ESTABLISHING EFFECTIVE CONTROL OVER SALES AND MARKETING ACTIVITIES

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Establishing Effective Control Over Sales and Marketing Activities (Customer Engagement Activities)

- Role of senior management
- Effective policies
- Active process to assess risk and monitor compliance
- Ongoing auditing

Role of Senior Management

- Set the appropriate tone for engaging customers
- Establish reward structures that incent compliance
- Values vs. rules based ethics programs
- Support for ongoing compliance monitoring

Effective Policies Around Customer Engagement Activities

- Establish appropriate boundaries for decision making
- Develop with active input from relevant functions
 - Sales and Marketing
 - Legal
 - Compliance
- Compliance and legal resources must remain active and close to the business
 - Adapt policies to business changes
 - Environmental changes
- Policies must be available
 - Use of technology
 - Ongoing Communication
- Effective and ongoing training

Assessing Risk and Monitoring Compliance

- Ongoing process to evaluate risk in context of changing business and regulatory environment
 - Multi functional approach
 - Link to policy update process
 - Communication
- Processes and controls for monitoring ongoing customer engagement activities
- Periodic auditing to assess compliance and quality of processes and controls

- Gifts and Entertainment
- Examples: Lunch/Dinner, gifts with patient benefit, entertainment associated with educational programs.
- Key Control Examples
 - Monitoring of travel and expense reporting
 - Application of policies
 - Appropriate follow up on exceptions
 - Pre approval limits/limits on types of expenditures
 - Monitoring by sales management
 - Ongoing training
 - Appropriate disciplinary processes

- Personal Services
- Examples: Consulting arrangements, advisory boards, preceptorships, LEP's, speaker programs
- Key Control Examples
 - Monitoring thru proper reimbursement channel
 - Check request
 - T&E (on limited basis)
 - Application of company policy
 - Pre-approval limits and documentation requirements
 - Written contract or documented arrangement where appropriate
 - Services to be rendered
 - Business Justification/Benefit
 - Fair market value of compensation

- Continuing medical education
- Examples: Accredited programs contracted through a third party or though use of grants
- Key Control Examples
 - Policies on allowable CME spending and appropriate use of grants
 - Pre-approval by appropriate responsibility
 - Contract / documentation
 - Program agenda
 - Approved list of third party service providers
 - Knowledge of company policies
 - Proven track record
 - Disclosure of relationships with faculty

- Free goods and services (excluding samples)
- Examples: Product trials, buy X get y free
- Key control examples
 - Clear policies around use and appropriate reporting to customers
 - Monitoring of commitments outside of base contracts
 - Order entry
 - Customer service
 - Credits and collections
 - Appropriate liaison with government pricing compliance group

- Co-promotion arrangements
- Agreement should address appropriate application of company commercial practices
- Joint marketing activities require a different evaluation process
- Sales force training on conduct of co-promotion activities
- Appropriate legal input to development of joint marketing strategies and plans

Ongoing Auditing

- Traditional financial and operational auditing may lack adequate focus on compliance
- Collaboration between legal, internal/external audit, operating divisions and compliance
- Emphasis on adequacy of process, policies and controls
 - Drive improvement activities
- Results should feed ongoing risk assessment process