

# Opportunities and Challenges in the Evolving World of CME

**Karen M. Overstreet, EdD, RPh, FACME, ELS**  
**President, Indicia Medical Education, LLC**

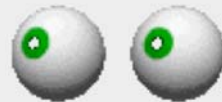
No financial relationships to disclose; is President of the North American Association of Medical Education and Communication Companies and on the Board of Directors of the National Commission on Certification of CME Professionals; is a site surveyor for the ACCME

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# Session goals

- Interact
- Give you my opinions
  - The evolving regulation of CME
  - Standards for Commercial Support (SCS)
  - Implications for medical writers
- Gather your opinions
- Open some eyes



***This is Your Meeting***



# Evolving Regulation



# The evolving regulatory environment

<b>1990</b>	AMA Ethical Opinions <ul style="list-style-type: none"><li>• Gifts to Physicians from Industry</li><li>• Continuing Medical Education</li></ul>
<b>1992</b>	ACCME Standards for Commercial Support
<b>1997</b>	FDA Guidance on Industry-Supported Scientific and Educational Activities
<b>2002</b>	PhRMA Code on Interactions with Healthcare Professionals
<b>2003</b>	OIG Compliance Guidance for Pharmaceutical Manufacturers
<b>2004</b>	AdvaMed Code of Ethics on Interactions with Health Care Professionals
<b>2004</b>	ACCME Updated Standards for Commercial Support
<b>2006</b>	ACCME Updated Accreditation Criteria



# SCS-04 changes

- Preeminence of EBM rather than FDA labeling
- Disqualification without disclosure or resolution of COI
- LOA must include provider, 3<sup>rd</sup> party partners, and commercial supporter
- Commercial agent can't provide activity to learner

# Recent conferences and publications

- OIG and states' Attorneys General have > 140 investigations ongoing\*
- Virtually all pharma companies have been investigated\*
- More whistleblowers are expected to come forward (qui tam cases)†
- Senate Finance Committee has requested information from pharma companies regarding the role of sales and marketing in educational grants†, as well as from ACCME

\* *Inside Medical Education*. 2006: 1(3): 2.

† *Medical Meetings*. 2006 (Dec): 13.



# How did this happen?

- Healthcare costs
- Media scrutiny
- Public perception
- Perceived bias in CME
- Undue influence
  - Parke-Davis and Neurontin
  - Serono and Serostim
- Government and other outside groups continue to force change on the industry

# CME stakeholders

## Providers

- Medical schools
- Specialty societies
- MECCs
- Hospitals

## Supporters

- Industry
- Government
- ACCME “parents”
- Payers

## Beneficiaries

- Learners
- Patients, care givers
- Public
- Stockholders

## Regulators

- ACCME, AMA
- FDA, OIG, DOJ
- State legislatures
- WLF
- Media



# What was...

- If a pharmaceutical company (commercial supporter) was thought to have violated the rules, the FDA could send a warning letter
- If an accredited provider was thought to have violated the rules, the ACCME could
  - Send a letter of reprimand
  - Place the offender on probation
  - Refuse to continue accreditation

# What is...

- New players with much bigger sticks
  - Office of the Inspector General
    - U.S. Department of Health and Human Services
  - Office of the U.S. Attorney
  - States' Attorneys General
  - Plaintiff's Bar

# Separation and firewalls

- All guidelines recommend (require) the separation of education from promotion
  - This is most important for faculty selection and interaction and content development and validation
- FDA goes farther than the others in mandating firewalls: individuals who work on non-CME (promotional or non-independent) activities should not be involved in developing certified CME activities
  - The FDA guideline has been in effect since 1997
  - OIG strengthens (mandates compliance with) it
  - ACCME SCS endorse FDA and OIG statements



# OIG: why this is serious

- Violations of the Anti-Kickback Statute and False Claims Act are criminal
  - Punishable by criminal penalties, civil monetary sanctions, and exclusion from federal healthcare programs
- More than \$11 billion in fines since 2000
- Manufacturers and health care professionals have liability



# What's the risk?

- If CME funded by manufacturers is not appropriately executed
  - The manufacturers can be fined
  - Individuals can be fined or imprisoned, including
    - Staff from the supporter (client)
    - Participating faculty
    - Staff from the CME provider and/or educational partners

**OIG Guidance makes  
*no distinction between promotion and education***



**So what do we do now?**



# Implications for writers

- Know the rules
  - Have a network of colleagues to discuss issues
- Select partners with shared values
- Learn about the changes going on in physician education and practice
  - MOC, P4P, QI
- Use credible reference sources (EBM); verify data
- Document peer review of content
- Disclose relationships if paid directly by supporter



# Participate

- Identify partners with shared values
- Read
- Talk
- Attend
- Publish

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# Resources

- Alliance for CME ([www.acme-assn.org](http://www.acme-assn.org))
- NAAMECC ([www.naamecc.org](http://www.naamecc.org))
- *Medical Meetings*
- *PharmaVoice*
- *Medical Marketing & Media*

# Thank you!

**Karen Overstreet, EdD, RPh, FACME**

**[karen.overstreet@indiciaed.com](mailto:karen.overstreet@indiciaed.com)**

**215-855-9090**

