# **Continuing Medical Education**

PO Box 245121 | Tucson, AZ, 85724-5121 Tel: (520) 626-7832 | FAX: (520) 626-2427

uofacme@email.arizona.edu | www.cme.arizona.edu



# **Enduring Materials Planning Guide**

Although enduring material CME is the most rapidly growing category of CME, particularly Internet CME, we see common mistakes and sources of confusion among educators. In particular, you must disclose a great deal of information to learners before they begin the activity. Please follow the links below to learn more.

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# What Is an Enduring Material?

*Enduring material* means certain types of CME that exist over time. Examples of enduring materials include:

- Written monographs,
- Audio-based program,
- Video-based (DVD or television) programs,
- Computer-based programs (CD-ROMs),
- Internet-based programs (excluding live Webcasts), and
- Smartphone-based programs (excluding live Webcasts).

The technology that is used to distribute a CME activity does not determine whether the activity is "enduring material" for CME purposes. For example, a simultaneous Webcast or video transmission of a live lecture, which is not recorded for later re-distribution, is a technology for distributing or presenting a live activity; it is not an enduring material.

However, not all CME that endures is "enduring material." The American Medical Association (AMA) has given special status to certain types of enduring or ongoing CME activities that are *not* considered "enduring materials." The following CME activities have their own categories and must be considered distinct from enduring materials:

- Journal-based CME Reading a peer reviewed published article and completing an assessment.
- Test Item Writing Developing questions for specified high stakes exams or self-assessments.

- Manuscript Review Preparing a review of an original manuscript that is accepted by a peerreviewed medical journal.
- Internet Point-of-Care Learning Self-directed review of online information used in clinical practice.

If you are not sure if your activity is an enduring material or which CME category best describes your activity, please consult the AMA's information about the <a href="https://example.com/Physician's Recognition Award">Physician's Recognition Award</a> (PRA) or contact us.

#### What Information Must Be Provided to Learners?

All approved CME activities must provide the following information to learners before commencing the activity.

1. Accreditation and CME designation statements.

You must present the required ACCME and AMA accreditation and designation statements to learners before they begin the activity exactly as:

For Directly Sponsored Enduring Materials (UA College of Medicine Department or Center):

The University of Arizona College of Medicine – Tucson is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The University of Arizona College of Medicine – Tucson designates this enduring material for a maximum of (# of credits) AMA PRA Category 1 Credit(s) $^{TM}$ . Physicians should claim only the credit commensurate with the extent of their participation in the activity.

For Jointly Provided Enduring Materials (External to the UA College of Medicine):

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education through the joint providership of The University of Arizona College of Medicine – Tucson and (name of your organization). The University of Arizona College of Medicine at the Arizona Health Sciences Center is accredited by the ACCME to provide continuing medical education for physicians.

The University of Arizona College of Medicine – Tucson designates this enduring material for a maximum of (# of credits) AMA PRA Category 1 Credit(s) $^{TM}$ . Physicians should claim only the credit commensurate with the extent of their participation in the activity.

### 2. Purpose of the activity.

You must communicate the purpose or objectives of the enduring material to your faculty and your learners. The best way to do this is to:

- Send written information about the overall needs and learning objectives to your faculty and ask them to develop specific objectives for their participation. Send one copy of your correspondence to us
- Include your overall learning objectives in your announcements and promotions when possible. Send copies of these to us.
- Present your objectives to your learners before the start of your activity. We must confirm that this has been done by reviewing the activity.

#### 3. Conflict of interest disclosures.

You must disclose to your learners whether or not there are conflicts of interest with your planning committee and faculty members. In CME, unlike other areas such as medical publishing, we are concerned about real versus potential conflicts of interest. However, also unlike many other areas, disclosure alone is not adequate. You must also resolve all conflicts and you must tell learners how this was done before the activity begins. (To read more about identifying and managing conflicts, and to view examples of disclosure statements, please see our **Conflict of Interest Policy** and our **Commercial Support Policy**.)

NOTE: Conflict of interest disclosures *must* be visible to learners before they begin the activity. They cannot be accessed via a link, tab, pop-up or other indirect means. Specifically, "...learners must be made to pass through the information in order to engage in the CME activity."

