

# **CME ACTIVITY DEVELOPMENT AND DOCUMENTATION GUIDELINES**

Office of Continuing Medical Education  
University of Missouri School of Medicine  
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**This document explains the requirements of the Accreditation Council for Continuing Medical Education (ACCME), and provides guidance on the Application for CME Credit.**

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## Section One: Introduction

The purpose of this document is to provide background information on CME accreditation requirements for preparing a CME Application for category 1 credit. The Application is used for CME activities that are not managed primarily by the Office of Continuing Medical Education, including Regularly Scheduled Series (RSS) such as Grand Rounds, etc.

The national standards for activities of this kind are established by the Accreditation Council for Continuing Medical Education (ACCME) and are called the CME Essentials. A significant shift has occurred in the CME enterprise over the course of the past five years. The updated ACCME Essentials, including the Criteria for accreditation, provide guidance to assist CME providers to incorporate many of the same adult learning principles that are reflected in undergraduate and graduate medical education and adult learning theory. CME should be designed to enhance physician competency and practice with the anticipated goal being the reduction of medical errors and patient harm.

All activities awarding category 1 credit must comply with the Essentials and the updated ACCME accreditation Criteria. The Criteria are specifically intended to foster measurable change and improved patient care through the delivery of continuous learning aimed at improving physician knowledge, competence, performance and patient care outcomes. The Criteria support the development of CME activities that contribute to improving physician practice.

To be sure that the Essentials, as well as the Criteria, are implemented, ACCME conducts random audits of activity files, and our overall CME program is reviewed in detail for re-accreditation every four to six years. The next section provides an explanation of areas of the Essentials. The Application for CME Credit is based on the Criteria.

ACCME requires that we - the CME Office - as the accredited program within the MU School of Medicine be involved early in the development of every educational activity for which category 1 credit(s) is provided. If the activity is organized by an entity outside of the School of Medicine, **significant** faculty involvement is required. **WE ARE NOT PERMITTED TO GRANT CME CREDIT UNLESS WE ARE INVOLVED IN AN ACTIVITY BEFORE TOPICS AND SPEAKERS ARE FINALIZED.**

ACCME's Essentials are based on a particular point of view regarding CME activities. This perspective suggests that CME activities should be done not for their own sake or as some sort of ritual, but as carefully designed interventions intended to respond to professional practice gaps in the practice of medicine. The ACCME defines a professional practice gap as the difference between current health care processes or outcomes observed in practice and those potentially achievable on the basis of current professional knowledge and standards of care. Basically, the gap is the difference between what your learner currently knows or has the ability to do and where they **SHOULD BE** in their knowledge, competence and/or performance. Following are some questions that can help identify **professional practice gaps**:

1. What data sources are available that might identify areas where improvement is needed? (for example, local or national quality data, departmental data, departmental reports, clinical reports, quality improvement and performance improvement committee reports)
2. What do learners report are their learning gaps? (for example, surveys of learners in which they can report key issues or obstacles to patient care)
3. Are there institutional data that illuminate challenging clinical situations for learners? (for example, Joint Commission on Accreditation of Healthcare Organizations core measures or other quality measures)
4. Are there patient cases that consistently present challenges in the learners' clinical practice (for example, the difficult patient, the co-morbid patient)
5. What are the most common cases seen in learners' practices and are there opportunities for improvement or coordination of care?
6. What are the most prevalent and serious medical problems in your local region or state?

ACCME's Essentials require a coherent approach to the development of CME activities to meet this challenge. The Essentials also address important concerns about the influence of commercial funding on CME activities.

## Section Two: The ACCME Essentials

### I. **MISSION** (Essential Area 1-PURPOSE AND MISSION *requires the CME office to have a written statement of its Mission*)

The mission for education for the University of Missouri, School of Medicine serves as the foundation for the CME mission. The Office of Continuing Medical Education serves as a liaison between the cutting edge research and standards of care implemented at the School of Medicine and University of Missouri Hospital and Clinics that is then shared with healthcare providers throughout the State of Missouri. The mission of the School of Medicine and the CME Mission guide our CME program overall and CME activities. (Copy of the Mission Statement is available on our website at <http://medicine.missouri.edu/CME> and look for the link to "About" CME).

