The Role of the HHS Office of Inspector General

National Disclosure Summit
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Overview

- Background about OIG
- Report from OIG Pharmaceutical Compliance Roundtable
- Recommendations

Office of Inspector General (OIG)

- OIG participates in settlements of health care fraud cases with Department of Justice
- Corporate Integrity Agreements (CIAs) are common elements of settlements
- CIAs are alternatives to exclusion

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

OIG Pharmaceutical Compliance Roundtable

- Day-long meeting with compliance professionals from 23 pharmaceutical manufacturers currently under CIAs
- Large and small group sessions
- Report issued on OIG website yesterday

OIG Pharmaceutical Compliance Roundtable

- Topic 1: Challenges in Implementing CIAs
  - Defining Relevant Covered Persons
  - Training Requirements
    - Training methods
    - Hours of training

OIG Pharmaceutical Compliance Roundtable

- Topic 1: Challenges in Implementing CIAs
  - Payment-Posting Requirements
    - CIA definitions consistent with Affordable Care Act (ACA) definitions
    - Differences between CIAs and ACA in “how” to report
      - Posting on company websites
      - Quarterly and annual posting requirements

OIG Pharmaceutical Compliance Roundtable

- Topic 2: Compliance Program Structure and Oversight
  - Board of Director Oversight of, and Participation in, Compliance Activities
  - Integration of Compliance into “The Business”

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- Topic 3: Risk Identification and Monitoring Activities
  - Risk-Assessment Practices
  - Monitoring Activities

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- Topic 3: Risk Identification and Monitoring Activities
  - Monitoring Activities
    - Call note and speaker program reviews
    - Ride-along activities
    - Management certifications
    - Flexibility in monitoring activities

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- Topic 4: Policies, Procedures, and Training Activities
  - Policies and Procedures
    - Process and timing for development and revision
    - Accessibility and format

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- Topic 4: Policies, Procedures, and Training Activities
  - Training
    - Goal is effective training
    - Training of contractors/vendors

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- Topic 5: Compliance Post-CIA
  - Compliance Measures Expected to Continue after CIAs Expire
    - Certifications and board involvement
    - Training and disclosure activities
    - Field force monitoring
    - IRO-type reviews

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- Topic 5: Compliance Post-CIA
  - Predicted Future Compliance Challenges
    - Changing legal/regulatory requirements
    - Technology and social media
    - Changing business models and activities

OIG Pharmaceutical Compliance Roundtable

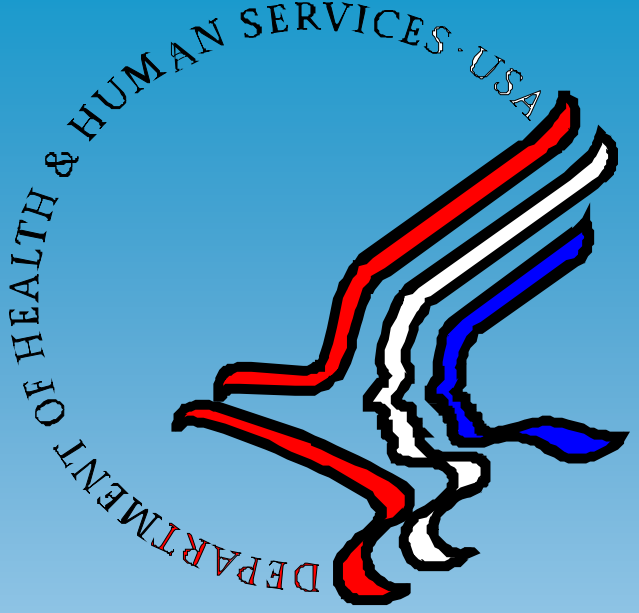
- Conclusions
  - Constructive dialogue
  - Positive feedback
  - OIG to consider comments for future CIAs

Recommendations

Consider Transparency and Disclosure Broadly, for example in:

- detailing relationships and activities
- consulting/contractual arrangements
- research activities
- publication activities
- educational activities

Questions?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