#### 4. Sources of commercial support.

We require you to visibly disclose all sources of commercial support for your CME activity. If you have received commercial support, please do not include logos, tag lines, or other forms of marketing messages in your acknowledgement. If you have not received commercial support, we recommend that you note this as well.

NOTE: Commercial support disclosures *must* be visible to learners before they begin the activity. They cannot be accessed via a link, tab, pop-up or other indirect means. Specifically, "...learners must be made to pass through the information in order to engage in the CME activity."

# 5. Proper use of the term, AMA PRA Category 1 Credit<sup>TM</sup>.

The University of Arizona College of Medicine is an ACCME accredited provider of AMA PRA Category 1 CME Credit<sup>TM</sup>. The brand, AMA PRA Category 1 CME Credit<sup>TM</sup> is owned by the AMA and the AMA has requirements about its use. The phrase should always be trademarked, italicized, and used in its entirety. The phrase "Category 1 Credit" must never be used when referring to AMA PRA Category 1 Credit<sup>TM</sup>.

### **Additional Requirements for Enduring Materials**

The ACCME and the AMA have additional requirements for enduring materials. The ACCME requires that the provider must communicate the following additional information to participants prior to starting the enduring materials educational activity. This information can be supplied via indirect access, where feasible, such as a link, tab, or pop-up:

- 1.) Conflict of Interest disclosure statements for Faculty, Planning Committee Members, and the CME Reviewers, whether a conflict of interest exists or not. (See <u>Conflict of Interest Policy</u> for appropriate disclosure verbiage depending on your situation.)
- 2.) The source of any financial support that has been received from an ACCME-defined "commercial interest" (i.e., a pharmaceutical company or medical device manufacturer).
- 3.) Original release date, date of most recent review, and termination date.

In addition to the foregoing, the AMA also requires that all enduring materials meet certain requirements. The 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.
- Communicate to the participants the minimum performance level that must be demonstrated in the assessment in order to successfully complete the activity for AMA PRA Category 1 Credit™.
- Provide access to appropriate bibliographic sources to allow for further study.

### Use of University of Arizona Logo

You may use the University's logo on CME certificates that we approve, but you may not otherwise use our logo unless your CME program is a directly sponsored activity. If you use the logo, you must comply with <u>University of Arizona trademark requirements</u>. Please do not use the University's logo or other branded material in any way without our prior authorization.

#### **How Do I Issue CME Credit?**

CME organizers may issue certificates or transcripts to physicians to record the amount of credit that has been claimed for participating in a CME event. There is no required format for this documentation, but there are required elements. Documentation provided to participating physicians must accurately reflect, at a minimum, the following:

- 1. Physician's name
- 2. Name of accredited CME provider
- 3. Title of activity
- 4. Learning format
- 5. Location of activity (if applicable)
- 6. Date(s) of live activity or date that physician completed the activity
- 7. Number of AMA PRA Category 1 Credits™ awarded (claimed)

Nonphysician health professionals and other participants may not be awarded AMA PRA Category 1  $Credit^{TM}$ . However, organizers may choose to issue documentation of participation to nonphysicians that states that the activity was certified for AMA PRA Category 1  $Credit^{TM}$ . An example of wording that might be used on documentation for a nonphysician participant follows: The University of Arizona College of Medicine certifies that (name of nonphysician participant) has participated in the (learning format) titled (title of activity) (at location, when applicable) on (date). This activity was designated for (number of credits) AMA PRA Category 1  $Credits^{TM}$ .

### **Assigning CME Credit for an Enduring Material**

Although the official term is AMA PRA Category 1 Credit<sup>m</sup>, the term "credit" remains closely related to hours of live activity seat time. As defined in the <u>PRA handbook</u>,

"60 minutes of physician participation in a certified live activity equals one (1) AMA PRA Category 1 Credit ™; credit is designated in 15 minute or 0.25 credit increments; accredited CME providers must round to the nearest quarter hour."

"Credit designation for ... enduring material must be determined by a mechanism developed by the accredited CME provider to establish a good faith estimate of the amount of time a physician will take to complete the activity to achieve its purpose and/or learning objectives."

