Enduring Materials Planning Guide

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.

- Manuscript Review – Preparing a review of an original manuscript that is accepted by a peer-reviewed 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 Physician’s Recognition Award (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 Provided Enduring Materials (UVM Department):*

The University of Vermont College of Medicine (UVM) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

UVM designates this [activity] activity for a maximum of [number of hours] AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.
For Jointly Provided Enduring Materials (External to the UVM 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 (ACCME) through the joint providership of The University of Vermont College of Medicine (UVM) and [please insert your organization name].

UVM designated this __________________ activity for a maximum of [number of hours] AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Types of activities:

An **internet enduring material** activity is available when the physician participant chooses to complete it. It is “enduring,” meaning that there is not just one time on one day to participate in it. Rather, the participant determines when he/she participates. (Examples: online interactive educational module, recorded presentation, podcast).

An **enduring material** is a printed, recorded, or computer-presented CME activity that may be used over time at various locations and which, in itself, constitutes a planned activity. In an enduring material the provider creates the content.

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.

**NOTE: Conflict of interest disclosures must be available to learners before they begin the activity. They can be accessed via a link, tab, pop-up or other electronic mechanisms to transmit the information.**

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 available to learners before they begin the activity. They can be accessed via a link, tab, pop-up or other electronic mechanisms to transmit the information.

5. Proper use of the term, *AMA PRA Category 1 Credit™*.

The University of Vermont College of Medicine is an ACCME accredited provider of *AMA PRA Category 1 CME Credit™*. The brand, *AMA PRA Category 1 CME Credit™* 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™*.

**Additional Requirements for Enduring Materials**

The ACCME and the AMA have additional disclosure 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. Principal faculty and their credentials;
2. Method of physician participation in the learning process;
3. Estimated time to complete the educational activity (same as number of designated credit hours);
4. Dates of original release and most recent review or update; and
5. Termination date (date after which the enduring material is no longer certified for CME credit).

For Internet CME, the ACCME also requires that the provider:

6. Have a mechanism in place for the learner to contact the provider if there are questions about the Internet CME activity.

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 information gained within the activity (3-6 month survey).
- 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.
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)

Non-physician health professionals and other participants may not be awarded *AMA PRA Category 1 Credit™*. However, organizers may choose to issue documentation of participation to non-physicians that states that the activity was certified for *AMA PRA Category 1 Credit™*. An example of wording that might be used on documentation for a non-physician participant follows: The University of Vermont College of Medicine certifies that *(name of non-physician participant)* has participated in the enduring material activity titled *(title of activity)* *(at location, when applicable)* on *(date)*. This activity was designated for *(number of credits) AMA PRA Category 1 Credits™*.

Assigning CME Credit for an Enduring Material

Although the official term is *AMA PRA Category 1 Credit™*, the term “credit” remains closely related to hours of live activity seat time. As defined in the PRA handbook,

“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 Approval Period

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

**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.” 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.

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 Vermont must actually be a party to these grants and sign all associated LOAs. Additionally, we also need to receive LOAs for any advertisers or exhibitors that support your activity, although the University of Vermont 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.
• Links to products and/or pharmaceutical websites shall not be embedded in the CME Activity.
• If linking to other sites, you must give clear notification that the learner is leaving the educational website.
• 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 interleaved 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.

Required Information That Must Be Sent to Us During the Approval Period

Once you have begun distributing your enduring material, distributing CME certificates and collecting learner evaluations, please send us:

- Data on all CME certificates supplied by you. Please send this data twice a year (January 1 and July 1). Data must contain, at minimum:
  - Physician’s name
  - Date that physician completed the activity
  - Number of AMA PRA Category 1 Credits™ awarded per physician (claimed)
  - Email address of the learner
- A statement of revenues and expenses, including commercial support if applicable, every year (January 1).
- A count of physician and non-physician participants every year (July 1).
- Conflict of interest disclosures and a summary of content changes whenever relevant.
- A summary of learner evaluations every year (January 1).
ACCME Requirements for Enduring Materials and On-line Activities Checklist

The following must be included in each enduring material:

- Target audience of physicians
- Statement of Need/Measureable Gap
- Educational Objectives
- Principal faculty and their credentials
- Accreditation Statement
- Credit Designation Statement – AMA wording
- Disclosure/conflict resolution for all Faculty and planning committee members*
- Method of physician participation in learning process
- Estimated time to complete the activity
- Release date and expiration date
- Method of evaluation
- Follow-up 3-6 months after the activity to produce results of measureable gap**

In addition, the following are required for On-Line CME (on the home page):

- Activity must be posted on an independent website.
- Links to product websites shall not be embedded in the CME activity and must give clear notification that the learner is leaving the site.
- Advertising of any type is prohibited within the educational content.
- A mechanism must be in place for the learner to be able to contact the accredited provider for more information about the activity – include UVM’s contact information.
- Pre/Post test to help verify that participants viewed the program.

Please note that all recorded presentations have to be free of any confidential patient information. Also, speakers must submit written consent that they agree to be recorded.

*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 available to learners before they begin the activity. They can be accessed via a link, tab, pop-up or other electronic mechanisms to transmit the information.

**A pre/post test could meet this requirement, depending on the type of questions asked. Some questions obviously are only measuring knowledge but a case-based scenario that would ask the learner "what would you do?" would measure performance. Another example might be to ask the learners to identify "Intent to change" – this would be a way to measure competence.

September 2015