Pharmaceutical Compliance Forum

Auditing and Monitoring Programs
Points to Consider
Disclaimer

The statements and opinions shared today are our own based on our experience. They do not represent the views of our respective companies.
Auditing and Monitoring Compliance:

Suggestions from the OIG Compliance Program
Guidance for Pharmaceutical Manufacturers:

F. Auditing and Monitoring

An effective compliance program should incorporate thorough monitoring of its implementation and an ongoing evaluation process. The compliance officer should document this ongoing monitoring, including reports of suspected noncompliance, and provide these assessments to company’s senior management and the compliance committee. The extent and frequency of the compliance audits may vary depending on variables such as the pharmaceutical manufacturer’s available resources, prior history of noncompliance, and the risk factors particular to the company. The nature of the reviews may also vary and could include a prospective systemic review of the manufacturer’s processes, protocols, and practices or a retrospective review of actual practices in a particular area.

Although many assessment techniques are available, it is often effective to have internal or external evaluators who have relevant expertise perform regular compliance reviews. The reviews should focus on those divisions or departments of the pharmaceutical manufacturer that have substantive involvement with or impact on Federal health care programs (such as the government contracts and sales and marketing divisions) and on the risk areas identified in this guidance. The reviews should also evaluate the company’s policies and procedures regarding other areas of concern identified by the OIG (e.g., through Special Fraud Alerts) and Federal and state law enforcement agencies. Specifically, the reviews should evaluate whether: (1) The pharmaceutical manufacturer has policies covering the identified risk areas; (2) whether the policies were implemented and communicated; and (3) whether the policies were followed.
Auditing and Monitoring Compliance:

Key Elements for Auditing and Monitoring Compliance

(1) The company compliance plan should include a formal monitoring and auditing program.

(2) Chief Compliance Officer and staff should conduct “spot” reviews of sales and marketing activities.
   • Ride alongs – who should do them, how many, how to give feed back
   • Speaker programs – who is tracking them, how is it recorded, is there enough training?
   • Sales force documentation – who should conduct ride them, what follow-up?

(3) As a result of such reviews, the company should employ remedial training and disciplinary measures.
Auditing and Monitoring Compliance:  
Specific Suggestions for documenting sales and marketing activities

• **Monitoring**
  – **Monitor Inquiries**: Including an evaluation of whether a customer inquiry relates to information about an off-label indication and a record of the company’s response

  – **Field Force Monitoring Program**: Require a certain number of ride alongs per reporting period

  – **Establish a formal system to monitor financial and contractual arrangements**

  – **Modify documentation systems of sales and marketing activities** so that it is easier to monitor interactions that occur on the same date (i.e. to determine if they occurred during a speaker program, a meal, a conference, or an office visit.)
Auditing and Monitoring Compliance:
Specific Suggestions for documenting sales and marketing activities

• **Internal Auditing**
  – Audit internal controls and processes for sales/marketing activities for compliance with rules and regulations
  – Audit processes for Government Price Reporting implemented allowing required reporting to be fully compliant
  – Audit/review complaint reporting process
  – Audit to verify that the company’s documentation system for sales and marketing activities, and speaker programs, is being used as intended.
    • Consider auditing the documentation entries on the date of speaker programs. The audit could be coincidental with monitoring of speaker programs.
Auditing and Monitoring Compliance: Delegating among Departments

• Legal and Finance, personnel members of business unit senior staff
  – Mandatory legal, finance approval for sales and marketing activities subject to scrutiny per OIG Guidance

• Finance Department audits expense reports
  – For all employees, randomly select 20% of expense reports for auditing
  – PhRMA Code compliance questions should be referred to Compliance Officer

• Corporate Internal Audit review of compliance
  – Audit plan should call for annual review of government pricing, and sales and marketing compliance

*Quality or Regulatory groups can also be a resource.
Auditing and Monitoring Compliance:
Use the PhRMA Code

• PhRMA Code Distribution
  
  – Publicly declare company’s commitment to PhRMA Code, ethical sales practices, and integrity in general
  
  – Distribute copies of the *PhRMA Code on Interactions with Healthcare Professionals* (PhRMA Code) to all physician customers
  
  – Supply hotline number with PhRMA Code and encourage calls if aware of deviations from PhRMA Code
  
  – Field force refresher courses on PhRMA Code delivered by Legal and Compliance
Auditing/Monitoring Compliance

Some other suggestions

• Random e-mail audits
• Auditing text messages- retrievable
• Auditing entries of MSL activity
• Monitoring requests for Medical Information
• Auditing Grant Review Committee/ CME program
• Auditing of Publications process and review
• Data Mining
• Social media
• Speaker training