

**The University of Texas M. D. Anderson Cancer Center
Department of CME/Conference Management**

**Guidelines for Requesting and Obtaining Continuing Medical Education
AMA PRA Category 1 Credit™ for an Educational Conference**

The Accreditation Council for Continuing Medical Education (ACCME) has established guidelines and policies to ensure that the content of educational activities that CME providers designate for *AMA PRA Category 1 Credit™* are scientifically based, accurate, and are presented in an objective manner and in the best interest of the public. The University of Texas M. D. Anderson Cancer Center, as a nationally accredited CME provider, has implemented ACCME policies for M. D. Anderson to maintain its accreditation status and its ability to certify programs for physician credit. The program requirements and procedures described below have been established to assist program chairs and their faculty in providing continuing medical education activities that serve to maintain, develop or increase the competence, performance or patient outcomes of their physician audience and support departmental and institutional missions.

Definition

Continuing Medical Education (CME): Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

I. Application Approval Process

- Completed applications (with full documentation and signatures) for CME credit should be completed nine to twelve months prior to the scheduled conference. **Applications without a 6-month “lead time” of the proposed conference will not be accepted.**
- The program chair/co-chair or one of the “active” members of the planning committee for the conference must be a member of the clinical faculty of M. D. Anderson in order to request CME credit.
- Program chair obtains and completes the *Application for The University of Texas M. D. Anderson Cancer Center Sponsorship and Continuing Medical Education AMA PRA Category 1 Credit™ for an Educational Conference*. Program chair forwards the completed application, including all *Disclosures of Relevant Financial Relationships for Program Chairs and Program Planning Committee Members* and *Authorization Approval to Present* forms to CME/Conference Management, Unit 1381. The *Authorization Approval to Present* forms are submitted with the completed application if conference is managed by sponsoring department or by a 3rd party educational partner. If conference is managed by CME/Conference Management (CME/CM), CME/CM is responsible for this task.
- CME/Conference Management forwards the application and supporting documents to the CME Advisory Committee for review, resolution of conflicts of interest, and approval.
- CME Advisory Committee reviews application to determine that
 - the conference appropriately fulfills the definition of CME;
 - the goals and objectives of the conference are consistent with M. D. Anderson’s mission;
 - adequate linkage exists between the proposed activity topics and the needs assessment documentation;

- the activity content, as initially described, is based on valid content and the best available evidence and the information will be objectively presented and independent of commercial interests.
- Additionally, the CME Advisory Committee Members are charged with reviewing program chair(s)' and conference planning committee members' disclosure information so that conflicts of interest will be identified and resolved. Please see *Options for Resolving Conflict of Interest* and/or PowerPoint slide information, *Managing Conflicts of Interest* (ACCME presentation). The CME Advisory Committee must resolve conflicts prior to program approval.
- Program chair should allow at least 4 weeks for approval from the time the completed application is received by CME/Conference Management.
- CME Advisory Committee notifies CME/Conference Management of approval status of the application. Should additional information or clarification be needed, CME/Conference Management acts as the intermediary between program chair, the CME Advisory Committee members, and the Senior Vice President for Academic Affairs.
- CME/Conference Management forwards completed application, required attachments, and comments from the CME Advisory Committee regarding application to the Senior Vice President for Academic Affairs for review and approval. If there is a potential financial liability for M. D. Anderson or M. D. Anderson funds will be used, the application is then sent to the Provost & Executive Vice President for review and final approval.
- CME/Conference Management staff notifies program chair of the approval status of the conference.
- Once the application has received approval, the program chair may proceed with planning the conference in accordance with *ACCME Guidelines*.
- If application approval was denied, CME/Conference Management notifies the program chair of this decision and any changes recommended or comments made by either the CME Advisory Committee members who reviewed application and/or Senior Vice President for Academic Affairs and Provost & Executive Vice President.
- No promotional activity for the conference may occur until the approval process has been completed.

