Assessing the Need for
Peer Review of CME Content

Risk Stratification

Council of Medical Specialty Societies
CME Directors Component Group

Friday, March 18, 2011
2:30-3:15 p.m.

Presenter

Sandra T. Weaver, MS

Vice President, Strategic Alliances

CME Peer Review, LLC

- 20 years of training & development experience, with the past 11 years specifically in the area of CME compliance, accreditation and program development
- Past President for the National Association of Medical Education Companies (NAMEC) and previously served as Vice President and Secretary
- Served on several committees that are part of the Alliance for Continuing Medical Education
- Membership in the American Society for Training and Development
- Holds a BS in Education and a MS in Psychology
- Green Belt Certification in Six Sigma

DISCLOSURE: Does have an interest in selling a service to CME professionals.

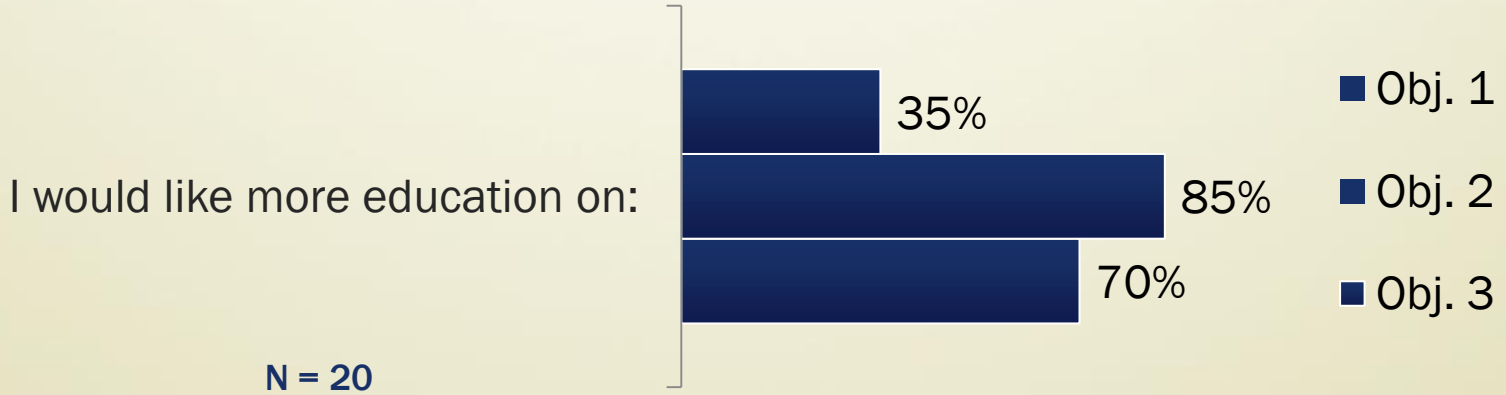
Agenda

- Introduction
- Related Regulations, Codes, Guidance, and Literature in the CME Industry
- Developing and Implementing Risk Assessment Tools
- Group Exercise

Objectives

At the conclusion of this session, participants should be able to:

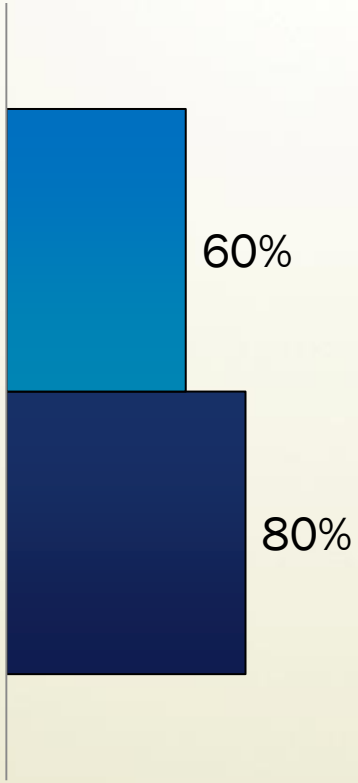
- Explain the regulations, guidance, and codes related to COI and independence.
- Identify areas of risk associated with CME Activities.
- Develop a comprehensive assessment tool to measure risk and identify the need for independent review.



Survey Responses

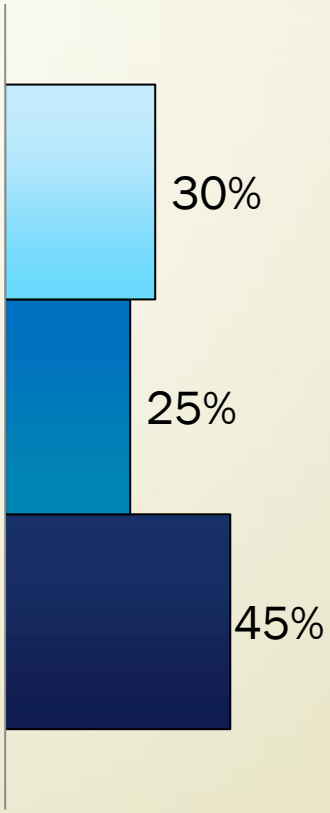
Survey Responses

We currently use a process to review content when risk is identified that is (check all that apply):



External
Internal

We currently have a risk stratification process in place that is:



None
Informal
Formal

N = 20

Related Regulations, Codes, Guidance, and Literature in the CME Industry

Regulatory Documents and Ethical Codes

Regulatory documents and Ethics Codes have precipitated change across the CME industry

Year	Document
1990	AMA Gifts to Physicians
1992	ACCME Standards for Commercial Support
1997	FDA Guidance for Industry-Supported Educational Activities
2000	AMA Addendum to Gifts to Physicians
2000	ACCME Firewall Policy
2002	AMA Revision to Addendum Gifts to Physicians
2002	PhRMA Code on Interactions with Healthcare Professionals
2003	OIG Compliance Program Guidance for Pharmaceutical Mfrs
2004	ACCME Updated Standards for Commercial Support
2006	ACCME Updated Accreditation Criteria
2007	ACCME Updated Policies
2008	ACCME Updated Policies
2008	PhRMA Revised Code on Interactions with Healthcare Professionals
2009	NAAMECC Code of Conduct
2010	CMSS Code for Interactions with Companies.