We expect that educators who develop enduring material CME activities will provide a description of the process they used to determine the amount of CME credit requested. It is important to reiterate that credit for participation in an enduring material CME activity can only be granted to physicians who have successfully completed an assessment.

# **Duration of CME Sponsorship**

Enduring materials can last forever, but CME sponsorship does not. ACCME policies require that CME sponsorship be renewed no less often than every 3 years. However, we require that CME sponsorship for enduring materials be renewed every 2 years.

- Following initial review and approval, CME sponsorship will be provided for an enduring material for 2 years from the date of release.
- The enduring material author/owner is expected to maintain the currency and scientific integrity of the activity. If the activity becomes outdated and cannot be revised (e.g., a written monograph), then the activity must be withdrawn. Review dates, along with dates of initial approval and termination, must be available to the learner.
- Renewal of an enduring material is based on our review of program updates, current conflict of
  interest disclosures, and evidence that all ACCME and AMA requirements have been met. Please use
  our Sponsorship Renewal Form when you wish to renew your enduring material.

# **Dealing with Commercial Interests**

A commercial interest is "...any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients." If you have questions about dealing with commercial interests, please see our **Commercial Support Policy**. You must assure that commercial interests cannot influence the content or delivery of your enduring material.

Before your proposal can be approved, you must send us conflict of interest disclosure statements on all Planning Committee members and faculty if the activity will discuss "...health care goods or services consumed by or used on patients." If there are any conflicts, these must be resolved before approval can be granted. Please see our **Conflict of Interest Policy**.

We also require that you send us letters of agreement (LOAs) for all commercial support you receive. In particular, for unrestricted educational grants that you receive from commercial interests, the University of Arizona must actually be a party to these grants and sign all associated LOAs, as explained in our **Commercial Support Policy**. Additionally, we also need to receive LOAs for any advertisers or exhibitors that support your activity, although the University of Arizona does not need to sign these agreements.

If you request renewal of your enduring material for an additional 2-year period, we require updated conflict of interest disclosures, if applicable, and letters of agreement for commercial support.

Because of the persistent, ongoing characteristics of enduring materials, there are several other unique requirements for dealing with commercial interests:

- You may not enlist the assistance of commercial interests to provide or distribute enduring materials to learners.
- You may not place your CME activities on a Website owned or controlled by a commercial interest.
- With clear notification that the learner is leaving the educational Website, links from the CME
  Website to pharmaceutical and device manufacturers' product Websites are permitted before or
  after the educational content of a CME activity, but shall not be embedded in the educational
  content of a CME activity.
- Advertising of any type is prohibited within the educational content of CME activities on the Internet
  including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer
  based CME activities, advertisements and promotional materials may not be visible on the screen at
  the same time as the CME content and may not be interleafed between computer windows or
  screens of the CME content.

# **Required Review of Enduring Materials**

We must be able to demonstrate that we (and you) have complied with all ACCME and AMA requirements. These requirements not only deal with required disclosures, they also address the quality of the educational content and the benefits of the activity for learners. Thus, before your enduring material can be distributed, we must review:

- Any marketing or advertising messages.
- The packaging (this can also be the Website) of the materials.
- The planned evaluation process.

 The specific educational content. If a College of Medicine faculty member has played a key role in developing the educational content, this requirement can be waived. If no College of Medicine faculty member has played such a role, we will usually require internal review at an additional charge before CME sponsorship will be granted.

# Required Information That Must Be Sent to Us During the Sponsorship Period

Once you have begun distributing your enduring material, either you or we will be distributing CME certificates and collecting learner evaluations. It is also possible that you may modify your activity if this is possible (e.g., for a Web program). We need documentation of all of this and more. Please send us:

- Data on all CME certificates supplied by you. Please send these data at least quarterly. These data must contain, at minimum:
  - o Physician's name
  - Date that physician completed the activity
  - o Number of AMA PRA Category 1 Credits™ awarded per physician
- A statement of revenues and expenses, including commercial support, every year.
- A count of physician and non-physician participants every year.
- Conflict of interest disclosures and a summary of content changes whenever relevant, but no less often than every 2 years.
- A summary of learner evaluations every 2 years.