### II. **IDENTIFYING AND DOCUMENTING PROFESSIONAL PRACTICE GAP** (Essential Area 2-EDUCATIONAL PLANNING)

There are many ways to assess professional practice gaps and determine educational needs, several of which are listed in the Introduction of this document as well as in the Application for CME Credit. The documentation of the gap and need should address one or more of the following three key areas: knowledge, competence and performance of the target audience. They may range from carefully designed surveys to informal discussions with members of the target group. Expert opinion is also a valid form of needs assessment. For example, we have often addressed needs expressed by a faculty member who had concluded from recent experience that the primary care physicians in the referral area too often mismanage a particular condition. Some examples of data sources for needs assessment documentation are as follows: QI data; New requirements for practice; Institutional strategic plans; Community health needs assessment; Information needs/library requests; Feedback from third party payers and regulators; Patient satisfaction surveys; and, Medical staff committees. As long as you can document that an organized effort was made to discover educational needs among members of your target group, you will have met the ACCME standard. **PLEASE SUBMIT ALL MATERIAL RELATED TO IDENTIFYING THE PROFESSIONAL PRACTICE GAP AND NEEDS ASSESSMENT DOCUMENTATION ALONG WITH YOUR CME APPLICATION** (i.e., minutes from your planning meetings, etc.).

Needs assessment implies a target group, in the sense that whatever needs are discovered belong to some particular group (such as QI staff/committee(s); Pharmacy and P&T committee(s); Infection control staff/committee(s); Librarian/information specialist; Electronic health record committees and staff; Compliance office(s); Strategic planning and marketing offices; Billing office; Office practice managers; Community organizations). Things don't always work in a predictable order when an activity is being planned. Sometimes the target group is a given, as when our School attempts to serve unmet CME needs among rural primary care physicians. In other cases there is a problem to be solved, and the target group is not clear until the situation is explored. In any case, needs assessment and the identification of a target group go hand-in-hand, and clear thinking on both are necessary if coherent educational planning is to occur. ACCME requires that needs assessment efforts and decisions regarding the target group be documented in the conference file, as the Application indicates.

### III. **LEARNING OBJECTIVES** (Essential Area 2-EDUCATIONAL PLANNING)

The Essentials require a clear and reasonably specific statement of what the activity is designed to accomplish. The educational objectives should be framed in terms of the expected changes in professional practice gaps in the key areas of:

- competence,
- performance and/or
- patient outcomes,

as a result of addressing the gaps. It is not enough, for example, to say only that an “activity will provide an update on the latest developments in cardiology”. It is necessary to list the areas of cardiology being addressed and to describe the educational impact you expect. For example: “Participants will understand the risks and benefits of balloon angioplasty”. Sometimes your reasons for doing a CME activity are much more specific. The more specific you can be the better.

It is important to note that if educational objectives are designed specifically to change patient outcomes, then we will ask for patient data to verify the outcome.

The value of objectives lies partly in the way they help activity planners to think more clearly. They help potential participants decide whether to attend the activity. Objectives also suggest the terms in which an activity's success or failure should be judged. When objectives are written with as little thought as possible, just to meet the requirement, an opportunity is wasted. Since you need to write objectives anyway, consider using them as an opportunity to think carefully about the activity you are planning.

The objectives must be shared with activity participants and should be included in any publicity materials. They must also be shared with speakers, since speakers are less likely to meet your objectives if they don't know what the objectives are. Speakers should also be given any other information (such as the nature of the target group) necessary for them to understand their role in addressing the objectives. If you do this by letter or email, then that becomes good documentation (a sample letter is available on our website) to accompany your application.

#### IV. **EDUCATIONAL METHODS AND PLANNING PROCESS** (Essential Area 2-EDUCATIONAL PLANNING)

The design of your educational activity is the most important part of the planning process. Too often in CME, topics are chosen and lectures are fit mechanically into a schedule as though no better alternatives exist. In almost every case, a CME activity attempts to convey not just a group of facts but a way of thinking about clinical situations or disease states. There is a very substantial research base showing that methods other than lecturing, especially formats providing a lot of interaction between learners and teachers, work better when you have objectives of this kind. Medicine has a rich history of using interactive techniques such as case discussions. ACCME merely requires that some thought be given to these alternatives, and that the choices you make are appropriate to the job you are trying to do. The Office of Continuing Medical Education is quite willing to work with you on these points.

The selection of educational methods should be discussed explicitly by activity planners, and this should be reflected in minutes or notes taken by activity managers. **These notes will become an important part of the application file.**

#### V. **EVALUATION** (Essential Area 3-EVALUATION AND IMPROVEMENT)

It is required that you provide an opportunity for participants to tell you what they like and dislike about your activity. It is helpful to assess expected or anticipated changes in knowledge and attitudes that result from an activity. Pre- and/or post-questionnaires or evaluations can be used for this purpose.

