Office Building (POB) to the leases. She found that the leases require annual rent increases based on COLA.
- The system did not invoice the physicians for rent increases and they have paid the same monthly rental rate for the past three years.

**B. Options**

1. Invoice the physicians for the increased rent for the next month (or “correct” lease)
2. Investigate why the rent was not increased
3. For the past
  - a. Calculate and invoice the physicians for the rent not paid, or
  - b. Amend the leases retroactively to provide for flat rent (document mistake in lease drafting and reform the leases)
  - c. Ignore the discrepancy
4. If the docs pay the past rent or you amend the lease, should you disclose the violation?
5. Do you add interest?
6. If the docs refuse to pay past rent, do you
  - Sue?
  - Disclose?
  - Seek removal from the medical staff?

**C. Disclose to...**

1. OIG (open letter re Stark)
2. CMS (within 6 months?)
3. Assistant US Attorney
4. “Taxpayers Against Fraud”
5. IRS (intermediate sanctions)

**VI. A. RAC Overpayment Example**

- Your hospital system has been audited by a recovery audit contract (RAC) during each of past 3 years
- Substantial overpayments, resulting from automated billing system errors, have been identified as the source of the problem
- The underlying system problems have not been corrected and it is likely that erroneous claims continue to be submitted to Medicare
- You are not sure why corrections have not been made

## **B. Options**

1. Hope the RAC does not revisit this issue for a 4<sup>th</sup> time
2. Hire a consultant to erase the system's claims history
3. Undertake a corrective action plan that addresses the system problem going forward

## **C. Disclose to...**

1. The RAC
2. CMS
3. Fiscal Intermediary or Carrier
4. Assistant US Attorney
5. OIG
6. "Taxpayers Against Fraud"
7. IRS

## **VIII. A. Bribe Example**

- New hospital employed service line administrator for orthopedics dept asks to see you
- He has found letter from ACME Device Co. to the orthopedics dept manager agreeing to pay \$50 "consulting fee" each time a physician uses an ACME prosthetic
- Physicians are not employed

## **B. Options**

1. Tell the administrator to destroy the letter
2. Investigate the utilization of ACME devices in the department
3. Contact the physicians and document your discussion in a letter
4. Schedule medical staff education about bribes and kickbacks
5. Review the conflicts of interest policy
6. File a qui tam

## **IX. A. Medical Necessity Example**

- Finance director notices significant increase in admissions in urology department
- He receives copies of consultant reports urging department to admit patients with positive lab test and positive ultrasound finding for procedure involving high cost infusion
- He also receives memo from department chair advising physicians that this procedure will be done inpatient only, due to inadequate reimbursement for procedure if performed outpatient

## **B. Options**

1. Tell the finance director to destroy the memos
2. Investigate whether any RAC or enforcement action is being undertaken related to this infusion procedure
3. Engage QI review to determine best clinical practices
4. Engage review of judgmentally selected files for medical necessity review
5. Reply difference between outpatient and inpatient stay to CMS

6. Disclose internal review to law enforcement

## **X. Laws and Regulations**

### **A. False Claims Act**

1. More than \$24 B recovered by Gov't under FCA since 1986
2. Pfizer in September 2009 -- \$2.3 Billion
3. "Healthcare has accounted for the lion's share of fraud
  - a. settlements and judgments" under the FCA
4. 515 criminal actions and 387 civil actions in FY 2009
  - a. According to Senator Charles Grassley, more than 1,000 *qui tam cases are awaiting an intervention decision by the government*

### **B. Fraud Enforcement and Recovery Act of 2009 (FERA)**

1. FERA modifies existing federal criminal, securities, and money laundering laws and increases funding available to combat fraud
2. Section 4 of the Act modifies the False Claims Act to clarify the scope of its application, which FERA's sponsors thought had "been undermined by court decisions"

### **C. Criminal Felony Statute**

1. "Whoever having knowledge of the occurrence of any event affecting
  - (A) his initial or continued right to any such benefit or payment, or
  - (B) the initial or continued right to any such benefit or payment of any other individual
2. in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized shall . . . be guilty of a felony. . . ."
3. 42 U.S.C. § 1320a-7b(a)(3)

### **D. HHS OIG Voluntary Disclosure Website**

1. <http://oig.hhs.gov/fraud/selfdisclosure.asp>
2. OIG Provider Self-Disclosure Protocol Resources
  - Open Letter to Health Care Providers (March 24, 2009)
  - Provider Self-Disclosure Protocol Federal Register Notice ) (October 30, 1998 [63 Fed. Reg. 58,399])
  - <http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf>
  - Open Letter to Health Care Providers (April 15, 2008) <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf>
  - Open Letter to Health Care Providers (April 24, 2006) <http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf>
  - Selected Settlements under the Provider Self-Disclosure Protocol

