

***Pharmaceutical Regulatory and  
Compliance Congress***

**The HHS OIG Model Compliance Guidance,  
Sarbanes-Oxley, and Other Hot  
Compliance Issues**

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# Overview

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  - Risk Areas
  - Compliance Program Structure
  - Compliance Activities
  - PhRMA Code
- Sarbanes-Oxley
- NYSE Corporate Governance Standards
- Questions and Answers

# HHS OIG Guidance -- Background & History

- HHS OIG and compliance guides for industry
  - Prior industry guidance
  - OIG guidances are “voluntary”
  - Consequences of not following “voluntary” guidelines
- Guidance for the pharmaceutical industry
  - Initial OIG solicitation (June 11, 2001)
  - Public comments (August 9, 2001)
  - Draft guidance (September 30, 2002)
- Remarks of IG Rehnquist on release

## HHS OIG Guidance -- Scope

- Focused on (1) the sales and marketing activities, (2) of pharmaceutical manufacturers
- Focus is more narrow than originally contemplated by the OIG as outlined in solicitation for comments
- Little overlap with FDA jurisdiction (exception: drug sampling)
- Does not address R&D issues (though discussion of grants, physicians as consultants may impact on R&D activities)
- Application to medical device and other industry sectors?

## HHS OIG Guidance -- Risk Areas

- Integrity of data used for gov't reimbursement
- Kickbacks and other illegal remuneration
  - Relationships with purchasers
    - Discounts and other terms of sales
    - Average wholesale price
  - Relationships with physicians and other HC professionals
    - Switching arrangements
    - Consulting and advisory payments
    - Other remuneration

## HHS OIG Guidance -- Risk Areas (cont'd)

### ■ Sales Agents

- Contains troublesome language that calls into question common industry practices with respect to compensation of sales representatives, use of contract sales forces
- "... any compensation arrangement between a ... manufacturer and a sales agent for the purpose of selling health care items or services [reimbursable by the government] implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent."
- OIG draft calls on companies to "establish an effective system for tracking, compiling, and reviewing information about sales force activities."

### ■ Drug samples

# HHS OIG Guidance -- Program Structure

## ■ Compliance officer

- “High-level” with “direct access” to Board, CEO, senior mgmt
- Needs sufficient funding, resources, and staff
- Should have access to all documents, materials
- “Optimal placement” of CO will vary, but OIG looks unfavorably on subordination to GC, CFO (no change)
- Divisional or regional compliance liaisons should be considered in companies with multiple divisions, regions
- Little change from prior guidances

## ■ Compliance committee

- No real change from prior guidances

## HHS OIG Guidance -- Program Structure (cont'd)

- Responsibility of senior management
  - Formal commitment of Board or governing body
  - Evidence of that commitment (e.g., adequate resources, timetable for implementation of compliance program)
  - Receiving “periodic” reports from compliance officer
  - Little change from prior guidances



# HHS OIG Guidance -- Compliance Activities

## ■ Education and training

- OIG considers this to be a “must” do
- General training for everyone on the compliance program
- Specific training on risk areas (those in guidance and those identified by other means) for employees associated with relevant activities
  - Guidance suggests sales representatives should receive training on anti-kickback safe harbors
  - Minimum number of hours per year (though number is unspecified)
- New employee and refresher training is important; failure to attend should result in disciplinary action; should be part of employee evaluation
- Documentation and tracking
- Flexibility on training methodology

# HHS OIG Guidance -- Compliance Activities

- Internal communication and reporting
  - Supervisors should serve as first line of communication, other mechanisms may include: emails, newsletters, exit interviews, hotlines
  - Calls for adoption of confidentiality and non-retaliation policies
  - Suggests use of rewards for appropriate use of reporting system, posting of HHS OIG hotline in employee areas
  - Record keeping is important, as is reporting to Board, CEO, etc.