II. Disclosure of Relevant Financial Relationships, Conflict of Interest Resolution, Disclosure of Off-label Use of a Commercial Product or an Investigational Product

- The ACCME has established standards and guidelines to insure that individuals participating in CME activities are aware of faculty/teacher/moderator/author, program chair, and planning committee member relationships with commercial interests that could potentially affect the information presented. M. D. Anderson has implemented a process whereby everyone who is in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest.
- CME/Conference Management obtains signed *Disclosures of Relevant Financial Relationships and Attestation for Faculty/Teachers/Moderators/Authors* forms and forwards these documents to the program chair(s) for review and resolution of potential conflicts of interest, if resolution is required.
- If relationships are indicated, the completed disclosures must be reviewed by the program chair. Should a conflict of interest exist as a result of a financial relationship, it must be resolved by the program chair prior to the activity. Please see *Options for Resolving Conflict of Interest* and/or PowerPoint slide information, *Managing Conflicts of Interest* (ACCME presentation).

- According to the ACCME guidelines, an individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher/moderator, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
- If faculty/teacher/moderator/author changes are made after the final program/syllabus has been printed, verbal disclosure and a slide with the presenter's disclosed information must be used prior to the presentation. Additionally program chair or designee must have the opportunity to review and resolve potential conflicts of interest prior to the presentation.
- Additionally, when an off-label use of a commercial product or an investigational product is discussed during an educational activity, the speaker must disclose this information to the attendees prior to the activity.

Definitions:

Commercial Interest: ACCME Definition: A **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. (from ACCME Policy Updates, August 2007)

The ACCME does not consider providers of clinical service directly to patients to be commercial interests.

Conflict of Interest: When an individual's interests are aligned with those of a commercial interest, the interests of the individual are in 'conflict' with the interests of the public. 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 potential for maintaining or increasing the values of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias.

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.

Financial Relationships: Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, grants/research support, honoraria, consultant fee, 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/educational grants), 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 relations of the person involved in the CME activity to include financial relationships of a spouse or partner. For this purpose M. D. Anderson considers the relevant financial relations of your spouse or partner, of which you are aware, to be yours.

Relevant Financial Relationships: ACCME focuses on financial relationships with a commercial interest in the 12 month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the

incentive to maintain or increase the value of the relationship. The ACCME defines “*relevant financial relationships*” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

Commercial Bias: ACCME defines a commercial bias as a personal judgment in favor of a specific proprietary business interest of a commercial interest.

III. Development of Marketing/Promotional Materials for the Educational Conference

When developing any marketing/promotional material for the educational conference, the following statements (bulleted items) must be included when there is a reference to the conference being designated for CME credit. The exception is a “save the date” announcement (i.e. a card mailer with limited space). A “save the date” announcement may indicate that *AMA PRA Category 1 Credit™* will be provided without stating the exact amount, but only if the activity has been reviewed and certified for *AMA PRA Category 1 Credit™*. A “save the date” announcement may read, “This activity has been approved for *AMA PRA Category 1 Credit™*.” **Promotional materials, in any format, may not indicate that “*AMA PRA Category 1 Credit™* has been applied for, is pending, or application made.”**

In other marketing/promotional materials, such as flyers, brochures, and electronic emails, the information below must appear prior to the program content and faculty listing:

- The University of Texas M. D. Anderson Cancer Center must be noted as the program sole sponsor or joint sponsor.
- Conference logistics.
- Goal of Conference: State the general goal or identify how the conference meets the educational needs of the target audience.
- Educational Objectives:
After attending this conference, participants should be able to...
Objectives must be stated in measurable terms and, if possible, measurable outcomes.
- Target Audience: Identify the specific audience(s) the conference is intended for.
- Educational Method: Lectures, Question and Answer Sessions, Panel Discussions, Posters, Exhibit Programs, etc.
- Evaluation verbiage included when CME/Conference Management standard evaluation survey is used: A course evaluation form will provide participants with the opportunity to comment on the value of the program content to their practice decisions, performance improvement activities, or possible impact on patient health status. Participants will also have the opportunity to comment on any perceived commercial bias in the presentations as well as to identify future educational topics
- Credit and Designation Statements:

