Continuing Medical Education and Industry Sponsorship

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The Anti-Kickback Statute

• Section 1128B(b) of the Social Security Act
• Criminal statute
• Prohibits purposeful payments, made directly or indirectly, to induce or reward the referral of items or services payable by Federal health care programs
The Anti-Kickback Statute

- Remuneration
- Offered, paid, solicited, or received
- To induce or reward Federal business
- Knowingly and willfully
The Anti-Kickback Statute

• “Arranging for or recommending”
• One purpose test
• Penalties:
  – Criminal
  – Civil
  – Administrative
Why Kickbacks Harm the Health Care System

• Overutilization
• Increased program cost
• Improper steering
• Unfair competition
• Systemic corruption
Ways Industry Sponsors Educational Activities

- Industry-run programs
- Grants to for-profit CME providers
- Grants to academic institutions
- Grants to professional organizations
Types of Kickbacks

• From drug or device manufacturer
  – to CME provider
  – directly to physician
  – indirectly to physician
OIG’s CPG for Pharmaceutical Manufacturers: CME Risk Areas

- Funding based on referral levels
- Sham education projects
- Funding conditioned on content or faculty of an educational program
- Manufacturer influence over the presenter of an educational program
- Violation of FDA rules
CPG Recommendations

- Separate grant making functions from sales and marketing
- Establish objective criteria that do not take into account the volume or value of referrals
- No manufacturer control over the speaker or content of the educational activity
- *Bona fide* educational purpose
- Documentation and regular monitoring
OIG’s CPG for Pharmaceutical Manufacturers: “Consultants” Risk Areas

- Sham consulting arrangements
- Payments for physicians to attend conferences in a passive capacity
- Payments for promotional activities
- Ghost written papers or speeches
- Gifts and gratuities
“Consultants” Recommendations

• Fair market value payments for reasonable, necessary, legitimate services
• Safe harbor whenever possible
• Disclose potential conflicts of interest
• Documentation
Conclusion

• Educational activities are important
• Funding must be accomplished in a fashion that is free from fraud and abuse
• Additional information is available on our website at http://oig.hhs.gov