# HHS OIG Guidance -- Compliance Activities

- Auditing and Monitoring
  - Little guidance offered on monitoring except a statement that it should be built into an effective program
  - Flexibility on frequency and subject of audits; could be prospective or retrospective
  - Use of “internal or external evaluators who have relevant expertise”
- Enforcement of disciplinary standards
  - Need for clear and specific disciplinary policies
  - Penalties to include termination
  - Language appears to say manufacturers not required (though encouraged) to screen employees/contractors against HHS OIG exclusion list

# HHS OIG Guidance -- Compliance Activities

- Mechanisms for corrective action
  - Duty to investigate “reasonable indications of suspected noncompliance”
  - Must take decisive steps to correct any problems
  - Actions could include a prompt report to the government where you believe that the misconduct may violate a law (no more than 60 days)

## HHS OIG Guidance -- Other Key Issues

### ■ PhRMA Code:

- “useful guidance for evaluating relationships with physicians and other healthcare professionals”
- “OIG recommends that pharmaceutical manufacturers at a minimum comply with” PhRMA Code
- “Arrangements that fail to meet the [Code’s] minimum standards ... are likely to receive increased scrutiny from government authorities”
- While a useful benchmark, compliance “will not necessarily protect a manufacturer from prosecution or liability”
- IG comments: Companies should view PhRMA Code policies as minimum, additional safeguards may be required in some areas

## HHS OIG Guidance -- Other Key Issues

- Vendors and other agents:
  - CO should “ensur[e] that independent contractors and agents ... are aware of company’s compliance program ...”
  - Companies should consider training vendors on compliance-related matters

## HHS OIG Guidance -- Future Action

- Comment period open through December 2, 2002
- Final guidance not likely before late Spring 2003 (at the earliest)
- Efforts of the Ad Hoc OIG Compliance Group

# **Sarbanes-Oxley:**

## **What It Means for Pharmaceutical Compliance Professionals**



## Sarbanes-Oxley: Overview

- New oversight responsibilities for Board, Audit Committee
- New provisions that overlap with HHS OIG Guidance
  - Internal controls and report
  - Hotline
  - Codes of conduct
  - Whistleblowers
- Document retention
- Other provisions

## Sarbanes-Oxley: Board, Audit Committee Issues

### ■ Audit Committee Resources:

- Can hire independent counsel
- Company must provide funding
- Audit Committee can hire auditors

### ■ Audit Committee Responsibilities:

- Directly responsible for “appointment, compensation and oversight” of auditors
- Complaint Procedures: Must establish procedures to receive and address complaints regarding accounting, internal accounting controls and auditing issues.

## Sarbanes-Oxley: Board, Audit Committee Issues (cont'd)

- Procedures include providing mechanism for employees to submit concerns -- on a confidential, anonymous basis -- regarding questionable auditing or accounting matters.
  - Must pre-approve all auditing and non-auditing service to be performed by outside auditors.
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- New Auditor Independence Requirements
    - Registered public accounting firms will be prohibited from providing eight types of non-audit services to audit clients

## Sarbanes-Oxley: Board, Audit Committee Issues (cont'd)

- Auditor Independence (cont'd)
  - Mandatory auditor rotation: Partner cannot be lead or review partner for more than 5 consecutive years
  - Auditor must timely report to Audit Committee:
    - All critical accounting policies and practices to be used in financial reports
    - All alternative treatments of financial information within GAAP that have been discussed with management, ramifications of their use, and treatment preferred by the auditor
    - Other material written communications with management

## **Sarbanes-Oxley: Board, Audit Committee Issues (cont'd)**

- Act requires an internal control report in company's annual reports
- Internal control report must:
  - (1) State management's responsibility for establishing and maintaining an adequate internal control structure and procedures for financial reporting, and
  - (2) Contain an assessment of the effectiveness of those controls, as of the end of the company's most recent fiscal year.
- Is internal control structure limited strictly to financial reporting issues?

# **Sarbanes-Oxley and Other Hot Issues: Special Issues for Compliance Professionals**

- Document retention and destruction
- Whistleblowers
- NYSE Listing Standards

# Documents

- 18 U.S.C. § 1519: “Whoever knowingly alters, destroys . . . with the intent to impede, obstruct, or influence the investigation or proper administration of any matter within the jurisdiction of any [U.S.] department or agency . . . or in relation to or contemplation of any such matter or case . . .”
- Highlighted language raises questions:
  - Could common document retention/destruction policies result in violations where they call for destruction of documents relevant to a matter that could arise in the future?
  - Potential problem if a document retention program is set up with the intent to avoid future Government liability.