It is helpful to ask for participants' ideas for future activities.

This can be done in many ways:

- Written questionnaire for all participants;
- Written questionnaire for a sample of participants;
- Individual interviews with a sample of participants;
- Focus Groups (also useful as needs assessment);

- Feedback session during the activity;

...and there are many others. In the absence of the opportunity to do evaluation research, the best approach is to use an evaluation method that will give you information you can use. Don't ask a question if you'll do the same thing regardless of the answer. Don't collect lots of apparently quantitative data if you will end up making an off-the-cuff guess as to its meaning. **DO ask specifically whether the learning objectives of your activity were met and solicit open-ended comments rather than only answers to multiple-choice questions.** The point here is not to discourage quantitative evaluation when it is possible, but to emphasize that the evaluation's main purpose is to help you do a better job of designing CME activities.

ACCME requires that every activity providing category 1 credits be evaluated in some organized way. The results of your evaluation effort must be documented and can be used in the planning of subsequent activities. A sample evaluation can be found on our website or provided upon request.

VI. **ADMINISTRATION** (Essential Area 2-EDUCATIONAL PLANNING)

ACCME's main administrative requirement is that CME activities be managed in a way orderly enough to permit the sponsor to exert control over important issues such as the handling of commercial support.

**A copy of the budget and all other financial records should be in the file. A complete income and expense statement is part of the final or post-activity report provided to the Office of Continuing Education. Copies of all agreements or contracts related to the conference will also be needed (sample documents can be found on our website or provided upon request).**

VII. **JOINT SPONSORSHIP** (Essential Area 2-EDUCATIONAL PLANNING)

In ACCME's terms, Joint Sponsorship means that an organization other than the School of Medicine, not having its own ACCME accreditation, has a significant role in the development and management of a CME activity. When another organization is simply listed as a sponsor in the brochure or endorses the activity, this in itself does not amount to Joint Sponsorship.

The ACCME requires that the accredited sponsor - in this case, the School of Medicine - be "integrally involved" in the management of activities for which they grant category 1 credit. We are no less responsible for the observance of a jointly sponsored activity than we are for activities that are not jointly sponsored. When there is a joint sponsor we assume a special burden to document that the School's involvement was sufficient to meet ACCME requirements. The Joint Sponsorship Supplemental Application addresses those issues, and must be submitted along with the usual Application for CME Credit (Joint Sponsorship Supplemental Application and materials are available upon request).

Integral involvement does not mean that a School of Medicine faculty member merely attends one or two committee meetings or reviews the activity schedule before it is published. It means that faculty or staff of the School of Medicine is actively involved in every aspect of the activity's development and management, as the Supplemental Application makes clear.

When approached by an outside group that wants CME credits but is not able to meet the standard of integral involvement, it is often helpful to remind them that the Missouri State Medical Association can provide category 1 credits for activities offered within Missouri. Their phone number in Jefferson City is 573/636-5151. In addition, any organization may apply to ACCME to become an accredited provider, although this process takes several months and involves an extensive application. The Office of Continuing Medical Education can provide information on how to begin this process.

VIII. **COMMERCIAL SUPPORT** (Essential Area 3-EDUCATIONAL PLANNING)

The ACCME has issued standards on commercial support for CME activities. A copy is available on our website or upon request. Their practical implications are addressed in the Application. It is important to know that it is School of Medicine policy to fully observe the ACCME Standards on Commercial Support. CME credit approval will be withdrawn from any activity that violates the Standards. Initial approval will not be provided unless it is clear that the Standards will be carefully observed.

Why all the concern over commercial support? Because there have been too many instances in which CME activities were used as a cover for product promotions by companies funding an activity. Both the pharmaceutical industry and the CME community had a role in creating these problems. Recent concern by Congress and the FDA has made commercial support one of the most visible issues in the field and one to which ACCME attends closely in accreditation reviews and file audits.

We have had many successful and mutually respectful relationships with commercial supporters, and most have observed the highest ethical standards in their CME funding. These rules are not meant to suggest in any way that there is something inherently wrong with commercial support or the people who offer it.

**The unifying principle of ACCME's Standards on Commercial Support is that companies providing commercial support may have no influence whatsoever over the content of CME activities, so that CME activities include no promotional activities.** While companies are certainly free to refrain from funding activities that do not interest them, they can have no role in planning the activities they do support. That means the impetus for an activity must come from a needs assessment effort or a need perceived by a member of the faculty or CME staff, not from the marketing agenda of a commercial supporter. Faculty members, not representatives of supporting companies, must select topics and speakers.

