

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>