## Documents (cont'd)

- Need to develop a business justification for every element of the document destruction plan
- Document destruction program should exempt from destruction all documents that could be used in future investigations
- Company's e-mail policy and document retention policies should be reviewed and revised to accord with new statutory requirements.



# Whistleblowers

- Sweeping new protections for whistleblowers--
  - Modeled after protections for airline employees reporting safety violations
- Two new criminal provisions to protect whistleblowers
  - 18 U.S.C. § 1513
  - 18 U.S.C. § 1514A

## Whistleblowers (cont'd)

- 18 U.S.C. § 1513: “Whoever knowingly, with the intent to retaliate, takes any action harmful to any person . . . for providing to a law enforcement officer any truthful information relating to the commission or possible commission of any Federal offense . . .”
- Elements added to 18 U.S.C. § 1513(e):
  - Knowing and intentional action to retaliate
  - Against any person (not just an employee)
  - Providing truthful information relating to commission or possible commission
  - A law enforcement official (not just a Federal agent)
  - Regarding any Federal offense

## Whistleblowers (cont'd)

- Elements of 18 U.S.C. § 1514A:
  - Prohibits a company from sanctioning an employee because of any lawful act to provide information about “fraud against shareholders” to (1) a Federal agency, (2) Congress, or (3) employee’s supervisor.
  - Authorizes civil action for damages and equitable relief, including reinstatement, back pay, attorneys’ fees, etc.
  - 90-day statute of limitations: employee must file claim within 90 days of retaliation.
  - Provision construed narrowly: applies only to information provided in connection with an ongoing proceeding.

## **New Felonies and Increased Criminal Penalties**

- Substantive new offenses added by the Act:
  - 18 U.S.C. § 1348: Scheme or artifice to defraud
  - 18 U.S.C. § 1350: Knowing violations involving new CEO/CFO certifications
- Enhanced Penalties:
  - Multiple directives to U.S. Sentencing Commission to boost penalties for obstruction of justice, criminal fraud, accounting and securities fraud, and the new “white collar” provisions in the Act related to document destruction or tampering

## **New Felonies and Increased Criminal Penalties (cont'd)**

- Enhanced penalties for conspiracies (from 5 years to same level as underlying offense)
- Stiffer penalties for criminal ERISA violations
- Doubles the penalties for criminal violations of Securities Act of 1934

## Sarbanes-Oxley: Code of Conduct

- Section 406 of Sarbanes-Oxley Act requires adoption of “Code of Ethics” for senior financial officers
  - Code is applicable to principal financial officer and controller or principal accounting officer, or persons performing similar functions
  - The term “code of ethics” is defined broadly to mean standards reasonably necessary to promote
    - (1) honest and ethical conduct,
    - (2) full, fair, accurate, timely, and understandable disclosure in periodic reports the company is required to file, and
    - (3) compliance with applicable Government laws and regulations.

## NYSE Listing Standards -- Codes of Conduct

- Listed companies must adopt a code of business conduct and ethics, and must promptly disclose any waivers of the code for directors or executive officers
- Code must address a variety of issues, including issues beyond financial reporting matters

## **Sarbanes-Oxley: Summary of Issues for Compliance Professionals**

- Clarification of responsibility for compliance with, oversight of financial reporting rules
- New requirement of process for internal reporting of financial fraud -- coordination with existing hotlines and internal reporting procedures
- Code of Conduct for financial executives -- develop separate Code or incorporate into existing Codes



## **Sarbanes-Oxley: Summary of Issues for Compliance Professionals (cont'd)**

- Whistleblowers -- review in light of heightened risks, ensure appropriate coordination
- Document retention -- review in light of heightened risks, establish and document business justification
- Implications of direct reporting to Board, Audit Committee of compliance issues outside traditional mechanisms