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Medical Education

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Practical Tips for Mitigating Risk

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Governmental attention to grant-supported continuing medical education (CME) has never been higher. This past April, the Senate Finance Committee (SFC) issued its report *The Use of Educational Grants by Pharmaceutical Manufacturers.* The SFC report was the result of a two-year investigation of CME and concluded that oversight of accredited CME providers is "insufficient to guarantee the required independence" of medical education and that there are still risks of kickbacks, veiled advertising of drugs, efforts to bias clinical protocols, and off-label promotion.

The Office of the Inspector General and Department of Justice have brought—and continue to bring—numerous cases against pharmaceutical and devices companies in the risk areas outlined by the SFC. In addition to those agencies, several states now have their own fraud and abuse legislation and successfully prosecute such actions at the local level.

In this time of increased governmental scrutiny, companies would do well to turn to a familiar scientific tool to guarantee the quality and independence of CME and minimize the risks of issuing CME grants. Perhaps it's time for peer review in CME.

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Internal Versus External

Many accredited providers use a peer-review process of one form or another, but the process can vary considerably from provider to provider. One fundamental difference is the use of internal versus external content review.

External content review—review by an independent third-party peer reviewer—can validate and document scientific integrity and freedom from commercial bias. It can help ensure that the discussion of off-label use is fair and balanced in the context of available treatment options and that it is supported by evidence and adequately addresses efficacy and safety.

Internal content review—review by employees or permanent contractors of the accredited provider—although useful for program management, should not be confused with independent peer review. An internal content reviewer's objectivity can be affected by personal income, job security, organizational revenue, and internal politics.

Two things set these two types of reviewers apart:

Independence An independent third party does not have relationships with the manufacturers of the products being discussed, the authors of the content, the activity chair, or the accredited provider.

Peer status "Peer" has been defined as someone of equal stature; in the case of reviewer qualifications, criteria should include relevant demonstrated experience, knowledge of the subject matter under review, and absence of real or perceived conflict of interest. Specifically, the reviewer should be a qualified expert for the topic area of the proposed activity. For example, a physician subject-matter expert would be most appropriate for clinical topics that discuss patient-care recommendations, while a pharmacist may be more appropriate for drug interaction or pharmacoecomomic topics.

Independent by Design

Although companies providing grants, may not make requirements of grant recipients, they may consider independent peer review as an objective criterion for grant review. Here are some other tips for building independent peer review into the CME your company sponsors:

Risks Associated with CME Grants

In order to mitigate regulatory risk, companies providing educational grants should address the following with accredited providers and their educational partners.

»**INDEPENDENCE** Accreditation Council for Continuing Medical Education (ACCME) data shows that, in 2005 and 2006, 24 percent of accredited providers "did not comply with at least one of the standards meant to ensure independence." Further, SFC's says its "review suggests that some CME programs that claim to be independent from commercial interests may not actually operate with true independence."

»**CONFLICT OF INTEREST** Both the 2005 and 2006 ACCME reports indicate that the highest rate of noncompliance (19 precent) is for failure to disclose potential commercial bias. The 2006 data indicates the next-highest rate of noncompliance (18 percent) is for failure to resolve conflicts. If faculty are not disclosing their relevant relationships to accredited providers, how then can providers possibly determine conflicts and resolve those that exist? The release of the SFC report was followed by the Institute of Medicine–funded study published in the New England Journal of Medicine on April 26, which found that 28 percent of physician survey respondents reported that they received payments for consulting, giving lectures, or enrolling patients in trials. The percentage of faculty that inadvertently omit and discount relevant disclosure is unknown.

»**CONTENT VALIDATION** ACCME introduced its content-validation policy in 2002. It consists of three value statements that are intended to express the expectations of the accreditation system with respect to content validity and eligibility for accreditation. However, as highlighted by the SFC report, ACCME does not conduct a content analysis that validates accuracy or balanced discussion of competing therapies nor does it identify bias toward the supporting drug company's products.

»**OFF-LABEL DISCUSSION** The SFC report acknowledges that it is "legal for independent third parties to run educational sessions that recommend those products for off-label uses, so long as the educational program is independent and the decision to favorably discuss the off-label use cannot be attributed to the drug company." It continues: "Whether or not FDA has authority to regulate these activities hinges on whether the product messages can be attributed back to the drug's manufacturer."

Put it in the budget Companies considering providing grants to CME providers should include the provision of independent peer review in their own budgeting, request information detailing the content-review process in their grant application, and look for a line item for independent peer review in the submitted activity budget.

The cost of peer review will vary depending on the accredited provider's process, the turnaround time, the number of reviewers, the topic/specialty area, the profession (physician, pharmacist, nurse, etc.), and the credentials required. The amount reflected in the line item may include honoraria and associated administrative fees for coordination. While this information may not be itemized in the grant request, it is worth noting that amounts may differ significantly among grant requests.

Look for it in the grant application Look for evidence that the peer-review process is independent. Reviewers' relationships with the grantor, the presenter/author, the activity chair, and even the accredited provider can bring their independence into question. In addition to relationships with pharmaceutical companies and medical device manufacturers, inherent conflicts exist for reviewers who are employees and contractors of accredited providers.

Evaluate it At a minimum, an effective review evaluates whether the content presents treatment options—including those that are off-label—in a fair and balanced manner, is free from commercial bias, and provides evidence to support treatment recommendations. The activity evaluation should provide participants the opportunity to evaluate these same elements. At the conclusion of the activity, companies may request summary data to verify favorable feedback on these critical areas of concern.

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