Pharmaceutical Regulatory and Compliance Congress

Special Pre-Conference Workshop: HHS OIG Model Compliance Guidance

November 13, 2002

Overview

- Background and history
- Scope
- Risk areas
- Structural issues
- Compliance activities
- Issues of particular concern to industry
- Timetable and next steps

Background and 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  - Draft guidance (September 30, 2002)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

Scope

- **Guidance limited to pharmaceutical manufacturers not other sectors of pharmaceutical industry (*e.g.*, retail pharmacies)**
- **Narrow focus differs from scope of original solicitation**
- **Little overlap with FDA jurisdiction (exception: drug sampling)**
- **Virtually no discussion of R&D-related issues**

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

Risk Areas (cont'd)

- **Sales Agents**
  - Draft Guidance contains troublesome language that calls into question common industry practices with respect to compensation of sales representatives, use of contract sales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**

Structural Issues

- **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

Structural Issues (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

Compliance Activities

- **Education and training**
  - Broad applicability (officers, directors, employees, and contractors)
  - 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

Compliance Activities

- **Internal communication and reporting**
  - Supervisors should serve as first line of communication
  - Encourages creation of open door, confidentiality and non-retaliation policies; suggests use of rewards for appropriate use of reporting system
  - Suggested mechanisms: emails, newsletters, exit interviews, etc; anonymous reporting should be permitted
  - States that companies should post HHS OIG hotline in employee areas
  - Record keeping is important, as is reporting to Board, CEO, etc.

Compliance Activities (cont'd)

- **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 internal standards**
  - Need for clear and specific disciplinary policies
  - Penalties to include termination

Compliance Activities (cont'd)

- **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)

Other Important Topics

- **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

Other Important Topics (cont'd)

- **Vendors and other agents**:
  - CO should "ensur[e] that independent contractors and agents … are aware of company's compliance program …"

Outcome on Issues of Industry Concern

- **Flexibility**
  - Draft provides substantial flexibility -- in what it says and what it doesn't say
  - Examples: recognition of prospective or systems audits, format for delivery of training
- **Overlap with FDA**
  - Little discussion of, overlap with FDA requirements (other than samples)
  - Virtually no discussion of R&D-related issues (with exception of grants)

Outcome on Issues of Industry Concern (cont'd)

- **Substantive guidance**
  - Provides little guidance above and beyond prior statements (*e.g.,* Fraud Alerts, advisory opinions) -- and the little guidance that is provided is not particularly helpful
  - Not surprising given focus of OIG guidances on compliance programs
  - Modest opportunity in next round for additional guidance on selected issues

Timetable and Next Steps

- Comment period -- 60 days from publication in Federal Register
- Potential roundtable with industry
- Ad Hoc OIG Group efforts

Questions?

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