CIAs and Compliance Programs

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Background information about HHS-OIG

- The Office of Inspector General (OIG) is one operating division of the United States Department of Health and Human Services (HHS).
- HHS-OIG is a nationwide organization with approximately 1600 employees.
- The mission of HHS-OIG is to:
  - Prevent and detect fraud and abuse in HHS programs (e.g., Medicare/Medicaid); and
  - Improve efficiency in HHS programs (including through program audits and reviews).

Background information about HHS-OIG

- Among other law enforcement activities, HHS-OIG works with DOJ to investigate and resolve health care fraud cases.
- The resolutions of civil False Claims Act matters typically include a monetary component (settlement amount) and a resolution of the OIG's exclusion authorities.
- OIG is authorized to exclude individuals/entities from participation in Federal health care programs.
  - 42 U.S.C § 1320a-7
- Exclusion is a prospective administrative remedy that prohibits payment by Federal health care programs for items and services furnished by excluded individuals or entities.

Compliance Related Resources

- OIG's website has many compliance-related resources that can be accessed at: https://oig.hhs.gov/compliance/index.asp
- The resources include the following:
  - Compliance Guidance - voluntary compliance program guidance documents directed at various segments of the health care industry
  - CIA documents
    - Active CIAs with individuals and entities
    - Closed CIAs
    - Risk Fraud Indicator
    - CIA enforcement summaries
  - Compliance Portal

OIG Considerations in Implementing Permissive Exclusion

- OIG considers health care fraud cases on a risk spectrum.
- OIG considers four broad categories of factors when determining whether to exclude or seek a CIA:
  - Nature and circumstances of the conduct
  - Conduct during the Government's investigation
  - Significant ameliorative efforts of the provider
  - History of compliance
- The existence of a compliance program that incorporates the 7 elements of an effective compliance program does not affect the risk assessment. The existence of a compliance program is a neutral factor.

What is a Corporate Integrity Agreement (CIA)?

- An agreement with HHS-OIG entered in connection with the settlement of a civil False Claims Act matter.
- Consideration for entering into a CIA is a waiver of OIG permissive exclusion authority.
- The agreement imposes upon a provider/corporation/individual (or requires a company to continue) certain integrity obligations on a going-forward basis for a period of years.
- Integrity obligations are based on 7 elements of an effective compliance program.
- CIAs typically are for a term of 5 years.

Overview of Corporate Integrity Agreements

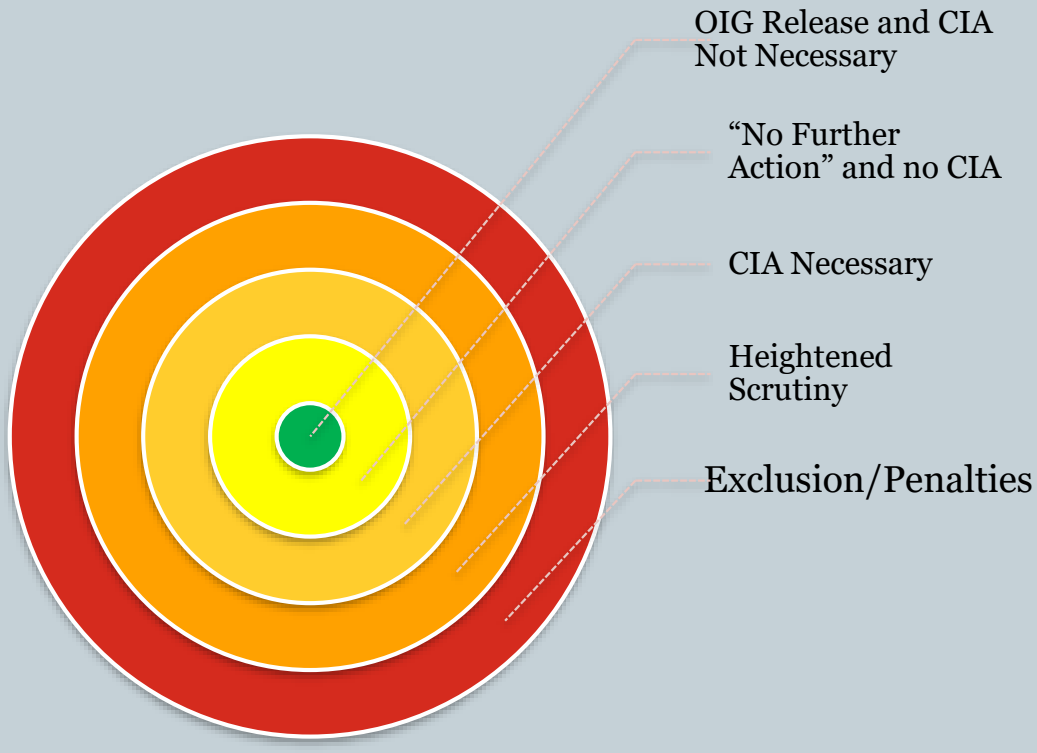
- OIG has entered CIAs with individuals and entities in virtually every health care sector.
  - Examples include: hospitals, nursing homes, pharmaceutical manufacturers, device manufacturers, DME suppliers, retail pharmacies, PBMs, billing companies
  - CIAs apply to direct and indirect billers and other entities
- A complete list of all current CIAs is available at: http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp

