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Hospital Compliance Under the OIG 2011 Work Plan

Preparing for Heightened Federal Scrutiny of Provider-Based Status, Quality Reporting and Reimbursement

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Today's faculty features:

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Hospital Compliance Under the OIG 2011 Work Plan:

Preparing for Heightened Federal Scrutiny of Provider-Based Status, Quality Reporting and Reimbursement

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March 17, 2011

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OIG 2011 Work Plan: OIG Mission and Activities

- OIG's mission is to protect program integrity and the beneficiaries by:
  - Detecting and preventing waste, fraud, and abuse;
  - Identifying opportunities to improve program economy, efficiency, and effectiveness; and
  - Holding accountable those who do not meet program requirements or who violate Federal laws.

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OIG 2011 Work Plan: OIG Mission and Activities (cont.)

- OIG activities:
  - Audits, evaluations, and investigations.
  - Guidance to industry.
  - Civil monetary penalties, assessments, and administrative sanctions.

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OIG 2011 Work Plan: OIG Component Groups

- The **Office of Audit Services (OAS)** provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others.
- The **Office of Evaluation and Inspections (OEI)** conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues.

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OIG 2011 Work Plan: OIG Component Groups (cont.)

- The **Office of Investigations (OI)** conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries.
- The **Office of Counsel to the Inspector General (OCIG)** provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations.

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OIG 2011 Work Plan: Purpose and Mechanics

- OIG issues a new Work Plan each fiscal year.
- The Work Plan describes the specific audits and evaluations OIG has underway or plans to initiate in the year ahead.
- The Work Plan provides general focus areas for OIG investigative, enforcement, and compliance activities.

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OIG 2011 Work Plan: Purpose and Mechanics (cont.)

- Many projects are carried over from year-to-year as priorities shift and projects planned in the beginning of the fiscal year are set aside.
- The fact that a project has not been carried over does not suggest the OIG is no longer interested in that area.

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OIG 2011 Work Plan: Hospital Part A Priority Issues

- **Priority Issues.**
  - Provider-Based Status for Inpatient and Outpatient Facilities.
  - Hospital-Reported Quality Measure Data.
  - Medicare Reimbursement.
  - Other Priority Areas.

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Provider-Based Status for Inpatient and Outpatient Facilities

"Doctor! Am I going to be all right?"

"Well, I'm afraid we're not sure yet. You appear to have over two hundred hard, white structures distributed throughout your entire body."

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Provider-Based Status for Inpatient and Outpatient Facilities (OAS).**
  - Third consecutive year for this issue.
  - When a hospital identifies a facility as provider-based, the services rendered there qualify for increased hospital-level inpatient or outpatient reimbursement — as compared to generally lesser reimbursement as a freestanding entity.
  - Provider-based status for outpatient clinics also may increase coinsurance liability for Medicare beneficiaries.

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Provider-Based Status for Inpatient and Outpatient Facilities.**
  - The OIG will determine the appropriateness of the provider-based designation and the potential impact on the Medicare program and its beneficiaries of hospitals improperly claiming provider-based status for inpatient and outpatient facilities.
  - Provider-based status remains an important area for internal compliance auditing and education:
    - Complex and subjective rules.
    - Potential to generate significant "supplemental payments" through the outpatient prospective payment system.

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Hospital-Reported Quality Measure Data

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Reliability of Hospital-Reported Quality Measure Data (OAS).**
  - Third consecutive year for this issue.
  - OIG will review hospitals' controls related to quality of care data submitted to CMS.
  - Hospitals are required to report quality measures for a set of 10 indicators to CMS. Failure to report the quality measures results in a two-percent payment reduction.
  - The OIG will determine whether hospitals have implemented sufficient controls to ensure the validity of their quality measurement data.

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Hospital Admissions with Conditions Coded Present-on-Admission (OAS).**
  - OIG will review Medicare claims to determine which types of facilities are most frequently transferring patients with certain diagnoses that were coded as being present on admission (POA).
  - For certain diagnoses specified by CMS, hospitals receive a lower payment amount if the specified diagnoses were acquired in the hospital rather than being POA.
  - OIG will determine whether hospitals have implemented sufficient controls to ensure the validity of their quality measurement data.

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Early Implementation of Medicare's Policy for Hospital-Acquired Conditions (OEI).**
  - OIG will review the early implementation of CMS's hospital-acquired conditions (HAC) policy.
  - The HAC policy prevents additional payment to hospitals under the IPPS for certain conditions or complications that are determined to be reasonably preventable.
  - OIG will review Medicare claims data to identify the number of beneficiary stays associated with HAC and determine their impact on reimbursement.

