

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

**Procedures and Guidelines for a
Regularly Scheduled Series (RSS)**

Introduction

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 credit is scientifically based, accurate, and is presented in an objective manner and in the best interest of the public. M. D. Anderson, as a nationally accredited CME provider, has implemented the following 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 knowledge, skills and professional performance of their physician audience.

ACCME Definitions

Continuing Medical Education (CME) 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 the 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 (American Medical Association).

A **Regularly Scheduled Series (RSS)** is defined as an activity that is planned as

- 1) a series with multiple sessions that
- 2) occur on an ongoing basis (offered daily, weekly, monthly, quarterly, etc.), and
- 3) are primarily planned by and presented to the accredited organization's professional faculty/staff.

Examples of activities that are planned and presented as a regularly scheduled series are Grand Rounds, Tumor Boards, and M&M Conferences.

I. Application/Certification Deadline Dates

- Applications for recertification of currently certified RSS activities as well as newly submitted RSS activities will be reviewed on July 2, 2009 and certified for a two-year period beginning September 1, 2009 through August 31, 2011. After the July 2, 2009 deadline for application submission, new applications will only be reviewed at the beginning of each quarter, with the last quarterly submission being March 1, 2011. The certification period for all programs submitted between July 2, 2009 and March 1, 2011, will end August 31, 2011, regardless of submission date.
- Program chairs are asked to update information following a one-year period of program certification. It is essential that CME/CM be contacted should the program chair, contact/administrator, or program logistics/content change. Activity files must be current in all areas so that appropriate documentation can be maintained by CME/CM throughout the two year certification period.

II. Certification Procedure

- Program chair (must be an M. D. Anderson clinical faculty member - MD or DO) obtains and completes an *Application for The University of Texas M. D. Anderson Cancer Center Sponsorship and Continuing Medical Education AMA/PRA Category 1 CreditTM for a Regularly Scheduled Series (RSS)*.
- Program chair forwards the completed application, together with completed **Disclosure(s) of Relevant Financial Relationships, Program Chairs and Program Planning Committee Members** to CME/CM, Unit 1381. CME/CM staff then takes the following steps:
 - forwards completed application and required attachments to the CME Advisory Committee and the Senior Vice President, Academic Affairs for review and final approval (activities utilizing departmental funds must have Executive V. P. and Provost approval as well);
 - notifies program chair of the approval status of the activity;
 - initiates a mandatory in-service training session with the activity's administrative contact person. Requirements for the documentation of attendance, program evaluation, other ACCME requirements, and questions and answers are addressed at this training.
- **Program certification is not complete until administrative contact training occurs.**
- Initiates a short meeting with each RSS activity chair to discuss program chair responsibilities, ACCME requirements, and to answer any specific questions the chair might have regarding RSS requirements.

III. 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, program chair, and planning committee member relationships with commercial interests that could potentially affect the information presented. 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.
- The procedures the chair/administrative contact uses to obtain disclosure information is dependent on the type of RSS activity.
 - If the RSS activity is didactic in nature, a disclosure form must be completed for each presentation by the faculty member.
 - If the RSS activity is case-based/patient planning/M & M/literature review, CME/CM recommends that disclosure information be completed by all presenting/consulting faculty members once a year and a summary prepared including information from all potential presenters, or one faculty presenter may take responsibility as the lead presenter and his/her information listed on the summary.
- If commercial interests are indicated, the ACCME considers those relationships to be a conflict of interest. The disclosed information must be reviewed and the conflict of interest resolved by the program chair prior to the activity.
- If any faculty/teacher, program chair, or planning committee member refuses to disclose relevant financial relationships, they must be disqualified from being a part of the planning and implementation of this CME activity.

- 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.

ACCME Definitions:

Commercial Interest: 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.

Financial Relationships: Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, grants/research support, consulting fee, 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, which you are aware of, to be yours.

Relevant Financial Relationships: ACCME focuses on financial relationships with commercial interests 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: A personal judgment in favor of a specific proprietary business interest of a commercial interest.

IV. Information that Must Be Disclosed to Participants via 1) Display of CME Information Sheet or 2) Participant Handout or 3) PowerPoint Slides

- To comply with ACCME guidelines, the following required information must be communicated in writing to all participants prior to the presentation:

- Disclosure summary of program chair, planning committee members and presenting faculty. If program chair, planning committee members or presenting faculty have no relationships, this fact must also be disclosed to the prospective audience to be compliant with ACCME guidelines.
 - Educational Objectives
 - Target Audience
 - Accreditation/Credit Designation Statement
 - Acknowledgment of Commercial Support, if applicable
- This information must be communicated at every session, prior to the presentation.
 - The procedure must be documented for participants to receive credit. Documentation of this requirement is met by attachment of the following document(s) to the activity roster for each session of the activity series: the *CME Information Sheet*, participant handout, or copy of the PowerPoint slides, which captures the required information. Incomplete attendance rosters or those rosters without the required attachments will be returned to the sponsoring department and marked as non compliant. **This information should be received within 10 days of the session. Documents not received within 30 days of a session will not be accepted and considered non compliant.**
 - In addition to use of the *CME Information Sheet*, a participant hand-out, or PowerPoint slides format of disclosure summary, verbal disclosure of planning committee and presenting faculty information prior to the actual presentation is encouraged. It is the best method to ensure that participants are aware of any possible conflicts of interest. However, verbal disclosure without the accompanying written handout or slide material does not fulfill the ACCME requirement for compliance.

