

UAMS



COLLEGE OF MEDICINE

UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

Office of Continuing Medical Education

**POLICIES, PROCEDURES AND INSTRUCTIONS
FOR
CME ACCREDITATION OF
ENDURING MATERIALS**

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Individuals or groups desiring to produce enduring materials (EM) for sponsorship and approval of *AMA PRA Category 1 Credit(s)[™]* by UAMS College of Medicine (COM) must comply with the all of the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) including the Standards for Commercial Support. This includes compliance with requirements of the UAMS College of Medicine. The UAMS COM Office of Continuing Medical Education (OCME) has developed the following guidelines for use when requesting sponsorship for enduring materials, to help assure that compliance is met.

Definition of Enduring Materials

An enduring material is a non-live CME activity that endures, or lasts, over time. It is most typically a videotape, monograph, DVD, CD-Rom or a web-based activity. When using an enduring material, the learning experience for the physician can take place at any time in any place, in contrast with the learning at a live CME activity that takes place at one time and in one place. Enduring materials in themselves constitute a structured CME activity.

ACCME Requirements

- 1) Enduring materials must comply with all [ACCME Essential Areas and Elements](#) (including the [Standards for Commercial Support](#)) and [Accreditation Policies](#). However, since there is no direct interaction between the provider and/or teacher and the learner, the provider of the enduring learning material must communicate the following information to participants so that they are aware of it prior to beginning the educational activity:
 - a) Names of the principal faculty members and their credentials;
 - b) Medium or combination of media that will be used within the enduring material;
 - c) Hardware and software requirements for studying the enduring material;
 - d) Method of physician participation in the learning process;
 - e) Estimated time to complete the educational activity (same as number of designated credit hours);
 - f) CME contact information (UAMS College of Medicine Office of Continuing Medical Education);
 - g) A link to the OCME Internet Privacy Policy Statement must appear within one of the opening screens or pages;
 - h) Copyright information and appropriate permissions;
 - i) Dates of original release and most recent review or update; and
 - j) Termination date (date after which enduring material is no longer certified for credit).
- 2) Enduring materials must be reviewed at least once every three years or more frequently if indicated by new scientific developments. The enduring material cannot be certified for credit for more than three years without some review on the part of the provider to ensure that the content is still up-to-date and accurate. That review date must be included on the enduring material, along with the original release and termination dates.
- 3) Enduring materials must **not**:
 - a) Reside on a pharmaceutical or device manufacturer's product website.
 - b) Include links within the activity to a pharmaceutical or device manufacturer's website.
 - c) Contain product specific references or advertising.

- 4) Commercial interests may not provide or distribute enduring materials to learners.
- 5) Each enduring material activity must provide an assessment of the learner that measures achievement of the educational purpose and/or objective(s) of the activity with an established minimum performance level. Examples include, but are not limited to, patient-management case studies, a post-test, and/or application of new concepts in response to simulated problems, in order to be awarded *AMA PRA Category 1 Credit(s)*[™]. This requirement is to ensure compliance with AMA requirements.
- 6) Each enduring material activity must include a means by which participants evaluate the activity, after having participated.
- 7) An enduring material may be developed from a live CME activity. When this is done, the ACCME considers these to be two separate activities – one live activity and one enduring material activity requiring two separate applications. Both activities must comply with all ACCME requirements, and the enduring material activity must comply additionally with all ACCME policies that relate specifically to enduring materials.

Procedures and Instructions

Step 1: Consultation and Obtaining Preliminary Approval for CME Sponsorship

- 1) An initial consultation must occur involving the individual(s) seeking CME approval for an EM and the OCME Director and/or the Associate Dean for CME. The purpose of this meeting is to:
 - a) determine that the concept and proposed content of the EM is appropriate for CME credits, if approved;
 - b) determine if the proposed educational activity falls within the CME Mission of the UAMS College of Medicine;
 - c) determine the individuals' level of knowledge about the ACCME Essential Areas, Policies and Standards;
 - d) discuss the target audience and marketing plan;
 - e) discuss the application process and CME requirements;
 - f) discuss whether commercial support will be sought;
 - g) discuss CME fee structure.

Step 2: Application Process

- 1) The Course Director or organizer/creator of the educational material obtains and completes the **CME Application Form**, checking the box on page 1 indicating the activity is an enduring material. The form can be found after this document.

*The following items must be submitted to the OCME at least 12 weeks **prior** to the desired release of the enduring material. The OCME will make every effort to assure that the testing, review, and approval process progresses in a timely manner.*

- 2) **Supporting documentation** must accompany the completed application form:
 - a) Provide documentation of at least two of the methods used in determining the need for the educational activity. This should succinctly describe the sources used to identify the

professional practice gaps that the enduring material intends to close (the difference between what is in practice and the ideal of where practice should be). Examples might include journal articles citing new information pertaining to the selected topics; copies of physician surveys; new procedures or guidelines, and past program or activity evaluations requesting as ‘future topics’ the content to be addressed in the proposed enduring material.