If activity is solely sponsored or co-sponsored (used if more than one of the sponsoring organizations are CME providers, and M. D. Anderson is the sponsoring organization that will provide *AMA PRA Category 1 Credit™*). **The statements below (two paragraphs) must be used verbatim.**

The University of Texas M. D. Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Texas M. D. Anderson Cancer Center designates this educational activity for a maximum of [number of credits] *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

If activity is jointly sponsored (used if M. D. Anderson is providing *AMA PRA Category 1 Credit™* and is sponsoring program with a non-accredited organization/sponsor/provider). **The statements below (two paragraphs) must be used verbatim:**

This activity has been planned and implemented in accordance with the Essentials and Standards of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The University of Texas M. D. Anderson Cancer Center and [name of non-accredited provider]. The University of Texas M. D. Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Texas M. D. Anderson Cancer Center designates this educational activity for a maximum of [number of credits] *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Ethics Designation Statement for an entire activity (if applicable)

This course has been designated by The University of Texas M. D. Anderson Cancer Center for [number of credits] *AMA PRA Category 1 Credits™* in medical ethics and/or professional responsibility.

For an ethics presentation within a larger activity (if applicable)

The presentation, [name of presentation], has been designated by The University of Texas M. D. Anderson Cancer Center for [number of credits] *AMA PRA Category 1 Credits™* in medical ethics and/or professional responsibility.

- The statements above may **not** be used until final approval for CME credit has been approved. CME/Conference Management will assign *AMA PRA Category 1 Credits™* based on the activity agenda.
- Mandatory notices within body of flyer/brochure (*verbatim*)
 - * The University of Texas M. D. Anderson Cancer Center has implemented a process whereby everyone who is in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest that could potentially affect the information presented. M. D. Anderson also requires that all faculty disclose any unlabeled use or investigational use (not yet approved for any

purpose) of pharmaceutical and medical device products. Specific disclosure will be made to the participants prior to the educational activity.

* Agendas are subject to change because we are always striving to improve the quality of your educational experience. M. D. Anderson may as needed substitute faculty with comparable expertise in the event of illness, scheduling conflicts, or other such reasons.

* Photographing, audiotaping, and videotaping are prohibited.

* The following statement is mandatory for programs managed by CME/Conference Management: Please let us know what specific topics, issues, or questions you wish to see covered or emphasized in this activity.

Fax or

e-mail CME/Conference Management. All responses will be forwarded to the program chair(s) for consideration.

- Acknowledgment statement is used if commercial funds are provided in support of the event. Acknowledgment of commercial support can be made only when a Letter of Agreement/Support Agreement has been executed between M. D. Anderson CME/Conference Management and the commercial interest and is on file in CME/Conference Management. The following is an example of acknowledgment:

The University of Texas M. D. Anderson Cancer Center wishes to thank [name of commercial interest] for an educational grant in support of this program.

- Registration form or other format. As the CME provider, M. D. Anderson must report the number of physicians (MD/DO) and number of non-physicians participating in the conference. It is recommended that this (highest degree) demographic information be captured on the registration form for the conference.

IV. Educational Grants from a Commercial Interest

- **CME Program Support Agreement**

If the conference receives support from a commercial interest, a *CME Program Support Agreement* must be completed, signed by the representative from the commercial interest and sent to the Department of CME/Conference Management for signature at least 4 weeks prior to the activity or prior to the printing of the final syllabus for the activity. If the commercial interest requests that their own support agreement be signed, **please DO NOT SIGN company's agreement, but forward the agreement to CME/Conference Management** for legal review, approval and signature. Many support agreements originated by commercial interests contain verbiage that cannot be agreed to by M. D. Anderson. It is important to remember that acknowledgment of the educational grant from the commercial interest can only occur after CME/Conference Management has received the fully executed support agreement (all signatures obtained).

- **Support Acknowledgment**

The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to

learners. Examples of in-kind support include lending equipment to use in hands-on activities, or lending an audience response system.

Commercial interests cannot directly pay for any conference expense such as food, social events, speaker expenses, etc. All such items are considered a direct contribution to an activity and therefore a financial gift. Commercial interests may assist the conference with expenses only through educational grants to the conference.

