Standards for Commercial Support: Common Compliance Issues
Disclosure Forms, Resolution of Conflicts

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Disclosure

I have no disclosures

Any opinions I express are my own and are not meant to represent ACCME opinions
Why do we care?
Responsibility to provide validated education to clinicians - independence

New Graduate of Medicine

CI sponsored CME live activities

Validated CME

Improve patient care

Physician practices non-standard of care
Poor patient outcomes

Physician prescribes brand name meds

CME with employees

Practicing Physician
Ensuring Independence....

• ACCME expects accredited organizations to:

• **Identifying** relevant financial relationships between commercial interests and those who plan, teach, and implement CME

• **Resolving** conflicts of interest that arise when those with relevant financial relationships with commercial interests have the opportunity to control CME content related to the products or services of those commercial interests

• **Disclosing** to learners the (identified) relevant financial relationships for those in control of CME content prior to the educational activity or disclosing that there were no relevant financial relationships.
Definition of Commercial Interest

- A *commercial interest* is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.
Organizations not considered to be Commercial Interest

- 501-C Non-profit Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For profit rehabilitation centers
- For-profit nursing homes
- Blood banks
- Diagnostic laboratories
Why is this important?

Helps us define what entities could bias our content

Helps us define what is a relevant financial relationship
Definition of Relevant Financial Relationships

- Financial Relationship
- Any Monetary value
- Within 12 months
- Relates to content of the activity

Conflict of Interest
Resolving Conflict of Interest

• ACCME Flow Chart
Site Survey.....Compliance and Noncompliance

• Pitfalls to avoid in case format
• Commonly seen during site survey or when providing documentation/self-study
  • Provide only what is asked
  • Remember to have honoraria policy/reimbursement policy
  • Remember to have the correct definition of Commercial Interest on your documents
Case #1 Criterion 7 SCS 2

Title: OB shoulder dystocia Simulation

Disclosures: Excel sheet completed during planning meeting by coordinator who collected the information verbally

Compliance?
Noncompliance?
Compliance

• **IF** she also provided those in control of content the full definition of commercial interest

• The ACCME does not require that providers use a **disclosure form** to gather information about relevant financial relationships of all persons in control of the content of an educational activity
  - Collecting the information verbally and recording it in a spreadsheet, table, or database
  - Collecting disclosure information electronically (for example, via e-mail, web-based form, or database)
Case #1 Criterion 7 SCS 2

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COMPLIANCE
Case #2 Performance in Practice RSS

- **Title-Grand Rounds:** Monthly session total of 12 sessions within RSS

- Attachment 1: Lists topics of all twelve sessions for the year with speakers
- Attachment 2: Disclosure form with correct definition of ACCME defined Commercial interest listed
- Attachment 3: Documentation of peer review and appropriate resolution of COI for the first topic are provided.
- Attachment 4: Presentation slide shown to the audience with COI for the first topic is provided

- Compliance vs. Noncompliance
Attachments for PIP Files....

Attachment 1: The activity topics/content (example agenda, brochure, program book, or announcement

Attachment 2: The form tool or mechanism used to identify relevant financial relationships of all individuals in control of content

Attachment 3: evidence that you implemented your mechanisms to resolve conflicts of interest for all individuals in control of content prior to the start of the activity

Attachment 4: the disclosure information as provided to learners about the relevant financial relationships or absence of relevant financial relationships that each individual in a position to control the content of CME disclosed to the provider

Remember.....RSS dont focus on information for only one session out of the entire RSS
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- Compliance vs. Noncompliance
Case # 3 Resolving COI PIP

• Title: IRB Research Practice
• Coordinator identifies articles to discuss, IRB chair moderates, Administrative assistant takes minutes, IRB committee participates in discussion
• Identified COI-Coordinator’s husband works for Pharma, remaining individuals have nothing to disclose.

How can you resolve COI?
Relevant Financial Relationships

Provider takes an active role to resolve conflicts by:

- **Recusing** person from controlling aspects of planning and content with which they have a conflict of interest and or
- Using **peer review** of planning decisions for planners by persons that do not have conflicts of interest related to the content and or
- Using **peer review** of content for authors presenters by persons that do not have conflicts of interest related to the content and/or
- Making sure to **ensure** that clinical recommendations are **evidence base and free of commercial bias** (ex peer reviewed literature adhering to evidence based practice guidelines and or using other methods that meet accmes expectations.)
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- Identified COI-Coordinator’s husband works for Pharma, remaining individuals have nothing to disclose.

Our solution:
Coordinator took on administrative role to take minutes and coordinate meeting, IRB chair chose articles and is non-conflicted
References

• 1. Standards of commercial support
  http://www.accme.org/accreditation-rules/standards-for-commercial-support
