

The Role of the HHS Office of Inspector General

Third Annual Summit on Disclosure,
Transparency, and Aggregate Spend

March 10, 2011

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Overview

- Varied Work of the OIG in the Transparency/Disclosure Areas
- Transparency/Disclosure Issues in the Law Enforcement Context
- Trends/Recommendations

Office of Inspector General (OIG)

- Separate agency within HHS
- Oversight of agencies and programs within HHS
- Auditors, evaluators, investigators, and attorneys

Relevant OIG Work

- Reports by Office of Evaluation and Inspections (OEI) and Office of Audit Services (OAS)
- OIG Work Plan
- Fraud and Abuse Work
 - ◆ settlements are public

OIG website: www.oig.hhs.gov

Relevant OIG Work

- OEI Conflict of Interest Reports
 - ◆ Institutional Conflicts of Interest at NIH Grantees (1/11)
 - ◆ Part of a series of reports that also examined:
 - ◆ Outside activities of NIH senior employees
 - ◆ NIH oversight of conflicts in grantee institutions
 - ◆ Grantee oversight of NIH-funded research

Relevant OIG Work

- Work in Medicare Part D Area
 - ◆ OEI Report: Concerns with Rebates in the Medicare Part D Program (3/11)
 - ◆ OAS Report: Medicare Part D – Prescription Drug Event Reconciliation Process (6/10)
 - ◆ Part D work plan items

Law Enforcement Work

- Lack of Transparency/Disclosure Are Underlying Themes in Law Enforcement Activities
 - ◆ Pricing practices
 - ◆ Alleged reporting of false/inflated prices
 - ◆ Kickback allegations
 - ◆ Post-market studies
 - ◆ Registries

Law Enforcement Work

- Lack of Transparency/Disclosure Are Underlying Themes in Law Enforcement Activities
 - ◆ Off-label promotion matters
 - ◆ Non-disclosure of negative study results
 - ◆ Ghostwriting issues
 - ◆ Failure to appropriately report to FDA
 - ◆ Non-disclosure of identified problems

Law Enforcement Work

- Role of the OIG
 - ◆ Investigators
 - ◆ Lawyers
- Resolution of exclusion issues
- Negotiation of Corporate Integrity Agreements (CIAs)

What is Exclusion?

- Prospective administrative remedy
- Exclusion = no payment for items/services furnished by excluded provider (including indirect provider)
- OIG has sole authority for federal exclusion
- 42 U.S.C. § 1320a-7, 42 C.F.R. 1001

What is a Corporate Integrity Agreement (CIA)?

- 5-year contract between OIG and provider
- Alternative to exclusion – often required in exchange for exclusion release
- Negotiated and monitored by OIG

Corporate Integrity Agreements

- Typically, a 5-year term
- Requires several measures, including:
 - ◆ Compliance Officer/Committee
 - ◆ Code of Conduct/Written Policies
 - ◆ Training
 - ◆ Audits
 - ◆ Reports to OIG

CIA Provisions

- Requirements Designed to Increase Accountability
 - ◆ Annual board of directors resolutions
 - ◆ Certifications from key members of management

CIA Provisions

- Requirements Designed to Increase Transparency
 - ◆ Posting of information about payments to HCPs on manufacturer's website
 - ◆ CIA requirements in light of section 6002 of the Affordable Care Act

CIA Provisions

- **Broad Scope of Transparency and Disclosure Requirements**
 - ◆ Require continued posting of grant, other information
 - ◆ Ensure that contracts with consultants and authors require disclosure
 - ◆ Require continued posting of clinical trial information
 - ◆ Compendia issues

Trends and Predictions

- Continued Enforcement Actions against Drug and Device Companies
 - ◆ Large numbers of FCA matters
 - ◆ Including against device manufacturers
 - ◆ Large numbers of criminal actions
 - ◆ Increasing scrutiny of individuals

What makes a compliance program effective?

- Support from top level of the organization
- Involvement/accountability at all levels
- Comprehensive, tailored program
- Ongoing assessments

Recommendations

- Key areas of focus
 - ◆ Payments to physicians
 - ◆ Affordable Care Act - Section 6002
 - ◆ Transparency around drug samples
 - ◆ Affordable Care Act – Section 6004
 - ◆ PBM transparency requirements
 - ◆ Affordable Care Act – Section 6005

Recommendations

- **Assess Transparency and Disclosure in:**
 - ◆ detailing relationships and activities
 - ◆ consulting/contractual arrangements
 - ◆ research activities
 - ◆ publication activities
 - ◆ educational activities



Questions?

