

Policies and Procedures

Title: Disclosure of Relevant Relationships and Conflict of Interest Resolution*Policy Number 7141.1***Administrative Approval:**

Norton Healthcare System CME Committee

Statement of Purpose

As a provider of continuing medical education accredited by the Kentucky Medical Association (KMA) and adhering to the guidelines set forth by the Accreditation Council for Continuing Medical Education (ACCME), Norton Healthcare must ensure balance, independence, objectivity and scientific rigor for all continuing medical education activities it accredits and supports. All educational content must adhere to Norton Healthcare's continuing medical education mission to provide evidence-based medical education programs for physicians that are designed to enhance participants' competence and performance continuously improving patient outcomes and/or community health.

This policy outlines the guidelines for identification of relevant relationships and the procedure for conflict of interest (COI) resolution for all planners and faculty members participating in CME activities sponsored by Norton Healthcare. Additionally, the process of disclosing relevant relationships to learners is outlined.

(See related ACCME definitions below)

Identification and Resolution of Conflicts of Interest (COI) Identification

As an accredited provider, it is the policy of Norton Healthcare to document that all individuals in a position to control the content of an educational activity disclose all relevant financial relationships with any commercial interest or provider. Individuals that can control content of an educational activity include but are not limited to members of the planning committee, faculty, authors and content reviewers.

The ACCME defines a commercial interest as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

The relevant relationship disclosed should relate to the content of the educational activity. Disclosure of a relevant relationship(s) should address both the individual and their spouse/partner, and must include:

- Financial relationships regardless of the amount,
- The time period of 12 months prior to the educational activity, and
- A relationship with an ACCME-defined commercial interest.

Note: When a person divests themselves of a relationship, it is immediately not relevant to conflicts of interest. This relationship must still be disclosed to learners for up to 12 months.

Individuals are asked to complete a 'Disclosure Form' prior to their participation in the planning and/or the educational activity. Activity chairpersons and planning committee members are asked to complete the disclosure documents prior to the selection of topics and speakers. Speakers, authors and moderators are required to complete all disclosure documentation prior to their presentation or the finalization of enduring materials.

Elements requested on the disclosure form include: 1) if they have a relevant relationship with a commercial interest, 2) identification of the commercial interest, 3) what benefit was received from a commercial interest, and 4) what role was filled to receive the benefit.

An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a speaker, or author of CME and cannot have control of, or responsibility for the development, management, presentation or evaluation of the CME activity.

Note: In adherence to the ACCME guidelines, employees of commercial interests cannot serve as planners or speakers in accredited CME activities if the content relates to their employer's business lines and products.

Resolution Process for Managing Conflicts of Interest

The Office of Continuing Medical Education or designee will review all completed disclosure forms. If there is no disclosure of a relevant financial relationship, no further action is required. If a relevant relationship is disclosed, the following outlines resolution strategy options to resolve the conflict of interest.

Planning Committee Members

Potential Resolution Strategies

1. Identify another planning committee member who has no relevant COI to assist/review the planning to ensure independence of selected topic(s) and speaker(s).
2. Replace the planner that has a relevant COI with an individual that has no relevant COI.
3. Identify a non-conflicted committee member to control the relevant conflicted portion of the agenda.
4. Document how topics and agenda were selected, and this is to be reviewed by the Office of Continuing Medical Education or designee to ensure that there is objectivity and balance in the planning of the educational activity.
5. Planning committee members may change their conflicting relationship with the commercial interest, but must still disclose that the relationship existed within that 12 month reporting period.

Note: If any member(s) of the Planning Committee has a relevant relationship, resolution of the COI should be resolved by the Office of CME prior to planning. Detailed documentation of the resolution is required. It is recommended that the Physician Course Director of an activity not have a relevant COI.

Speakers, Facilitators/Moderators and Authors

Potential Resolution Strategies

1. Presentation review; obtain the presentation prior to the event so content can be reviewed by an individual without a relevant relationship (COI). Content is reviewed to verify that:
 - All clinical recommendations are scientifically-based and within the accepted guidelines;
 - Presentation gives a balanced view of therapeutic options, including use of generic names when possible;
 - If trade names are used, several companies are represented;
 - All scientific research conforms to the generally accepted standards of experimental design, data collection and analysis;
 - Off-label or investigational use is noted;
 - Content promotes improvements in quality of care overall; and
 - No advertising, trade names, logos or product messages are used.
 - If applicable, revision of content may be requested
2. Replace individual, with an individual who has no COI.
3. Assign the person with a COI a role in which therapeutic options will not be recommended.
4. Individual may change their relationship with commercial interests, but must still disclose any relationship that existed within the past 12 months.

Note: If presentation is not reviewed prior to the activity and/or COI cannot be mitigated, CME credit for that specific lecture will not be provided.

Activity Disclosure

Learners are to be advised of the activity planners and speaker(s) relevant financial relationships prior to the activity. This disclosure will include the name of the individual, the name of the commercial interest(s) and the nature of the relationship the person has with each commercial interest. Additionally, if there is no relevant financial relationship, this information will also be provided to the learners.

The disclosure must not include the use of a corporate logo, trade name or a product-group message. Disclosures can be done in a variety of ways and can include but not be limited to: flier/brochure, disclosure slide on Power Point prior to the conference, presentation, signage at the registration table, handouts, verbal announcement, evaluation, confirmation letter, etc.

Additionally, conference attendees are asked to evaluate speakers for the ability to communicate effectively and the evidence of commercial bias or influence. Whenever necessary, this item will trigger appropriate follow-up with the offending speaker. That speaker will be noted and use of him/her as a speaker will be avoided in future.

ACCME Related Definitions

Commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

The ACCME does not consider providers of clinical service directly to patients to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.

Within the context of this definition and limitation, the ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

- 501(c) Non-profit organizations (Note, ACCME screens 501(c) organizations for eligibility. Those that advocate for commercial interests as a 501(c) organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint provider, but they can be a commercial supporter.)
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For-profit rehabilitation centers
- For-profit nursing homes
- Blood banks
- Diagnostic laboratories

ACCME reserves the right to modify this definition and this list of eligible organizations from time to time without notice.

Conflict of Interest: Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.

The ACCME considers **financial relationships** to create actual **conflicts of interest** in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest. The ACCME considers "content of CME about the products or services of that commercial interest" to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers' bureau, ownership interest (e.g., stocks, stock options or

other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. ACCME considers relationships of the person involved in the CME activity to also include the financial relationships of a spouse/partner.

The ACCME has not set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

With respect to personal financial relationships, *contracted research* includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

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