Sales representatives of commercial supporters may attend educational sessions but may not participate in discussions or engage in any sales or promotional activities of any kind, including one-to-one discussions of this nature with CME activity participants, during or immediately after an educational session. The operational point here is that educational sessions may not become tools by which sales representatives gain access to customers for promotional purposes. If such access is to be provided, it should occur in designated exhibit areas (which must be separate from educational sessions) or during social functions.

For the same reason, printed and audiovisual materials used at a CME activity may not contain any promotional material. For example, a handout that would otherwise be perfectly acceptable may not be used if promotional material (such as an ad for a particular product) is printed inside the back cover, or if a large company logo appears on the cover. In both printed materials and presentations, generic rather than brand names should be used for drugs. If the generic is not widely known, this can be addressed by briefly defining it when it is first mentioned in the presentation or handout.

**A second important principle is that the existence of commercial support must be clearly acknowledged.** The Application provides standard text that may be used in brochures. Such acknowledgements must not be in the fine print or in an obscure location. On the other hand, they must not become ads for supporting companies. We will be happy to provide examples.

**A letter of agreement must be signed by a representative of each supporting company and must be in the file.** This letter of agreement documents that you have informed the company of the ground rules, and that its representative has accepted them. A model letter of agreement is available on the website or upon

request. We will be happy to assist you in the education of any commercial representatives who may not know about these requirements.

Honoraria received by speakers may also create the appearance or reality of a conflict of interest. The same points apply to other financial interests speakers may have in companies that make products related to the subject of their presentations. For example, some academicians receive very large research grants from pharmaceutical companies. Others may be principles or major investors in the maker of a new medical device or genetically engineered drug. Frequently it is these people who are the world's best speakers on these topics. The answer is not to prevent such presentations, but to disclose the existence of relevant financial relationships and to maintain an activity that has been developed independent of any financial influence. **Every speaker at a CME approved activity must complete a conflict of interest disclosure form** (a copy is available on our website or upon request). All completed disclosure forms must be reviewed and signed by the activity chairperson; any potential conflicts must be resolved and the resolution indicated on the form. The conflict of interest form must be shared with the participants as a handout placed in the front of the activity packet or otherwise included in the speaker's presentation. You are also required to print the disclosure statements on your sign-in sheets. Please show documentation as to how you handled this policy.

Commercially supported social events may not, in the words of the Essentials, "compete with [or] take precedence over the educational events." It is easy enough to avoid competition - just schedule these activities at different times. If an activity involves as much commercially supported entertaining as it does education, it is legitimate to question which takes precedence. In addition, commercial support cannot be used to provide especially lavish catered or social events, since that would violate the AMA and FDA rules against gifts to physicians of substantial value. This is admittedly somewhat subjective. It is permissible to provide good meals as part of a CME activity. Lavish receptions with champagne fountains or multi-course gourmet dinners with expensive wines are another matter. Of course, the simple passage of commercial funds through a University account does not alleviate these concerns. Any activity receiving commercial support must observe these constraints. If you have any questions about this, be sure to consult the Director of Continuing Medical Education. **Note that your plans in this regard must be described in the Application for CME credit.**

The Standards on Commercial Support address other issues such as exhibits, the handling of commercial support funds, and the clear identification of off-label uses that may be discussed at an activity. These are addressed in the Application. Read the ACCME Standards carefully. Do not hesitate to contact the CME Office if you have any questions about the meaning of the Standards.

If you should become aware of any attempt to circumvent these standards, whether by a company representative or faculty member, it is your responsibility to inform the Director of Continuing Medical Education. We take these standards very seriously, because their principles are sound and because our accreditation literally depends on their observance.

**SECTION THREE: REGULARLY SCHEDULED SERIES** (i.e. Grand Rounds and similar series)

Grand Rounds and similar series require an approach slightly different from that used for a typical one time CME activity although the application and documentation requirements are the same.

A CME series consists of many relatively brief presentations occurring over a period of time. It would be impractical to undertake a complete planning effort for each of these brief presentations. Instead, the entire series is viewed as a CME activity. Taken as a group, its several presentations must amount to a coherently planned activity, no less so than an activity consisting of several presentations on a single date. For ongoing series such as Grand Rounds, a planning process, needs assessment and CME Application must be prepared and documented at least annually.

Since needs change during the course of a year, ACCME requires an interim review of the series and a report to the CME Office at least every six months. More frequent reviews are encouraged. Details on the review and report are included in the Application.