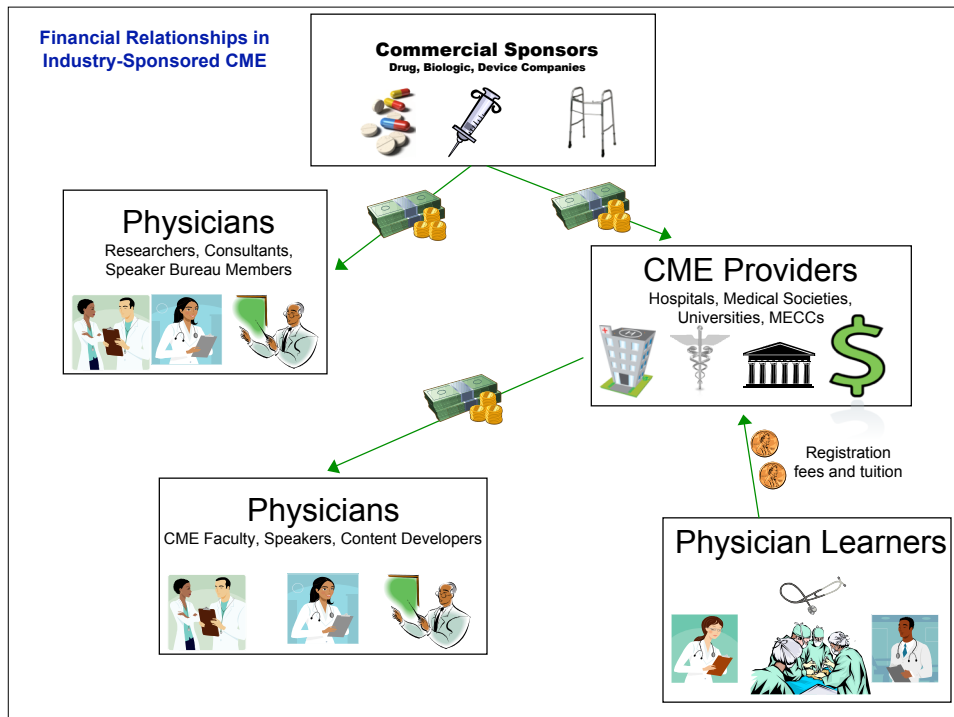


# Industry Funding of Continuing Medical Education

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## Why OIG Cares

**OIG's mission is to promote the integrity of the Federal health care programs and protect the health and welfare of program beneficiaries.**

- This mission is served when physicians recommend treatments based on their best clinical judgment.

**If medical education is biased or inaccurate, medical decision making may be compromised and resulting harms may include:**

- **Poor patient care**
- **Overutilization**
- **Increased program costs**
- **Improper steering**
- **Unfair competition**
- **Systemic corruption**

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## Federal Enforcement Tools: Anti-Kickback Statute

**42 U.S.C. § 1320a-7b(b) prohibits remuneration (anything of value), offered or paid, directly or indirectly, to induce or reward the referral of items or services payable by Federal health care programs.**

- This means it is illegal to buy or sell referral of Medicare or Medicaid services.

**•Types of kickbacks from drug, biologic or device manufacturers**

- to CME provider (e.g., hospital, university, specialty society, medical education and communication company, group practice)
- directly to physician (e.g., learner, speaker, faculty member, course developer)
- indirectly to physician via CME provider

**Sanctions:**

- Jail and criminal fines
- Civil monetary penalties
  - \$50,000/kickback and up to 3 times the remuneration
- Exclusion from participation in the Federal health care programs
- False Claims Act liability

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## Federal Enforcement Tools: False Claims Act

**31 U.S.C. § 3729 et seq. makes it illegal to submit a claim or statement to Medicare or Medicaid knowing it is false or fraudulent.**

### Sanctions:

- 3 times the Government's damages
- \$5,500-\$11,000 penalty, per claim

### Procedural note:

- Whistleblowers can bring a *qui tam* action on behalf of the government
- Whistleblowers may share up to 30% of the money collected

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## OIG Compliance Program Guidance

- **The 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers**  
<http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>
- **Offers general principles and compliance guidance on industry relationships with physicians**
  - Whenever a manufacturer provides something of value to a physician, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals.
- **As well as specific compliance tips on CME**

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## Compliance Program Guidance: Continuing Medical Education

### 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

### Compliance tips:

- 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

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## Compliance Program Guidance: Consulting Arrangements

### Risk areas:

- Payments for physicians to attend conferences in a passive capacity
- Payments for detailing or other promotional activities
- Ghost written papers or speeches
- Gifts and gratuities

### Compliance tips:

- Payments should be fair market value
- Services should be reasonable, necessary, and legitimate
- Written agreement between company and physician
- Safe harbor whenever possible
- Disclose potential conflicts of interest
- Documentation

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## Enforcement Examples

- **Serono - \$704 million for illegal marketing of Serostim**

- False claims: prescriptions induced by kickbacks and off-label promotion
- Company-sponsored CME designed to promote Serostim for off-label uses
- Kickbacks to physicians in the form of all expense paid trips to medical conference in Cannes
- \$51.8 million shared by whistleblowers

- **Pfizer/Warner-Lambert - \$430 million for illegal marketing of Neurontin**

- False claims: prescriptions induced by kickbacks and off-label promotion
- Company-sponsored CME designed to promote Neurontin for off-label uses
- Kickbacks to physicians in the form of free travel and payments to attend “consultants meetings”
- \$26.6 million paid to whistleblower

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## Future Directions

- **The Patient Protection and Affordable Care Act of 2010**

- Health care reform law includes sunshine provision on physician payments. Beginning in 2013, drug, device, and biologic companies must publicly report nearly all payments to physicians.

- **International marketing**

- DOJ has warned of possible liability under the Foreign Corrupt Practices Act.

- **Private sector trends**

- Reducing grants to medical education and communication companies
- Awarding multi-year institutional grants
- Distancing industry sponsors from specific CME programs

- **Possible limits on industry’s educational control**

- Pooled funding mechanisms
- Activity-level accreditation
- Elimination of industry funding

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## Questions

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