Applying CACME’s Risk Stratification Process to Mitigate Potential Non-compliance with the Standards for Commercial Support

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The speakers disclose that they have no financial relationships relative to the content of this presentation.
Objectives

- Apply a risk stratification process to case studies of CME activities
- Identify best practices and develop strategies in managing activities to reduce non-compliance with the Standards for Commercial Support

Agenda

- Introduction
- Demonstration: Case 1
- Group Exercise: Discuss Case 2/Case 3
- Facilitated Discussion
  - Develop a Management Plan
- Key Points & Wrap-Up
Introduction

Why do we need it?
What is risk stratification?

Environment for Commercial Support

- 2008 ACCME Annual Report: Commercial Support totaled $1,035,942,134 (primarily to MECs, Schools of Medicine, and Physician Organizations)
- Intense scrutiny and controversy over commercial support of CME
- ACCME defense: We have the SCS
  - If providers comply, the opportunity of commercial bias reduced/eliminated commercial support in CME
- Monitoring for compliance likely to increase in frequency/detail in the future
Risk Stratification Tool (RST) has Been Analyzed and Validated

1998
Design & Pilot process

1999
Implementation across four schools

2000
Analysis & redesign

2004
Reliability & Validity study conducted

2007
Validation completed, published


Risk Stratification Allows Providers to Identify, Quantify and Modify Risk

- Identify issues that increase risk for
  - injecting bias in the educational content
  - non-compliance with accreditation standards
  - endangering accreditation status

- Aid providers in decisions about whether and/or how to certify a “risky” program

- Stimulate providers to apply strategies to assure that compliance is achieved
What affects Risk?
Commercial Support, Delegation, Experience

- Elements of Risk Stratification Tool
  - Primary control vs. delegation of functions
  - Involvement of for-profit organizations
  - Potential reach of activity
  - Previous experience with partners
  - Nature and degree of conflict of interest
  - Nature and degree of commercial support
- Develop a management plan to reduce risk

Risk Category Drives Decisions

- Whether to certify the activity
- Oversight plan for ensuring compliance
- Selection of methods for monitoring
- High risk activities $\rightarrow$ greater CE resources
- Lower risk activities $\rightarrow$ fewer CE resources
- High/Very high risk $\rightarrow$ higher review levels
- Allocating resources to activities at highest risk for non-compliance
- Supports a variable CE management fee
Case 1: Immunization
(risk score = 2 [low risk])

Description
The state Department of Health conducts an annual half-day conference to improve compliance with immunization guidelines in state health centers and physician practices. Curriculum is developed by a committee comprising DOH physicians and pediatricians from the accredited institution. The course director and faculty have no relationships with industry.

Logistics Management
Speaker and planning logistics are handled by DOH. The joint sponsors have worked on a number of previous projects, all of which are in good compliance.

Budget
The CME office processed all income. All expenses are paid by the DOH. No commercial support, no exhibits.

Case 1: Management Plan

Planning
- CME office involvement in early content development meetings
- All required forms (CME application, disclosure) submitted to CME

Implementation
- DOH submits minutes of planning calls

Delegation
- DOH is primary contact for speakers
- CME handles all income; DOH pays expenses

Review
- CME office reviews slides in advance. Referral to content expert if necessary.

Monitoring
- No monitoring needed based on past experience.

Evaluation
- Review of bias indicators on standard evaluation form
Case 2: “Love Boat” CME (risk score = 5 [moderate risk])

Description
CME office will work with No Frills Travel Agency to offer a series of CME programs on multiple topics on select cruises throughout the year. Curriculum to be developed by a medical director from the accredited institution and two faculty members. The medical director and faculty have no relationships with industry.

Logistics Management
All meeting/travel logistics and funds management will be handled by the travel agency. CME office and travel agency have no experience working together.

Budget
All expenses will be paid by participant fees.

Case 3: Satellite Symposium (risk score = 16 [high risk])

Description
- An unaccredited MECC and an Academic CME provider collaborate to successfully respond to an RFP. Content will be jointly developed to produce a 3.5 hr symposium during a national association meeting. The MECC and CME Provider have worked on RFPs before, but this is the first time they will implement a CME activity together.

Logistics
- The MECC will handle logistics, including marketing, faculty coordination, hotel and travel arrangements.

Budget
- The budget is $500,000, 100% funded by a single commercial supporter, with no prior experience. No exhibits.
- The funder requires the CME Provider to receive the funds. The CME provider will then transfer all the funds to the MECC since they are handling logistics.
- The 3.5 hour Satellite Symposium will include dinner ($75 pp) and will be held at the convention hotel. No registration fee.
Small Group Exercise: Dealing with the Results of Risk Assessment

- Break into groups
- Discuss the cases
  - What are the major risks?
  - What tools/techniques would you use to manage these risks?

Management Plans – Areas to Consider

- Content development
- Process and timeline
- Communication
- Review of documents
- Who handles what?
Large Group Discussion

- What are the components of your management plan?
- How do the management plans differ between the two cases?

Key Points

- Decide if/how to proceed with activity
- Determine appropriate activity management plan
- Allocate CE office resources according to risk/need
  - Set appropriate fees to implement management plan
Key Points: Components of a Management Plan

- Planning
  - Involvement of CME office
  - Involvement of Dean, CME committee, advisory board
- Implementation
  - Regular communications between partners
  - Sign offs at established milestones
- Delegation
  - Budget review and approval
  - Funds management
  - Logistics

Key Points: Components of a Management Plan

- Review
  - By CME office
  - CME committee or advisory board
  - Independent academic review (internal or external)
- Monitoring
  - by CME, content expert, or both
  - Announced or unannounced? How often?
- Evaluation
  - Consider multiple methods of evaluation
Acknowledgements

The RST was developed by the Consortium of Academic CME, which consisted of the following Pennsylvania medical schools (alpha order – gotta get the names right)

Penn State College of Medicine
Temple University School of Medicine
Jefferson Medical College of Thomas Jefferson University
University of Pittsburgh

Staff from each school made contribution to the development of the RST.


Resources

- Accreditation Council for Continuing Medical Education (ACCME) website: [http://www.accme.org/index.cfm/fa/home.home/home.cfm](http://www.accme.org/index.cfm/fa/home.home/home.cfm)
Thank you!

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