Literature Review

Evaluating Conflicts of Interest in Research Presented in CME Venues

Journal of Continuing Education in the Health Professions
Volume 28, Issue 4, Date: Autumn (Fall) 2008, Pages: 220-227
Nancy L. Davis, James M. Galliher, Mindy S. Spano, Deborah S. Main, Michael Brannigan, Wilson D. Pace http://onlinelibrary.wiley.com/doi/10.1002/chp.188/pdf

This pilot study investigated the presence of perceived bias in oral and print content of research findings presented in certified CME activities.

- Knowledge of the presenter's COI may increase learners' awareness of a single product in the presentation.
- Knowledge of the COI appeared to have little effect on evaluators' assessment of the presenters' strong opinion regarding the nature of care.
- There was no consensus from evaluators whether knowledge of COI affected perception of strength of evidence in presentations.
- CME providers must be diligent about investigating potential conflicts of interest in the reporting of original research. Researchers are often not aware of the need to disclose conflicts of interest during presentation of findings.
- More study is required to guide resolution of conflicts of interest in research and CME.

Literature Review

A Risk Stratification Tool to Assess Commercial Influences on Continuing Medical Education

Journal of Continuing Education in the Health Professions
Volume 27, Issue 4, Date: Autumn (Fall) 2007, Pages: 234-240
Barbara E. Barnes, Jeanne G. Cole, Catherine Thomas King, Rebecca Zukowski, Tracy Allgier-Baker, Doris McGartland Ruio, Luanne E. Thorndyke
http://onlinelibrary.wiley.com/doi/10.1002/chp.143/pdf

Measurement tool developed by CACME available to CME providers for their use to:

- help identify activities that must be closely monitored for potential industry influence
- become aware of factors that place programming at risk for noncompliance with accreditation standards
- appropriately allocate resources by the CME office.

Literature Review

Commercial Influence and Learner-Perceived Bias in Continuing Medical Education

Academic Medicine
Volume 85, Issue 1 2010 January, Pages: 74–79
Michael A. Steinman, MD, Christy K. Boscardin, PhD, Leslie Aguayo, CCMEP, Robert B. Baron, MD, MS
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2801075/pdf/nihms127880.pdf

- Example of a provider that used a modified version to assess bias in their activities
- Heightened concerns about industry influence on continuing medical education (CME) have prompted tighter controls on the management of commercial funding and conflict of interest.
- Potential for industry influence can be difficult to assess at a stage in the planning process when mitigation strategies can assure balance and content validity.

Developing and Implementing Risk Assessment Tools

Why a Standardized Process?

- **Mitigate Risk**
  - Important to Assess Potential Commercial Bias **Prior** to Implementing an Activity
- **Process Driven**
  - Important to Standardize Process and Document it for Both ACCME and Commercial Supporters
- **Objective**
  - Takes the Burden Off the CME Director for Determining Whether Internal Peer Review is Sufficient vs. External Review for Higher-Risk Activities

Before You Begin

1. Identify stakeholders in your organization
2. Establish goals for the process
3. Review internal policies
4. Review ACCME criteria
5. Determine areas of risk
6. Define terms
7. Consider how you will stratify the risk
8. Who will be responsible for completing the form?
9. What will be done with the information?
10. What level of risk are you willing to accept?
11. What actions will be taken?

Potential Areas of Risk

Overall Activity

- If first time activity or previous feedback
- Number of commercial supporters

Third Parties

- Joint sponsors, Co-providers, Event planners?
- If so, consider their history with the provider

Course Directors, Editors

- If first time activity
- Previous activity feedback
- Disclosures
- Course Director's history with provider

Faculty, Planners

- The percent of speakers/faculty/planners have relevant financial relationships
- Whether COIs have been resolved and documented

Content

- Whether information presented is evidence based
- The level of evidence
- Whether off-label use or investigational products are discussed

After Developing The Tool

Pilot the Tool

- Ease of use
- Consistent responses among users
- Test the risk thresholds established and subsequent actions
- Compare results with participant evaluation data

Survey the Staff

- Comfort level in completing the Risk Assessment Tool
- Instructions provided were easy to understand and follow
- Investment in time was worth the added confidence I felt after completing the tool
- Took no more than 30 minutes to complete the tool
- Would consider utilizing this tool for future activities in determining peer review

Group Activity

Group Activity

SAMPLE

Risk Assessment of St Patrick's Day Activities in Chicago

Item	Reference	Risk Level				
		False	Low	Mod	High	Rating
Dyeing of the Chicago River and its impact on the environment	The Go Green Blog	0	1	3	5	0
1. TRYING TO CROSS COLUMBUS DRIVE DURING THE PARADE	WWW.CHICAGOSTPATS PARADE.COM	0	1	3	5	1
2. GETTING A TATTOO OF A SHAMROCK	FDA - TATOOS AND PERMANENT MAKE-UP	0	1	3	5	3
3. DRINKING GREEN BEER ALL DAY AND ALL NIGHT	ILLINOIS LIQUOR CONTROL COMMISSION	0	1	3	5	5

Q & A