3. Open Letter to Health Care Providers (March 24, 2009)

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Office of Inspector General  
Washington, D.C. 20201

**An Open Letter to Health Care Providers**

March 24, 2009

This Open Letter refines the OIG's Self-Disclosure Protocol (SDP) to build upon the initiative announced in my April 24, 2006, Open Letter. The 2006 Open Letter promoted the use of the SDP to resolve matters giving rise to civil monetary penalty (CMP) liability under both the anti-kickback statute and the physician self-referral ("Stark") law. As part of our ongoing efforts to evaluate and prioritize our work, these refinements aim to focus our resources on kickbacks intended to induce or reward a physician's referrals. Kickbacks pose a serious risk to the integrity of the health care system, and deterring kickbacks remains a high priority for OIG.

To more effectively fulfill our mission and allocate our resources, we are narrowing the SDP's scope regarding the physician self-referral law. OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation. We will continue to accept providers into the SDP when the disclosed conduct involves colorable violations of the anti-kickback statute, whether or not it also involves colorable violations of the physician self-referral law. Although we are narrowing the scope of the SDP for resources purposes, we urge providers not to draw any inferences about the Government's approach to enforcement of the physician self-referral law.

To better allocate provider and OIG resources in addressing kickback issues through the SDP, we are also establishing a minimum settlement amount. For kickback-related submissions accepted into the SDP following the date of this letter, we will require a minimum \$50,000 settlement amount to resolve the matter. This minimum settlement amount is consistent with OIG's statutory authority to impose a penalty of up to \$50,000 for each kickback and an assessment of up to three times the total remuneration. See 42 U.S.C. § 1320a-7a(a)(7). We will continue to analyze the facts and circumstances of each disclosure to determine the appropriate settlement amount consistent with our practice, stated in the 2006 Open Letter, of generally resolving the matter near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred.

These refinements to OIG's SDP are part of our ongoing efforts to develop the SDP as an efficient and fair mechanism for providers to work with OIG collaboratively. Further information about our SDP can be found at: <http://oig.hhs.gov/fraud/selfdisclosure.asp>. I look forward to continuing our joint efforts to promote compliance and protect the Federal health care programs and their beneficiaries.

Sincerely,  
/Daniel R. Levinson/  
Daniel R. Levinson  
Inspector General

4. Sample - Selected Settlements under the Provider Self-Disclosure Protocol  
04-20-2010

After it self-disclosed conduct to the OIG, St. Elizabeth Hospital and Mercy Medical Center of Oshkosh, Inc. (hospitals), Wisconsin, both part of the Affinity Health System, agreed to pay \$54,124 for allegedly violating the Civil Monetary Penalties Law provisions applicable to the Stark Law. The OIG alleged that the hospitals disclosed payments to three independent psychiatrists who provided behavioral health services at the hospitals' emergency rooms. Specifically, the on-call coverage arrangements between the psychiatrists and hospitals failed to comply with Stark Law requirements.

03-31-2010

After it self-disclosed conduct to the OIG, St. James Healthcare (SJH), Montana, agreed to pay \$275,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to the Stark Law. The OIG alleged that SJH entered into a space lease, an employee lease, and a medical services arrangement with an entity partly owned by SJH that failed to meet Stark Law requirements because they were not set forth in writing and signed.

03-01-2010

After it self-disclosed conduct to the OIG, Liberty HealthCare Systems, Inc. (Liberty), New Jersey, agreed to pay \$225,000 to resolve its liability for allegedly violating the Civil Monetary Penalties Law provisions applicable to the Stark Law. The OIG alleged that Liberty made an improper bonus payment to an employee physician based, in part, on the volume and value of referrals made by the physician.

**E. Health Reform Stark Voluntary Disclosure Protocol**

**1. H.R. 3590, Pub. L. No. 111-148, Section 6409**

**2. SEC. 6409. MEDICARE SELF-REFERRAL DISCLOSURE PROTOCOL.**

(a) DEVELOPMENT OF SELF-REFERRAL DISCLOSURE PROTOCOL.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in cooperation with the Inspector General of the Department of Health and Human Services, shall establish, not later than 6 months after the date of the enactment of this Act, a protocol to enable health care providers of services and suppliers to disclose an actual or potential violation of section 1877 of the Social Security Act (42 U.S.C. 1395nn) pursuant to a self-referral disclosure protocol (in this section referred to as an “SRDP”). The SRDP shall include direction to health care providers of services and suppliers on—

(A) a specific person, official, or office to whom such disclosures shall be made; and

(B) instruction on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements.

