Corporate Integrity Agreements and Emerging Issues

A presentation to the Fifth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

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Corporate Integrity Agreements and Emerging Issues

CIA Implementation – 10 Steps to Success

Arjun Rajaratnam, Esq., Compliance Officer, Global Pharmaceuticals, GlaxoSmithKline
CIA Implementation – 10 Steps to Success

1. Understand requirements of Corporate Integrity Agreement
   - Who is a Covered Person?; Who is excluded?
   - Do you have to train secretaries on healthcare law?

2. Seek clarification from Legal and Office of Inspector General
   - Obtain clear guidance on all major interpretations
   - Which contractors are included?
   - Which activities and departments are covered?

3. Form a cross-functional team with senior management support
   - Establish CIA Steering Committee
   - Hire a full time dedicated manager
   - Secure the right budget

4. Determine deliverables and best method to implement
   - Annual Worker Screening
   - CIA Training

5. Develop Project Plan to include:
   - Annual report production and delivery
   - Development and implementation of processes / operations
CIA Implementation – 10 Steps to Success

6. Communicate
   o Communicate requirements and plans to all involved staff
   o Establish collaborative work environment
   o Keep executives informed of progress through regular updates

7. Track Progress against Plan
   o Assign and track actions/issues to completion
   o Discuss progress at regular meetings

8. Maintain Regular communications with Independent Review Organization

9. Check on progress and direction with OIG; seek further clarification if necessary

10. Create a new CIA delivery plan for each year
    o Hold oneself accountable to other stakeholders as a model
### Key Dependencies

- CIA Deliverable Timeline: 2004 to 2005

#### SPCM
- **3Q 2004:** Systems Review
- **4Q 2004:** Systems Review
- **2005:** Response & Corrective Action Plan of Issues Raised by IRO

#### Managed Markets Operations
- **3Q 2004:** Specific Training to Relevant Covered Persons
- **4Q 2004:** General Training to Covered Persons
- **Jan:** Annual Process Assessment
- **Feb:** Track & Record Distribution of Changes
- **Mar:** Changes Communicated to All Covered Persons
- **Apr:** Annual Report
- **May:** Annual Report
- **Jun:** Copy of Training Materials
- **Jul:** Annual Report

#### Training
- **3Q 2004:** Annual Report
- **4Q 2004:** New Hire Training
- **2005:** Annual Report

#### IRO
- **3Q 2004:** Draft Medicaid Drug Rebate Systems Report
- **4Q 2004:** Draft IRO Report
- **2005:** Final IRO Report
- **2006:** Certification of Prof. Independence

#### Annual Training
- **3Q 2004:** CIA eLearning Modules Developed
- **4Q 2004:** Verity Certifications for Refresher Training

#### Systems Review
- **2005:** Contract Pricing Review Complete
- **2006:** Annual Report
Corporate Integrity Agreements and Emerging Issues

Deconstructing Recent CIAs – Implications to Risk Management and Compliance Programs

Jonathon Kellerman, Director, PricewaterhouseCoopers
Deconstructing Recent CIAs – Implications to Risk Management and Compliance Programs

New elements of CIA/IRO requirements

1. Government Pricing
   - MMA mandated ASP reporting and testing of transactions to methodology
   - Broader scope from government reimbursed products to “covered products”
   - Inclusion of AMP in scope
   - Certification of MMA ASP by CFO or “high managerial agent”

2. Off Label Promotion
   - IRO - Comprehensive promotional and product services systems review
   - IRO - Transactions testing from inquiry management system (i.e., focusing on medical inquiries through sales reps)
   - IRO - Transactions testing of financial programs or relationships with HCPs
   - CIA – Notification of communications regarding off-label uses issues
   - CIA – Review of records reflecting content of detailing sessions
Deconstructing Recent CIAs – Implications to Risk Management and Compliance Programs

“Setting the bar”

1. A formal system, supported by policies, to ensure that medical inquiries from HCPs are unsolicited and to “monitor” alerts

2. A computer system through which information and documentation relating to the financial programs or relationships that may be initiated by the sales force is tracked and tied back to budgeting

3. Using and “testing” commercially available non-company records reflecting the content and subject matter of detailing interactions between sales reps and HCPs (e.g., Verbatims)
Deconstructing Recent CIAs – Implications to Risk Management and Compliance Programs

Other new areas of focus:

1. Greater focus on the sales force, their interaction with HCPs
2. Focus on sales force interactions with medical affairs specialists and medical affairs specialists with HCPs
3. Focus on process and controls around handling requests for participating in a company-sponsored clinical trial or for sponsoring independent research (including the referral of any requests or inquiries of other companies)
4. Focus on processes and controls around disciplinary action for violations of policies (not broad CIA, but specific policies)
5. Focus on systems, policies, processes for compensating sales force personnel (base compensation and compensation for product performance)
Deconstructing Recent CIAs – Implications to Risk Management and Compliance Programs

Implications

1. Investigations/Settlements
   o Understand the scope and limitations (e.g., information systems) of existing controls
   o Focus on clear definitions (e.g., what is promotional) and expectation-setting regarding scope (e.g., coverage of medical affairs)
   o Make sure what is covered is in line with the core investigation issues

2. Proactive Risk Management
   o Ensure current compliance program address these and other emerging risks
   o Use the new CIAs as “templates” to guide the development of and/or testing/monitoring of internal controls, policies, etc.
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CIAs Reflect the Changing Enforcement Environment

Paul Kalb, JD, MD, Partner, Sidley, Austin, Brown and Wood
Plaintiffs Are Attacking Allegedly “False” Claims

1. Reimbursement
   - AWP
   - Estimated Acquisition Cost

2. Medicaid Rebates
   - Grants
   - Repackaging/Relabeling
   - Nominal
   - Bundling
   - Service Agreements

3. 340B Program

4. Federal Supply Schedule/Federal Ceiling Prices
Plaintiffs Are Pushing Legal Boundaries

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Investigations Part of Broader Focus on “Marketing”

1. Privacy
2. Antitrust/Hatch-Waxman
3. False Advertising
4. GMPs
Implications for CIAs

- Pricing
- Marketing
- Off-Label

- Privacy?
- Hatch-Waxman?
- False Advertising?
- GMPs?