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Hospital Reporting for Adverse Events (OEI).**
  - OIG will continue its review of hospital reporting for adverse events.
  - Reviews will include an examination of the national incidence of adverse events among hospitalized Medicare beneficiaries and the extent to which hospital systems captured adverse events and reported the information to external patient-safety oversight entities.
  - OIG also will review responses to adverse events in hospitals by Medicare oversight entities.

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Medicare Reimbursement

Awesome, a turkey sandwich and a milk box. I can't believe my insurance company doesn't want to pay $245 a meal for this.

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Medicare Reimbursement Issues: Excessive Payments (OAS).**
  - OIG will review Medicare claims with high payments to determine whether they were appropriate.
  - Prior OIG work has shown that claims with unusually high payments are incorrect for a variety of reasons.
  - OIG will review certain outpatient claims in which payments by Medicare exceeded charges by the provider and the billing codes appear to be aberrant, and will review the effectiveness of the claims processing edits used to identify excessive payments.

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Medicare Reimbursement Issues: Hospital Inpatient Outlier Payments (OEI).**
  - Recent whistleblower lawsuits have resulted in millions of dollars in settlements from hospitals charged with inflating Medicare claims to qualify for outlier payments, which are supplemental Medicare payments to hospitals when patients incur extraordinarily high costs.
  - OIG will focus on hospital inpatient outlier payments and identify characteristics of hospitals with high or increasing rates of outlier payments.

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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Medicare Reimbursement Issues: Medicare Disproportionate Share Payments (OAS).**
  - Second consecutive year for this issue.
  - Because of increasing DSH payments, OIG will review whether these payments were in accordance with Medicare methodology and will examine the total amounts of uncompensated care costs that hospitals incur.

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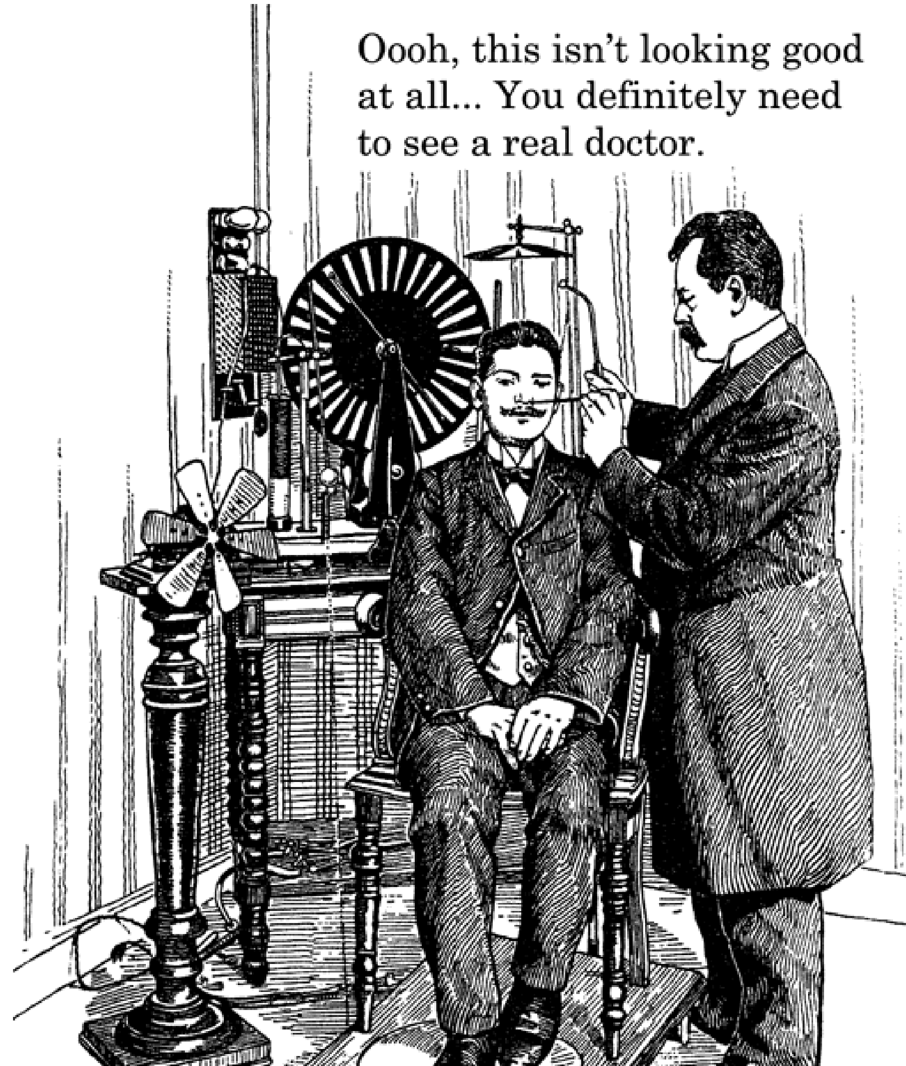
Other Priority Areas



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OIG 2011 Work Plan: Hospital Part A Priority Issues (cont.)

