The Role of the HHS Office of Inspector General

Third Annual Summit on Disclosure, Transparency, and Aggregate Spend
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Mary E. Riordan, Office of Counsel to the Inspector General
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)
  - 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?