(2) PUBLICATION ON INTERNET WEBSITE OF SRDP INFORMATION.—

The Secretary of Health and Human Services shall post

information on the public Internet website of the Centers for Medicare & Medicaid Services to inform relevant stakeholders of how to disclose actual or potential violations pursuant to an SRDP.

(3) **RELATION TO ADVISORY OPINIONS.**—The SRDP shall be separate from the advisory opinion process set forth in regulations implementing section 1877(g) of the Social Security Act.

(b) **REDUCTION IN AMOUNTS OWED.**—The Secretary of Health and Human Services is authorized to reduce the amount due and owing for all violations under section 1877 of the Social Security Act to an amount less than that specified in subsection (g) of such section. In establishing such amount for a violation, the Secretary may consider the following factors:

H. R. 3590—655

(1) The nature and extent of the improper or illegal practice.

(2) The timeliness of such self-disclosure.

(3) The cooperation in providing additional information related to the disclosure.

(4) Such other factors as the Secretary considers appropriate.

(c) **REPORT.**—Not later than 18 months after the date on which the SRDP protocol is established under subsection (a)(1), the Secretary shall submit to Congress a report on the implementation of this section. Such report shall include—

(1) the number of health care providers of services and suppliers making disclosures pursuant to the SRDP;

(2) the amounts collected pursuant to the SRDP;

(3) the types of violations reported under the SRDP; and

(4) such other information as may be necessary to evaluate the impact of this section.

#### **F. FERA FCA clarifications**

1. Clarifies the applicability of the FCA to claims submitted to government contractors and grantees

2. Expands definition of “claim”

3. Codifies and defines materiality requirement (“natural  
a. tendency” test)

4. Expands false claim liability for certain retentions of overpayments

5. Partially retroactive effective date (subject to constitutional challenges)

6. Procedural amendments strengthen DOJ’s authority

#### **G. Health Reform and Expansion of FCA Liability for Retention of Overpayments**

1. Previously, a “false record or statement” was required to violate the FCA

2. Now, “knowing” and “improper” concealment or avoidance of an obligation is sufficient

3. Combine with Health Reform – required to repay an overpayment within 60 days of “identifying” the overpayment

#### **H. Executive Order 13520**

1. In response to a GAO report, President Obama issued an executive order requiring the Secretary of the Treasury to publish:
  - a. Names of entities that have received the greatest amounts of improper payments
  - b. Matters that have been or may be referred to the DOJ would not be published
  - c. Contractors who receive significant overpayments, but knowingly fail to disclose these overpayments to the Government
2. *Only if publication would not interfere with ongoing criminal or civil investigations*

#### **I. Federal Sentencing Guidelines**

1. Effective 11/1/2010--added steps
  - a. for corporations
2. To respond appropriately to criminal conduct that is detected and act to prevent further similar conduct
  - a. provide restitution or remediate harm if there is an identifiable victim or victims
  - b. self-report, cooperate with authorities, or undertake other remediation
  - c. assess risk and enhance the compliance and ethics program
  - d. ensure effective compliance presence

#### **J. McAllen Hospitals**

1. Hospital group paid illegal compensation to doctors to induce referrals
2. Payments were disguised through sham contracts, including
  - a. medical directorships and lease agreements
3. \$27 million
4. 5-yr CIA requires
  - a. Establishment of procedures for tracking and evaluating financial arrangements between health care facilities and referral sources
  - b. Training for employees involved with financial arrangements
5. Annual review by independent third party of compliance with the CIA

#### **K. Arlington Memorial Hospital**

1. Longstanding contract with a physician group to interpret arterial blood gas tests potentially violated the Stark Law and Anti-Kickback Statute
2. The hospital through its former president, paid a physician group for ABG tests even though the tests did not require any professional interpretation
3. To correct the compensation, the hospital’s former president agreed to pay the group for uncompensated charity care and oversight of the hospital’s blood gas lab

4. Settlement: \$990,509 (January 2010)

**L. Covenant (Waterloo, Iowa)**

1. Five employed physicians
2. Productivity bonuses and very high compensation
3. Settlement was a business decision “to avoid the uncertainty of litigation,”
4. Physicians were specialists who had been working in understaffed areas
5. Settlement: \$4.5 million ( August 2009)