



Living Under and Negotiating a Corporate Integrity Agreement

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Understanding CIAs

Corporate Integrity Agreements

- Over 450 CIAs on record
- Typically 3 to 5 years in duration (precedent being set for 8 years for high-profile providers)
- Requires corporate integrity program
 - ❖ Compliance oversight structure
 - ✧ senior management
 - ✧ in most CIAs not the CFO or GC
 - ✧ regular reports to the CEO and/or Board
 - ✧ Compliance Committee
 - ❖ Written policies and procedures to be established
 - ✧ Code of Conduct (content & distribution)
 - ✧ element in evaluating performance
 - ✧ policies for complying with all laws & regs

Corporate Integrity Agreements

continued

- Training & Education
 - ❖ General Training (within 120 days, 2 or 3 hours, all employees)
 - ✧ CIA requirements, Compliance Program, Code
 - ❖ Specific Training (within 120 days, 2 to 4 hours, covered employees)
- Annual audits reported to OIG (internal/external)
- Confidential Disclosure Program (24hour/7days)
 - ❖ non-retribution, promotion, anonymous
- Pre-screening of potential hires (excluded, suspended, debarred)
- Compliance and Pricing Reviews

Corporate Integrity Agreements

continued

- OIG right to inspect records and to conduct audits
- OIG right to interview
- Stipulated damages assessed for non-compliance
- Independent review organization requirement

Independent Review Organization

- IRO independence can be an issue
- Ensure that the IRO is expert in your business
- Two types of reviews -
 - ❖ Performance or Pricing review
 - ✧ Reported Price Procedures
 - ✧ Testing of Rebate Amounts
 - ✧ Systems Procedures
 - ❖ Compliance review
- IRO function can be “negotiated”
 - ✧ ambiguity
 - ✧ attach a work plan
 - ✧ transition work away from IRO to organization

CIA Challenges

- OIG resources and understanding of your business
- CIAs must be written so that they may be objectively tested
- Difficult to do for entities that have not implemented compliance programs
- Requires evaluation of
 - ❖ Current processes and controls
 - ❖ Planned or future processes and controls

Bayer CIA - The Industry Model

- Standard Corporate Integrity Program
- Policies, Procedures, Training
 - ❖ Focused on proper price reporting and legal marketing strategies
 - ❖ First CIA to acknowledge web-based training
- Novel price reporting obligation “Average Sales Price”
 - ❖ To States and OIG
 - ❖ In addition to AWP

Bayer CIA - The Industry Model

continued

- ASP - all non-governmental sales (except direct sales to hospitals) exclusive of bona fide grants and charity care
- Special rules re: rebate forecasting



Negotiating the CIA

Negotiations with OIG

- Potential for “Standard Draft”
- Understand OIG: Position on Issues
 - ❖ Demonstrate “ how this problem will not happen again”
 - ❖ Establish Communications
- Prepare for Negotiations
 - ❖ Involve client’s compliance team
 - ❖ Involve IRO in scope development

Negotiations with OIG

continued

- Present current Compliance Structure
 - ❖ Use to reduce scope of IRO
 - ❖ Shift monitoring to internal resources
 - ❖ Present alternatives to address OIG concerns
- Incorporate Re-negotiation Options

CIA Negotiations

- Standard clause
- Frequently asked questions
- Annual report contract checklist
- Pick your battles

CIA Issues

- Definition of “Covered Persons”
- Limits on Training
- Government access issues / interview rights
- Definition of “Material Breach”
- Appellate Rights
- Sampling Issues
 - ❖ Probes
 - ❖ Triggers

CIA Issues

continued

- Systems Procedures
- Retention of Records
- Independence of IRO
- Involvement of Compliance or Internal Audit
- Sunset Provisions



Lessons to be Learned

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1. Understand enforcement issues
2. Understand what your company is doing
 - ❖ Price Setting AWP
 - ❖ Marketing the AWP spread
 - ❖ Price reporting - AWP, BP, PHS, FSS
 - ❖ Sampling
 - ❖ Incentives - to physicians, pharmacists, PMBs, government agents
 - ❖ Educational & research grants
 - ❖ “Value Added” services
 - ❖ Private labeling, repackaging, relabeling

Lessons to be Learned

continued

- Ensure adequate compliance resources
- Review and revise relevant policies
- Separately, review and revise relevant procedures
- Review systems
 - ❖ AMP
 - ✧ appropriate transactions?
 - ✧ rebates?
 - ❖ BP
 - ✧ all appropriate transactions?
 - ✧ rebates?
 - ✧ PBM rebates?

Lessons to be learned

continued

- Web based training



Questions & Answers

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