- b) Provide a list of all the activity’s planning committee members and author(s) with credentials.
 - c) Provide a curriculum vitae or bio for each author who will contribute to the enduring material.
 - d) Provide a completed [Disclosure of Relevant Financial Relationships Form](#) for each planning committee member and author.
 - e) If the activity is supported through an unrestricted educational grant from a commercial supporter, provide a completed, signed and dated Commercial Support Agreement, also referred to as a Letter of Agreement (LOA), for each company supporting any portion of the activity. A company’s own agreement, written or electronic, is acceptable as long as it meets the ACCME criteria. This agreement must be signed by all parties to meet compliance with the Standards for Commercial Support.
- 3) The CME Payment Agreement for Enduring Materials along with payment of the predetermined fees must accompany the completed application form. CME fees are NOT REFUNDABLE once the application has been reviewed and initial approval is granted.
- a) Fees, determined in advance, will cover the following components and be charged as appropriate to each client.
 - b) Direct Sponsorship vs. Joint Sponsorship
 - i. Basic direct sponsorship fee - see annual CME fee schedule (www.uams.edu/cme)
 - ii. Basic joint sponsorship fee - see annual CME fee schedule
 - c) Costs of peer review
 - i. Peer review fees are based on paying 1-3 UAMS faculty members (\$125 per hour multiplied by 2.5 times the estimated length of the EM) to cover actual time spent on the review work.
 - ii. Appropriate peer-review is a requirement. OCME staff will work with each client to determine the most appropriate means of accomplishing this requirement, and its documentation.
 - d) Costs of pilot testing
 - i. Pilot testing fees are based on paying 1-3 CME staff members (\$50 per hour multiplied by 2.5 times the estimated length of the EM) to cover actual time spent on the review work.
 - e) Costs of assistance in obtaining and managing commercial support for the enduring material
 - i. The OCME requires a minimum of 10% of any commercial support obtained to support the activity.
 - f) Costs of CME certificates and tracking of CME credits to participants in the enduring material. OCME staff will determine with each client how learner participation in the

activity will be verified and how learner evaluation of the enduring material will be transmitted to the OCME. The means by which these actions are taken will be considered in setting the fees for participants' CME certificate and the tracking of their CME credits.

- i. If the required information can be electronically transferred to the OCME, including recording of credit within the OCME database, these fees will be waived.
 - ii. If OCME staff time is required for data entry, OCME staff will negotiate the appropriate credit tracking fee with each client, carefully considering the amount of staff time required to accomplish the tasks.
- g) Renewal fee
- i. If the EM is to be renewed at the credit expiration date (normally after three years), the original basic approval fee will be levied, plus a possible charge for repeat peer review, if the Associate Dean for CME determines that the EM should be reviewed for content validity.
 - ii. Authors must inform the OCME six months before the credit expiration date if they intend to continue offering the CME credit.
- h) Fee Payment
- i. The sum of the fees for peer review and CME credit approval work must be paid prior to the activity release.
- i) Additional Fees
- i. If additional testing and/or review work is necessary to correct issues identified through peer review, an additional fee will be charged, determined by the actual time spent doing the work.
- j) All additional testing and review fees must be paid before the final credits are approved and the enduring material is released.
- 4) Once the application is reviewed by the OCME reviewer, an initial approval is conveyed to the Course Director or organizer to proceed with the development of the educational material.

Step 3: Developing the Educational Product (Enduring Material) – components required for CME credits and the educational content

When developing the enduring material the following components must be included at the beginning of the educational content of the material itself as well as on the program packaging:

- a) The UAMS College of Medicine must be noted as the “sponsor” (UAMS COM department) or “joint sponsor” (course sponsors are not from a UAMS COM department).
- b) OCME staff and each client must determine appropriate use of the UAMS College of Medicine logo.
- c) Accreditation statement (verbatim):
 - i) Directly (COM department) sponsored activity: “The University of Arkansas for Medical Sciences (UAMS) College of Medicine is accredited by the Accreditation

