

The National Task Force on CME Provider/Industry Collaboration is committed to fostering, furthering and enhancing quality Continuing Medical Education (CME).

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## Continuing Medical Education: Addressing Conflict of Interest (COI)

- The potential for conflict of interest exists in all aspects of human interaction. The Accreditation Council for Continuing Medical Education (ACCME), the national body that accredits providers of continuing medical education (CME) for the purpose of certifying activities for *AMA PRA Category 1 Credit™*, has defined a conflict of interest in CME to be present “...when a planner, speaker or author has **both** a current financial relationship with a commercial interest **and** the opportunity to affect content relevant to products or services of that commercial interest.”<sup>1</sup>

Conflict of interest is a reality in medical education, research, and publishing environments and therefore must be recognized, mitigated, and negated to protect the independence of the environment, that is, all decisions must be free of the control of commercial interests in any and all aspects of relationships involving the support of medical education, research, and publications. For example, ACCME accredited CME providers are required to have and enforce a mechanism to resolve conflicts of interest in the management of their certified educational activities.<sup>1</sup>

- With regard to certified CME, anyone (planners, authors, reviewers, faculty, etc.) who is in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest before engaging in the certified CME process. A relevant financial relationship is defined as any amount of financial gain occurring within the last 12 months prior to the activity by the disclosing individual. Financial relationships of spouses and partners are included in this requirement.<sup>1</sup>
- Disclosure is the first step in a process for the CME provider to determine if the financial relationship is relevant to the content of the certified CME activity and the role and responsibility of the disclosing individual. When the content, role or responsibility is relevant, the second step is for the CME provider to resolve all conflicts of interest prior to the certified educational activity being delivered to learners. This process requires interventions by the provider to negate the COI or disqualify the conflicted party from participation. Anyone in a position to control certified CME content who refuses to disclose is disqualified from further involvement in the current certified CME activity. Finally, learners must be informed of relevant financial relationships prior to the beginning of the certified educational activity.<sup>1</sup>
- The content or format of the certified CME activity and its collateral materials must promote improvements or quality in healthcare and not any proprietary business of a commercial interest. Therefore, processes such as independent peer review of content and changing the role and responsibility of the conflicted party in a manner to negate control of content are required to resolve conflicts of interest. The inability of the CME provider to resolve the COI also results in disqualification of the conflicted party.<sup>1</sup>
- The U.S. Food and Drug Administration, the Department of Health and Human Services Office of the Inspector General, the Pharmaceutical Research and Manufacturers of America and the Advanced Medical Technology Association have established compliance guidelines and codes of conduct governing drug and device manufacturers in their interactions with healthcare professionals. These documents are congruent with and support the ACCME Standards regarding conflicts of interest.<sup>2-5</sup>
- Protecting the integrity, quality, and validity of certified CME is of utmost importance to CME providers, healthcare professionals, and the public. Negation of conflicts of interest in certified CME must be a priority function of CME providers to best serve the profession and the public health.

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(1) Identifying and Resolving Conflicts of Interest in Continuing Medical Education: *An Educational Resource for Implementing the ACCME Standards for Commercial Support*: [http://www.accme.org/dir\\_docs/doc\\_upload/dc0e76c4-16bd-4b78-819b-912ff57ca936\\_uploaddocument.pdf](http://www.accme.org/dir_docs/doc_upload/dc0e76c4-16bd-4b78-819b-912ff57ca936_uploaddocument.pdf)  
(2) FDA Final Guidance: <http://www.fda.gov/cder/guidance/isse.pdf>  
(3) HHS OIG Compliance Guidance: <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>  
(4) The PhRMA Code: <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>  
(5) [http://www.advamed.org/NR/rdonlyres/FA437A5F-4C75-43B2-A900-C9470BA8DFA7/0/coe\\_with\\_faqs\\_41505.p](http://www.advamed.org/NR/rdonlyres/FA437A5F-4C75-43B2-A900-C9470BA8DFA7/0/coe_with_faqs_41505.p)