V. Correspondence with Faculty/Teachers/Moderators/Authors

- ACCME requires that certain information including the program goal(s), educational objectives, and target audience be provided to program faculty/teachers/moderators/authors prior to the preparation of presentations. CME/Conference Management suggests that the following verbiage be included in correspondence to faculty/teachers/moderators/authors:

Relevant Financial Relationships with Commercial Interests

The University of Texas M. D. Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME). As such, we have made the choice to meet the ACCME's expectations for our practice of continuing medical education. Our accreditation is important to us.

In accordance with the 2004 ACCME Standards for Commercial Support, The University of Texas M. D. Anderson Cancer Center has implemented a process whereby everyone who is in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest. In addition, should a conflict of interest exist as a result of a financial relationship you may have, this will need to be resolved prior to the activity. In order to do this, please complete the enclosed disclosure form and return it to us by <insert date>. This information will be forwarded to the program chair(s) for review and resolution of any conflicts of interest. This process is necessary in order to move to the next steps in planning this CME activity. **If you refuse to disclose relevant financial relationships, you will be disqualified from being a participant in the planning committee and/or participating in the development/implementation of this CME activity.**

We expect that all CME programs will adhere to the ACCME's content validation statements. Please refer to the *Disclosure of Relevant Financial Relationships and Attestation for Faculty/Teachers/Moderators/Authors* for specific information.

Educational Goals, Objectives, and Target Audience

Based on identified learning needs of the target audience, the program chair(s) have formulated specific educational objectives. To ensure the effectiveness and relevance of your presentation, please refer to the conference brochure for a description of the goals, objectives, and target audience. (If conference brochure with these items is not available, then these

information items need to be included directly in the correspondence or as an enclosure/attachment).

Authorization Approval to Present

The Provost & Executive Vice President has requested that all Department Chairs be given an opportunity to review speaking commitments of their faculty prior to speaker confirmation. Completed *Authorization Approval to Present* forms should be included with the application upon submission if the conference is managed by the sponsoring department or by a 3rd party educational partner. If the conference is managed by CME/Conference Management (CME/CM), CME/CM is responsible for this task.

- CME/Conference Management requires that a copy of the faculty correspondence (letter/fax/email) including the items as described above be submitted. To assist you, CME/Conference Management will review a draft of the proposed correspondence to make sure that all required ACCME information is included.

VI: Disclosure Information and Disclosure Policy Required in Final Program Syllabus

In addition to the information provided in bulleted items listed in Section III for promotional and marketing materials, the following additional information must be included in the final program/syllabus:

- Speaker disclosure information must appear prior to the program content in final program/syllabus.
- Additionally the following Disclosure Policy must appear with the disclosed information (verbatim):

The University of Texas M. D. Anderson Cancer Center Disclosure Policy

The Department of CME/Conference Management makes every effort to develop and implement educational activities that are scientifically based, accurate, current, objectively presented, and in the best interest of the public.

In accordance with the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support*, The University of Texas M. D. Anderson Cancer Center has implemented a process whereby everyone who is in a position to control the content of an educational activity (program chair, planning committee members, faculty/teacher/moderators/authors, CME committee reviewers) must disclose all relevant financial relationships with any commercial interests that could potentially affect the information presented. Individuals who have control of educational content must disclose to participants the existence or non-existence of financial relationships in place at the time of the activity or within one year prior to the activity.

The University of Texas M. D. Anderson Cancer Center has, through a formal review process, resolved all potential conflicts of interest prior to this activity.

For information on this process, please contact the Department of CME/Conference Management at 713/792-5357.

VII. Exhibits, Attendees from Commercial Interests

- Commercial exhibits or advertisements cannot influence planning or interfere with the presentations, nor can they be a condition of the provision of commercial support for CME activities. Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.
- Representatives from commercial interests should not be present in the room when any patient information is discussed.
- One standard exhibit fee is to be charged for each activity. Provision of an educational grant does not entitle the grantor to an exhibit table – exhibits must be purchased separate from the educational grant.