- Council for Continuing Medical Education to provide continuing medical education for physicians.”
- ii) Jointly sponsored (not a COM department) activity: “This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of The University of Arkansas for Medical Sciences (UAMS) College of Medicine and <name of joint sponsor(s)>. The UAMS College of Medicine is accredited by the ACCME to provide continuing education for physicians.”
 - iii) Co-sponsored activities use the directly sponsored activity statement of the accredited provider taking responsibility for the accreditation.
- d) The educational purpose or objectives must be stated.
 - e) The target audience must be explicitly identified.
 - f) Principal faculty/authors and their credentials must be listed. Producers have some latitude as to how extensively the authors' credentials are noted. At a minimum, terminal degrees and institutional affiliation(s) should be included. More details may be appropriate, and noted within brief biographical sketches that clarify why specific individuals were selected as faculty authors of the enduring material.
 - g) A description of the medium or combination of media that will be used within the enduring material must be specified.
 - h) A description of the hardware and software required to study the enduring material must be specified.
 - i) The method of physician participation in the learning process must be specified.
 - j) Estimated time to complete the educational activity.
 - k) Dates of original release and most recent review or update, or dates valid for CME credit.
 - l) Disclosure of Relevant Financial Relationships for each activity organizer, planner, author and faculty member regarding financial relationships and off-label discussions pertaining to this activity. (Note, any faculty or planning member who refuses to disclose significant financial relationships may **NOT** participate in the planning or presentation of the CME activity. Failure to return the disclosure form equates refusal to disclose. Refer to the [UAMS Disclosure of Financial Relationships and Resolution of Conflicts of Interest Policy](#).)
 - m) Credit Designation Statement must be specified (verbatim):
“The UAMS College of Medicine designates this educational activity for a maximum of [number of credits] *AMA PRA Category 1 credit(s)*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.”
 - n) Disclosure Policy Statement must be included (verbatim):
“It is the policy of the University of Arkansas for Medical Sciences (UAMS) College of Medicine to ensure balance, independence, objectivity, and scientific rigor in all sponsored or jointly sponsored educational activities. All individuals who are in a position to control the content of the educational activity (course/activity directors, planning committee members, staff, teachers, or authors of CME) must disclose all relevant financial relationships they have with any commercial interest(s) as well as the nature of the relationship. Financial

relationships of the individual's spouse or partner must also be disclosed, if the nature of the relationship could influence the objectivity of the individual in a position to control the content of the CME. The ACCME describes relevant financial relationships as those in any amount occurring within the past 12 months that create a conflict of interest. Individuals who refuse to disclose will be disqualified from participation in the development, management, presentation, or evaluation of the CME activity."

- o) Acknowledgement of any commercial support received for the activity. This acknowledgement must be placed at the beginning of the activity:
"We gratefully acknowledge {Insert name of commercial supporter} for their generous support of this educational activity."
(NOTE: Commercial advertising or promotional materials may not appear within the pages, computer windows or screens of the CME educational material content. No commercial breaks of any type may be inserted into or may interrupt the educational content of the enduring material.)
- p) Instructions to participants describing how to receive credit for participating in the activity, must include:
 - i) How the participant will verify participation in the activity and how the participant will evaluate the activity;
 - ii) The cost, if any, to receive credit;
 - iii) The procedures required to obtain credit;
 - iv) UAMS OCME contact information.

Step 4: Final approval

- 1) A final draft of the educational product, which includes the packaging, post-test or other means of verifying learner participation in the enduring material, evaluation, and associated handouts, is submitted to the OCME for a complete review by the OCME and CME Advisory Committee's selected pilot testers and content peer reviewers. If an individual client and the OCME negotiate alternative means of peer review, the written summary of the peer reviewers' findings must be submitted to the OCME as part of the final approval review processes.
 - a) The peer reviewer(s) (1-3 UAMS Faculty Members) will provide feedback about the following issues:
 - i) medical content is appropriate;
 - ii) educational design is sound;
 - iii) whether the presentation is balanced, independent of commercial bias, objective, and is evidence-based and contains sufficient scientific rigor;
 - iv) HIPPA compliance and patient privacy issues are met;
 - v) means of evaluating learner participation is appropriate;
 - vi) amount of time required to study the enduring material.
 - b) Once the peer reviewers have completed their work, the EM is either sent back to the client for revisions or it is sent forward to the pilot testers.
 - c) The pilot testers (1-3 UAMS CME staff or CME Advisory Committee members) will provide feedback about the following issues:

- i) average time required to study the materials to determine number of credits that should be awarded;
 - ii) whether the ACCME requirements are met;
 - iii) HIPPA compliance and patient privacy issues are met;
 - iv) independent of commercial bias;
 - v) ease of use of the EM;
 - vi) post-test or other means of evaluating learning participation is appropriate.
- d) If the pilot tester(s) identifies any deficiencies, the EM will be sent to the client for revisions.
 - e) The Course Director is notified by the OCME of final approval when all questions and concerns of the OCME and reviewers have been satisfactorily addressed.
- 2) The official release and expiration dates are established by the OCME and inserted into the product by the producers.

Step 5: Reproduction and Distribution

- 1) The production company or organizer reproduces the enduring material and distributes or makes it available to the target audience. Commercial interests or supporters **MAY NOT** distribute the material. A commercial interest may inform interested learners about the existence of the enduring material and may provide such individuals with OCME or the producer's contact information, thereby facilitating a learner obtaining access to the material.

Step 6: Copies of Final Product

- 1) Course Director or organizer provides the OCME with five copies of the enduring material.

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