The Role of Internal Audit in Health Care Compliance

Pharma Congress
June 2003

Audit/Compliance Interaction

Immediate Investigations

Mid-year Plan Adjustments

Annual Audit Planning

Annual Audit Plan

- Areas at risk identified
 - Educational grants
 - Speakers' programs
 - Samples
 - Medicaid and contract rebates
 - Clinical grants
 - Other promotional activities
- Greater risk weighting assigned
- Areas audited more frequently

What Do We Look For?

- Awareness of the laws by appropriate employees
- Procedures in place to ensure compliance with laws
- Test of transactions to help ensure laws are actually being complied with
- Work closely with Legal to resolve "grey" areas identified through audits

Role of Internal Audit

- Work with Legal and Pharmaceuticals
 Division to ensure procedures put in
 place are appropriate and auditable
- Train audit staff on the appropriate laws
- Investigate potential violations of laws

Audit Workprograms

- Compliance approach to workprograms:
 - —Educational Grants
 - -Speakers Programs

Educational Grants

- Ensure avoidance with anti-kickback statutes
- Nature and purpose of the grant
- Monies spent in the proper manner
- Monies left on the table

Speakers Programs

- Review the content of programs selected for audit
- Review of attendees and costs should be modest
- Review of accompanying activities