Standard CIA Provisions

- Compliance officer, compliance committee
- Board obligations
- Policies and procedures
- Training
- Independent Review Organization (IRO) review provisions
- Disclosure program
- Screening against OIG/GSA databases
- Reporting (e.g., Annual Reports, Reportable Events, Government Investigations, Overpayments)
- Certifications from Compliance Office and Chief Executive Officer
- Breach and Default Provisions

CIA Negotiation: When do you need a CIA?

OIG relies on a series of risk factors to create a "risk score." Depending on a risk score, the agency will identify one of five outcomes



CIA Negotiation

- Negotiation of compliance obligations, whether as part of CIA or with DOJ, has unique implications that require careful consideration
  - Begins the relationship with government monitor/overseers
  - Fundamentally different from negotiation of a criminal resolution or False Claims Act settlement
    - Affirmative obligations imposed on company that require substantial monetary and human resources
    - Failure to meet CIA obligations may result in stipulated penalties (e.g., fines) or exclusion

CIA Negotiation

- The vast majority of CIA requirements are standard and largely non-negotiable
  - Some room to negotiate the scope of those provisions
- Certain key CIA requirements raise significant operational and resource challenges
  - Requires knowledge of business model, compliance resources and day-to-day operations

CIA Negotiation – Some Key Provisions

- Covered Persons
  - Entities and affiliates
  - Contractors and subcontractors
- Certification Requirements for senior managers
- Scope of Board oversight of compliance program
- Notice to health care providers/customers
- Monitoring programs
- Scope of IRO Reviews
  - E.g., claims reviews may have consequences for non-CIA entities (i.e., customers)

CIA Negotiation

- Prepare business and compliance program before implementation
  - All aspects of company will be affected (not just compliance)
    - Business needs to “own” compliance
    - Educate on interactions with IRO and government monitors
    - Mock/shadow IROs
    - Education of senior managers and Board
  - Anticipate expected provisions and tailor programs to company’s resources
- Understand each company’s unique circumstances and priorities

ABOUT FDA

- FDA is a federal science-based law enforcement agency mandated to protect the public health.
- FDA is the oldest comprehensive consumer protection agency, beginning with the 1906 Pure Foods and Drugs Act.
- FDA is an agency of the United States Department of Health and Human Services.
- FDA has over 16,000 employees, including scientists, investigators, medical doctors, and other professionals.
- FDA regulates products representing roughly 25 percent of all U.S. consumer spending.

FDA is Responsible For

- Protecting the public health by assuring that
  - foods are safe, wholesome, sanitary and properly labeled;
  - ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations

FDA Components

Office of the Commissioner (OC)

Office of Regulatory Affairs (ORA)

Center for Food Safety and Applied Nutrition (CFSAN)

Center for Drug Evaluation and Research (CDER)

Center for Devices and Radiological Health (CDRH)

Center for Biologics Evaluation and Research (CBER)

Center for Veterinary Medicine (CVM)

Center for Tobacco Products (CTP)

National Center for Toxicological Research (NCTR)

FDCA Section 302 (21 U.S.C. § 332)

Federal Courts have the power to enjoin conduct that violates the FDCA.

Relief sought is forward looking; i.e., to enjoin a firm from manufacturing until it is in compliance with the FDCA.