VIII. Honorarium Policy for Faculty

Honoraria paid to guest speakers will be paid by the sponsoring department and per M. D. Anderson's PRS Guidelines issued September, 2004. *"Limited to \$1,000 per visit. Up to \$1,500 per visit for exceptional speakers or events. Amounts above \$1,500 require the President's, or his designee's prior approval."* In conferences managed by external communication companies or medical organizations, in which M. D. Anderson does not assume any financial liability, the program chair determines reasonable honorarium.

IX. Reimbursement for Travel and Accommodation for Faculty

The University of Texas reimburses reasonable travel, accommodations, and meals for external faculty. If teachers, moderators or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only. Faculty must have a bona fide teaching role to receive compensation or reimbursement for attending CME activities.

Internal faculty expenses are also reimbursed when conference is not held within a fifty-mile radius of Houston. Reimbursement guidelines established by M. D. Anderson Travel Management Services are followed.

Please see url: inside.mdanderson.org/departments/travel-mgt-services/guidelines.html.

It is against ACCME Standards and Guidelines for anyone other than the provider, or its agents, to receive direct financial benefit or payment from commercial support.

X. Evaluating the Conference

- The program chair works with CME/Conference Management to develop an appropriate conference evaluation tool for participants. CME/Conference Management is also able to provide a standardize evaluation survey used for clinical conferences.

- CME/Conference Management collects evaluation data, creates evaluation survey, and provides evaluation summary report to program chair for use in planning for future conferences.

XI. Outcome Surveys

- Program chairs will be asked to report the degree to which the desired results of the conference have been met, and changes/improvements that will be considered/made in future events.
- Participants will be asked to evaluate the level to which overall knowledge gained has impacted their practice and/or barriers preventing proposed change(s).

Results of these surveys will be distributed to the program chair(s).

XII. Final Financial Report

CME/Conference Management requires a final financial report on the conference income and expenses.

XIII. Summary of Compliance Responsibilities for Program Chair

As the CME/Conference Management designee, the program chair is responsible for compliance with ACCME essentials and other requirements as specified in Program Chair Responsibilities-Accountability and Attestation listed on the last page of the application. As required by ACCME, all program documentation will be continuously monitored for compliance.

The University of Texas M. D. Anderson Cancer Center reserves the right to withhold or withdraw credit from any CME activity that is found to be non-compliant with any of the aforementioned policies and procedures.

Guidelines for Joint Sponsorship of an Educational Conference

For a jointly sponsored educational conference, CME/Conference Management requests that the preceding *Guidelines for Requesting Continuing Medical Education AMA PRA Category 1 Credit™ for an Educational Conference* be followed. As M. D. Anderson will be involved in the planning and implementation of a jointly-sponsored event with a non-accredited organization, the following additional requirements apply specifically to jointly sponsored events.

Responsibility for Academic Standards and Compliance with ACCME Essential Areas and Policies

The Department of CME/Conference Management of M. D. Anderson is solely responsible for ensuring compliance with academic standards and adherence to the ACCME Essential Areas and Policies.

Eligibility

M. D. Anderson limits its joint sponsorship of CME activities to programs in which the non-accredited institutions/organizations are:

- Non-profit medical associations/organizations/colleges
- Non-profit healthcare associations/organizations
- Hospitals and healthcare facilities

Direct Conflict

M. D. Anderson will not jointly sponsor a CME activity that is being offered in direct conflict with an M. D. Anderson sponsored activity. Conflict includes activities encompassing the same target specialty, date(s), and/or location.

Demonstration of Need for the Educational Program

The non-accredited institution is responsible for demonstrating the need for joint sponsorship of the activity.

Subject Matter/Content

The subject matter, its intent, and philosophy of the educational activity must be within or an extension of the mission of M. D. Anderson and the Department of CME/Conference Management. One of the chairs of the organizing committee or the program chair for the conference must be from M. D. Anderson in order to request and receive co-sponsorship. Guideline: At least 50% of the educational content must be oncology-related; 50% of the expected target audience must be physicians or physician assistants.