- **Other Priority Areas.**
  - Hospital Payments for Non-physician Outpatient Services Under the Inpatient Prospective Payment System (OAS).
  - Critical Access Hospitals (OAS).
  - Medicare Inpatient and Outpatient Hospital Claims for the Replacement of Medical Devices (OAS).
  - Observation Services During Outpatient Visits (OEI).

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Access the complete article on OIG's 2011 Work Plan at:
http://www.foley.com/publications/pub_detail.aspx?pubid=7586

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COMPLIANCE ACTIVITIES HEALTH CARE ORGANIZATIONS SHOULD UNDERTAKE IN RESPONSE TO THE OIG 2011 WORK PLAN

Presented by: Michael A. Dowell, Esq.

Arizona California Florida Illinois Indiana Massachusetts Minnesota Missouri New York Oregon Rhode Island Wisconsin

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Compliance Committee

- Discuss the 2011 OIG Work Plan
- Develop an annual work plan
- Identify Risk Areas that Impact You
- Document Efforts

Compliance Program

- Review compliance program
- Amendments Required?
- New Risk Areas to Add?

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Compliance Risk Assessment

- Risk Identification
- Risk Impact
- Vulnerability
- Compliance program controls assessment
- Rank risk areas and risk concern level
- Incorporate risk assessment results in the compliance program work plan.

Federal Sentencing Guidelines

- Periodically assess the risk of criminal conduct
- Take steps to reduce the risk of criminal conduct identified
- Proactive vs. Responsive
- Good Business Practice

Identifying Your Risks

- The 2011 OIG Work Plan;
- OIG fraud alerts
- Issues common to your healthcare industry
- New circumstances
- Licensing, accreditation, and certification requirements;

Factors to Consider in Risk Assessments

- Performance pressure.
- Incentives to engage in wrongdoing.
- Organizational culture.
- Internal controls.
- Lack of appreciation of applicable egal/ethical standards.
- Third-party-related risks.

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Risk Assessment Methods

- Risk Identification Surveys
- Interviews
- Focus groups
- Review company documents
- Review external industry information

Compliance Work Plan

- Develop an annual work plan
- OIG work plan
- Semi-annual risks assessments
- Audits (internal & external)
- Regulatory requirements
- Seven elements – education, training

Resources to Consider in Preparing a Compliance Work Plan

- The 2011 OIG Work Plan;
- State and federal laws,
- Licensing, accreditation, and certification requirements;
- OIG advisory opinions;
- OIG audit services and investigation reports;
- Local Medical review policies;
- Local coverage decisions;
- Medicare bulletins and CMS updates

Elements of a Compliance Program Work Plan

- Audits
- Investigations
- Consulting services
- Training and education
- Compliance services

Auditing and Monitoring

- Auditing
- Monitoring
- Formal Review
- Documentation
- Role of Legal Counsel

Educate Personnel

- New Risk Areas
- Mechanisms to reduce risk of noncompliance
- New policies and procedures
- Documentation

SAMPLE COMPLIANCE TOOLS

- Compliance Risk Identification Survey and Risk Assessment Tool (http://www.compliance-institute.org/pastCIs/2007/106-610-HambletonCooper/CD1_CHW-RiskAssessmentFacilitatorGuide.pdf)

- Compliance Work Plan (http://webdoc.nyumc.org/nyumc/files/compliance/attachments/FY_2011_WORK_PLAN_Final_9-16-10_cm.pdf)

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Potentialities

- Investigatory letter from the Department of Health and Human Services Office of the Inspector General (“OIG”).
- Time consuming, costly audit/investigation.
- Civil monetary penalties.
- Treble damages.
- Criminal penalties, including jail time.

Qui Tam Trends

- False Claims Act
  - Any person who knowingly presents, or caused to be presented, to an agent or officer of the United States government a claim for payment or approval that is false or fraudulent is liable to the United States for a civil penalty of not more than $11,000 per claim plus three times the amount of the government's damages.
  - The *qui tam* provision allows private citizens to sue on the government's behalf ("whistleblowers"). A whistleblower can receive 15-30% of the total proceeds from a successful case.
- DOJ recovered $2.5 billion in 2010 for False Claims Act violations related to health care fraud.
- Amendments since 2009 broadened the scope of the Act (FERA, PPACA).

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Qui Tam Trends Continued…

- The 60-Day Rule
  - PPACA expanded the definition of a "reverse false claim" to include the knowing retention of overpayments.
  - Overpaid funds must be reported and returned either within 60 days of identification or when the corresponding cost report is due.
  - Increased exposure. Potential for whistleblowers.
- Civil Investigative Demands
  - FERA authorized the U.S. Attorney General to issue Civil Investigative Demands ("CIDs"). U.S. Attorneys may issue a CID to any person believed to have possession, custody, or control over documents or documentary information relevant to an investigation of false claims prior to government intervention into a qui tam suit.
  - A CID can consist of (a) a request for the production of documents; (b) a demand for oral or deposition testimony; (c) service of interrogatories requiring written response; and (d) any combination of these devices.
  - FERA also authorizes U.S. Attorneys to share information obtained pursuant to a CID with counsel for a *qui tam* relator.
  - Increased exposure. Potential for whistleblowers.