Civil injunctive matters are typically resolved with a consent decree negotiated by the parties.

Consent decrees:

- Have the force of law once entered by the court
- Are punishable by civil or criminal contempt

Standard Consent Decree Provisions:

- Broad prohibitory language
  - Enjoined From directly or indirectly, doing or
  - causing . . . violations of the Act.
- "Up Front Shutdown" Provision
- Future Inspections and Investigations
- Defendants pay costs
- "Letter Shut Down" Provision
- Notice provisions
- Arbitrary and Capricious Standard of Review
- Liquidated Damages

- Other possible provisions:
  - Independent Expert and Continuing Audits
  - Destruction of existing inventory

Compliance Agreements

- Civil Consent Decrees
  - U.S. v. Ranbaxy (D. Md.) – 2012
- Criminal Plea Agreements
  - U.S. v. Abbott Labs. (W.D. Va.) – 2012
  - U.S. v. AmerisourceBergen (E.D.N.Y.) – 2017

U.S. v. Ranbaxy

- Adulteration of Drugs – due to rampant cGMP and data integrity failures (also false statements)
- Civil Consent Decree – 2012
  - U.S. v. Ranbaxy Labs., et al., 1:12-cv-250-JFM (D. Md.)
- Criminal Plea & FCA Settlement – 2013
  - $150 million criminal fine and forfeiture
  - $350 million settlement FCA and related state laws
  - Relator share approx. $48.6 million

Ranbaxy Consent Decree

U.S v. Ranbaxy Labs., et al., 1:12-cv-250-JFM (D. Md.)

- Detailed data integrity provisions before FDA resumed reviewing drug applications
  - third party expert to conduct review
  - implement procedures and controls
  - withdraw any applications with irregularities
- Once in compliance, third party expert must conduct audits of the facilities to confirm ongoing compliance
- Individual responsible for all quality assurance and quality control activities
- Office of Data Reliability to conduct pre-submission audits of all applications

U.S. v. Abbott Labs.

- Misbranding of Drugs – inadequate directions for use for unapproved uses
- Criminal Plea – 2012
  - U.S v. Abbott Labs., 1:12-cr-00026-SGW (W.D. Va.)
  - $700 million criminal fine and forfeiture
- Civil Settlement – 2012
  - $800 million for FCA and related state law violations
  - Relators' share approx. $84 million

Abbott Labs Compliance Agreement

U.S v. Abbott Labs., 1:12-cr-00026-SGW (W.D. Va.)

- Compliance measures contained in the plea agreement and condition of probation (5 years)
- Annual CEO certification and Board Resolution
- Policies and procedures designed to prevent violations of the FDCA
- Reporting requirements
- Restructuring of salesforce compensation
- Separation of sales and marketing from decisions on grants for CME; third-party CME provider
- Disclosure of role in funding in all scientific publications and research

U.S. v. AmerisourceBergen

- Misbranding of drugs – establishment not registered with FDA (also repackaging for overfill)
- Criminal Plea – 2017
  - U.S v. Amerisource Bergen, 17-cr-507-NG (E.D.N.Y.)
  - $260 million criminal fine and forfeiture
- Civil Settlement – 2018
  - $625 million for FCA and related state law violations
  - Relators' share approx. $93 million

AmerisourceBergen Compliance Agreement

U.S v. Amerisource Bergen, 1:17-cr-507-NG (E.D.N.Y.)

- Compliance measures attached to plea agreement
- Program to prevent, detect, and correct violations of law and company policies and procedures
- Policies and procedures designed to prevent violations of the FDCA
- Chief Compliance Officer reports to Board of Directors
- Notification and display on website for reporting
- Log of reports and calls and Certifications
- Resolution of Board of Directors
- Filing of Certifications with United States
- Liquidated damages
- Three years

Compliance Agreements

- Common Requirements
  - Chief Compliance Officer
  - Policies and procedures designed to prevent violations of the FDCA
  - Detection; training; reporting; corrective action plan
  - Independent Expert and Continuing Audits
  - Notice provisions and violation reporting
  - Certified Logs
  - Liquidated Damages
  - CEO and Board Oversight and Certifications

- FDA oversight factors to prevent violations
  - Risk to public health (likelihood; magnitude)
  - Ongoing vs. past conduct