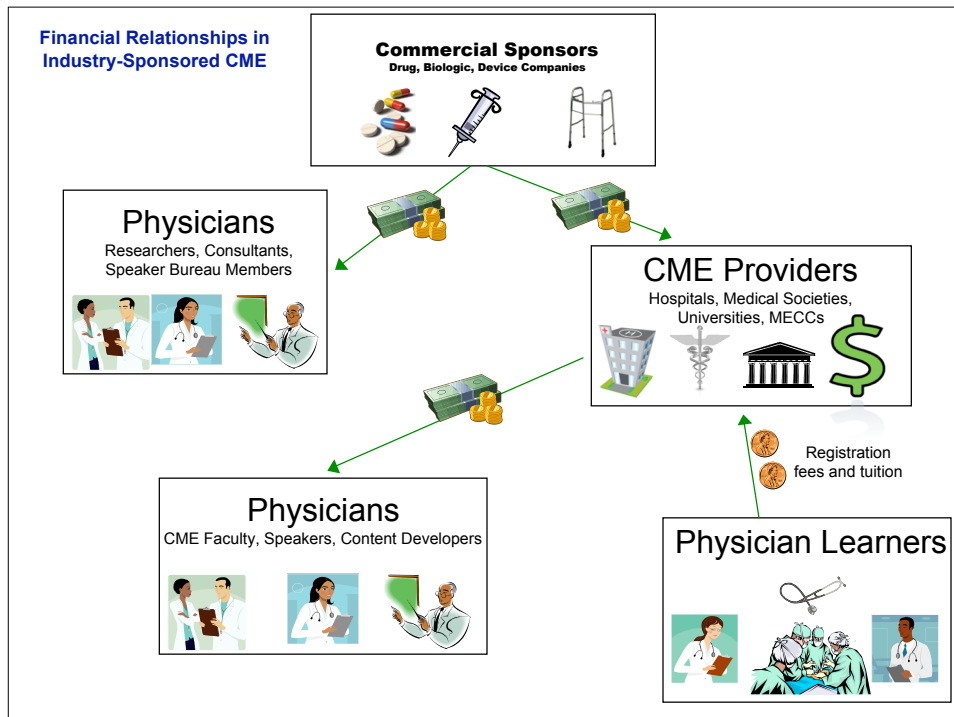


Industry Funding of Continuing Medical Education

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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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