Plan for Addressing Problems

- From OIG's website:
  - If you are engaged in a relationship you think is problematic or have been following billing practices you now realize were wrong:
    - Immediately cease filing the problematic bills.
    - Seek knowledgeable legal counsel.
    - Determine if any funds were collected in error from your patients and from the federal health care programs. Report and return overpayments.
    - Unwind the problematic investment.
    - Disentangle yourself from the problematic relationship.
    - Consider using OIG's or the Centers for Medicare and Medicaid's ("CMS") self-disclosure protocols.

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Internal Investigations

- Purpose: seek to uncover the truth about alleged misconduct within the organization.
- Typical elements:
  - Collect and examine written or recorded evidence.
  - Interview suspects and witnesses.
  - Obtain written statements.
  - Conduct computer and network forensics.
  - Consult with managers, human resources, and legal personnel.
- Helpful to have clear policies on conducting internal investigations.
- Document everything.
- Need-to-know-basis: inform only those necessary.

Self-Disclosure

- OIG Self-Disclosure Protocol (Anti-Kickback, False Claims Act violations)
- CMS Self-Referral Disclosure Protocol (Stark violations)

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OIG Voluntary Self-Disclosure Protocol ("SDP")

"The OIG's use of voluntary self-disclosure programs . . . is premised on a belief that health care providers must be willing to police themselves, correct underlying problems and work with Government to resolve these matters."

Federal Register, Vol. 63, No. 21, October 30, 1998.

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OIG Voluntary Self-Disclosure Protocol

- Matters that are “potentially violative of Federal criminal, civil or administrative laws.”
- OIG “may conclude that the disclosed matter warrants referral to DOJ.”
- No firm commitments about resolution – OIG is “not obligated to resolve the matter in any particular manner.”
- Opening lines of communication at an early stage “generally benefits” the provider.

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CMS Self-Referral Disclosure Protocol ("SRDP")

- Mandated by PPACA.
- Describes process for providers and suppliers to voluntarily disclose actual or potential violations of the physician self-referral or Stark law, and the associated actual or potential Medicare overpayment.
- CMS open to resolve certain Stark violations for less than the maximum possible penalties for disclosures through the SRDP.
- The Stark Law is a strict liability statute with huge potential penalties that could attach to even technical violations of the law, such as a lapsed contract or a missing signature. The SRDP represents a chance to reduce potential exposure to Stark Law penalties.
- Among concerns: CMS has "encouraged" parties to place anticipated repayments in an "interest-bearing escrow account." May be difficult for some providers.

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Decision to Voluntarily Self-Disclose: Considerations

- Why disclose?
  - Disclosure is a mitigating factor in determining the severity of the penalties.
  - Increased opportunity to negotiate a fair monetary settlement.
  - Offers providers the opportunity to minimize costs and disruptions from a full-scale audit/investigation.
  - Potential to avoid exclusion from federal health care programs.
  - Potentially high overpayment (>$1 million).
  - Right thing to do.
- Why not?
  - Does not guarantee protection from civil, criminal, or administrative actions from another agency.
  - Admission will likely carry substantial civil penalties.
  - May be used against you by private insurers.
  - Potential waiver of attorney-client privilege, information may become discoverable by a qui tam plaintiff.

Guidance

- OIG Self-Disclosure Guidelines:
  www.oig.hhs.gov/fraud/selfdisclosure.asp
- OIG SDP Guidance after 2003:
  www.oig.hhs.gov/fraud/openletters.asp
- CMS Self-Referral Disclosure Protocol:
  https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf

Responding to an OIG Investigatory Letter

- Litigation hold.
  - Communicate to all employees that they are not to destroy any documents related to the investigation.
- Conduct internal investigation.
- Cooperate with investigators.
  - Provide complete, truthful, accurate information to investigators.
  - Supply documents and materials within your control.
- OIG has the power to:
  - Obtain statements under oath.
  - Gather evidence.
  - Serve subpoenas.
  - Review documents relevant to a matter under investigation.
  - Under special authorities, make arrests.

Takeaways

- Take control and define scope.
- Obtain expert advice – bring counsel in early.
- Understand options for self-reporting.
- Address all elements of the protocol (whether OIG or CMS).
- Expect delays.
- Keep CEO and Board informed.
- Do not underestimate the benefits of a robust Compliance Program and Cooperative Approach.
- Anticipate publicity.