V. Commercial Support

- **CME Program Support Agreement:** If the educational activity receives support from a commercial interest, a letter of agreement must be executed and signed by a representative from the commercial interest. This may be a M. D. Anderson CME Program Support Agreement or an agreement provided by the commercial interest. If the commercial interest submits their agreement to the sponsoring department, do not sign, but forward to CME/CM for approval and signature. Many agreements originated by commercial interests contain verbiage that cannot be agreed to by a state institution. It is important to remember that acknowledgement of the educational grant from the commercial interest can only occur after CME/CM has received the fully executed support agreement (all signatures obtained). If the educational grant is for a specific session of the series, the support agreement must be executed prior to the educational session. Please forward to CME/CM all support agreements and a copy of support check(s) upon receipt. The program chair, as the delegated CME representative, is ultimately responsible for the enforcement of all conditions described in the agreement. The money received from the commercial interest must be in the form of an educational grant to the sponsoring department.
- **Support Acknowledgement**
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 for a presentation.

Meals are a direct contribution to an activity and are considered a financial gift. Food costs must be covered through grants to the sponsoring department. Letters of agreement are needed and the provider (sponsoring department) is responsible for making arrangements for food service and for paying all related expenses.

VI. 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.

VII. High Risk Presentations Which Have Potential for Being Commercially Biased

- Should your Department be asked by either a 3rd party entity or a commercial interest to host a Speaker Bureau type presentation, please contact CME/CM to receive additional information, guidelines, and evaluation on this type of presentation. Invited presenters employed by commercial interests (i.e. Merck, Lilly, etc) are also included in this category.

VIII. Documentation of Attendance Using an Attendance Roster

- **Attendance Roster**

During the CME in-service training, the administrative contact will receive a unique attendance roster that reflects the program code (as assigned by CME), name of the sponsoring department, name of the activity or series, administrative contact, unit, phone and fax. The roster should be copied and the date, presentation topic, and faculty/teacher(s) name, institution (if guest) and employee ID number typed on the form for each activity or session.

Following this training, CME staff will e-mail an electronic version of this “WORD” document to the administrative contact along with electronic versions of the required forms that must be completed or displayed for each activity or session. The roster should be duplicated and the specific program information (date, program topic, faculty/teacher) for each activity should be recorded.

- **Automated Attendance Verification (AAV) System (Electronic Method of Attendance)**
CME/CM has implemented an electronic system whereby employees scan their ID badge to record their participation in each activity or session. The sponsoring department must have a laptop and a card/badge reader available during their program. CME/CM will provide reader equipment purchasing information upon request.
- **Outside Participants**
Participants who are not employees of M. D. Anderson who need documentation of their participation or CME credits, must create a six-digit ID number. This six-digit ID number must be recorded in the selected field on the attendance roster. The CME staff will create a profile so that each time the outside participant attends a regularly scheduled series (RSS)

his/her participation will be documented. Upon request, CME/CM will provide a transcript of the certified educational activities attended by an outside participant.

- **CME/CM will not complete attendance documentation of a session until a completed roster and all required documents/attachments are returned to CME/CM. This information should be returned within 10 days of each session. Documents not received within 30 days of session will not be accepted and considered non compliant.**

IX. CME Evaluation Form (Scannable)

- Regularly scheduled series must be evaluated by participants on a quarterly basis: September through November; December through February; March through May; June through August (unless program recesses). This is a standard form that is automatically tallied by the CME Staff, with a summary e-mailed to both the program chair(s) and administrative contact.
- 1st Quarter's evaluation forms will be mailed to each administrative contact prior to September 1. Completed evaluation forms from the sponsoring department should be received in the CME/CM office by the 2nd week in December, March, June, and "the last week" in August.
- Those presentations specifically funded by a single commercial interest or supporter must be evaluated separately for commercial bias. **Notify CME/CM at least three (3) weeks prior to the presentation date so that these forms can be coordinated in a timely manner.** Also, CME staff will arrange for a member of the CME Advisory Committee or designee to be in attendance.

X. Outcome Surveys

- Program chairs will be asked to report the degree to which the desired results of the RSS have been met. An outcomes evaluation form will be e-mailed to them midway through the certification term and again at the end of the 2-year certification.
- Participants will be asked to evaluate the level to which overall knowledge gained has impacted their practice and/or barriers preventing proposed change(s). These evaluations will be e-mailed bi-annually.

XI. Budgeting Updates

- CME/CM requires budget updates on educational grants received from commercial interests for RSS operations. This is required only from departments who have received this type of funding for their RSSs activity.

XII. Honorarium

- Honoraria paid to guest speakers will be paid by the sponsoring department and per 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."*

XIII. Monitoring the Series

- **Documentation Submission**

Monitoring of each occurrence of the activity begins with the submission of the activity roster and attachments. A checklist is provided to assist in determining the attachments required for the individual program. Incomplete information will be returned for completion and/or appropriate

attachments. Attendance will not be documented until the activity is in complete compliance with these requirements.

If the program is considered to be non-compliant, the Administrator and Program Chair will be contacted with improvements needed to make the program compliant.

- **On-Site Monitoring**

All activities will be visited by CME/CM staff at least twice annually for monitoring of compliance with the ACCME guidelines. Monitors will be assuring that appropriate information is provided to participants prior to the presentation, which includes:

- CME accreditation and designation statements,
- Educational objectives,
- Target audience,
- Faculty/teacher disclosure of relevant financial relationships, and;
- Acknowledgement of commercial support (if applicable).

Should the monitor find a deficit in any area, the Administrator and Program Chair will be notified by e-mail, so they may make appropriate corrections. A follow-up visit will occur to assure advised corrections have been made.

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

If a program becomes non-compliant and remains so through the end of any quarter, CME certification will be revoked.