Navigating the Slippery Slope of Commercial Support: Applying the Principles of Risk Stratification

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What is Risk Stratification?

- Risk stratification: a statistical process to determine detectable characteristics associated with an increased chance of experiencing unwanted outcomes.

- By identifying factors before the occurrence of an event, it is possible to develop targeted interventions to mitigate their impact.

Risk Stratification Process Application to CME

- Allow providers to identify issues that place an activity at risk for non-compliance with accreditation standards
- Aid providers in decision-making process about whether to certify a “risky” program
- Allow providers to determine appropriate strategies to assure that compliance is achieved
CACME Risk Stratification Tool Development Process

Risk Stratification - a mechanism to provide oversight of CACME activities

CACME developed a tool to prospectively and objectively identify activities at high risk for violation of the SCS

Quick CACME Facts:
- 2000-Accredited w/commendation
- Certified over 650 activities annually
- Dissolved in 2005
CACME Risk Stratification Tool Development Process

1998: Tool designed and piloted

1999: Implemented consortium-wide

2000: Formally analyzed & redesigned (via external consultant)

2004: Study to determine reliability & validity, and to assess usefulness and potential applications
Purpose of Risk Stratification

- Prospectively and objectively predict relative risk for non-compliance with SCS
- Appropriate resource allocation/management
  - Lower risk activities may have certain responsibilities delegated
  - Higher risk activities require greater direct involvement of CE office in planning, monitoring and evaluation
CACME Risk Stratification

- Utilizing the risk score and category
  - CE office develops a plan for ensuring compliance
  - Designs and implements methods for monitoring and evaluation
  - Allocates greater resources to higher risk programs, less resources to lower risk activities
  - CACME Board review and approval

- Provides rationale for allocation of resources to those activities at highest risk for non-compliance
Risk Stratification Criteria

- Partner Information
  - Content and/or logistics
  - Relationship, nature of partner, past experience
- Type of design: repeated vs. single
  - Same live curriculum repeated multiple times in a commercially supported activity
- Level of involvement of accredited sponsor
- Responsibility for funds management
Risk Stratification Criteria (cont’d)

- Commercial Support Aspects
  - Number of commercial supporters
  - Amount of commercial support
  - Amount of exhibit support
   \[
   \text{\% of income}
   \]
- Off-label or experimental therapies
- Relationship between Course Director and commercial supporter
Use of Risk Stratification Tool

- Every activity* assessed in the planning phase
- Weighted score assigned for each criteria
- Each criteria assessed and scored
- Overall risk score determined from sum of various criteria
- Risk score determines risk category
  - Low, moderate, high, very-high risk
- CACME reviewed all high, very high risk activities
  - Retrospective and prospective review

*non RSC activities
What IF...HIGH RISK?
Sample plans for higher risk programs

- Discussion and involvement of dean for CME, liaison committee/advisory board
- Complete involvement of CE office
- Direct approval of logistics planning
- Independent academic review
- Mandatory monitoring
- Multiple methods of evaluation
Impact of Risk Tool in Practice

- Ensures prospective (and retrospective) oversight and management
- High risk, very-high risk activities not inherently “bad” or “off limits”
- Allows appropriate distribution and balancing of finite resources within CE office
- Allows profiling of the overall CE program
Summary Points

- CACME Risk Stratification Tool delineates elements that place activities at risk for non-compliance with SCS
- Prospective assessment of risk can aid in appropriate management of activities
- Profiling of CE program allows allocation of CE office resources to ensure compliance with standards and regulations
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