



## ACCME® and ISMA\* POLICY UPDATES AUGUST 2007

The ACCME announces several new policies related to the following topics: the ACCME Standards for Commercial Support<sup>SM</sup>, activities in which the learner participates electronically, elements of journal-based CME, and the link between accreditation and credit. Each of the new policies is effective January 1, 2008, unless otherwise indicated.

To assist accredited providers in understanding and implementing these policies, the ACCME is providing explanatory information, examples, and "Q&A" as applicable. The information on the ACCME website [policy pages](#) has been updated to reflect these changes.

\*The following ACCME policies have been adapted by the ISMA.

### NEW POLICIES:

1. *An accredited provider can fulfill the expectations of SCS 3.4-3.6 by adopting a previously executed agreement between an accredited provider and a commercial supporter and indicating in writing their acceptance of the terms and conditions specified and the amount of commercial support they will receive.* (Click here for more information)
2. *A provider will be found in Noncompliance with SCS 1.1 and SCS 3.2 if the provider enters into a commercial support agreement where the commercial supporter specifies the manner in which the provider will fulfill the requirements of the ACCME's Elements, Policies and Standards.* (Click here for more information)
3. *For CME activities in which the learner participates electronically (e.g., via Internet, CD-ROM, satellite broadcasts), all required ACCME information must be transmitted to the learner prior to the learner beginning the CME activity.* (Click here for more information)
4. *Accredited providers may not place their CME activities on a website owned or controlled by a 'commercial interest.'* (Click here for more information)
5. *The ACCME considers information required to be communicated before an activity (e.g., disclosure information, disclosure of commercial support, objectives), CME content (e.g., articles, lectures, handouts, and slide copies), content-specific post-tests, and education evaluation all to be elements of a journal-based CME activity.* (Click here for more information)
6. *A 'commercial interest' is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.* (Click here for more information)
7. *All CME educational activities developed and presented by a provider accredited by the ACCME system and associated with AMA PRA Category 1 Credit<sup>TM</sup> must be developed and*

*presented in compliance with all ACCME accreditation requirements - in addition to all the requirements of the AMA PRA program. All activities so designated for, or awarded, credit will be subject to review by the ACCME accreditation process as verification of fulfillment of the ACCME accreditation requirements.*

(Click here for more information)

## Adding signatures to a written agreement...

The ACCME Standards for Commercial Support (SCS) require that the accredited provider sign a written agreement whenever commercial support is accepted for an activity. Sometimes the process begins with an agreement between a 'commercial interest' and another accredited provider.

The SCS imply that the accredited provider taking responsibility for the activity must go to the 'commercial interest' and execute a new written agreement – which does not, on the face of it, add value to the system.

The ACCME has acted to simplify the process by allowing an accredited provider to “sign on” to a previously executed written agreement. This can be accomplished through an addendum to the original agreement or a cover letter that refers to the original agreement.

*An accredited provider can fulfill the expectations of SCS 3.4-3.6 by adopting a previously executed agreement between an accredited provider and a commercial supporter and indicating in writing their acceptance of the terms and conditions specified and the amount of commercial support they will receive. (Effective immediately.)*

### Related Question and Answer



**Can an accredited provider be added as a party to a written agreement for commercial support after the original agreement was executed?**

Yes. An accredited provider can fulfill the expectations of SCS 3.4 to 3.6 by adopting a previously executed agreement between an accredited provider and a commercial supporter and indicating in writing their acceptance of the terms and conditions specified and the amount of commercial support they will receive.

## Regarding written agreements for commercial support...

Earlier in 2007, the ACCME released the following proposed policy for comment:

*A provider will be found in Noncompliance with SCS 1.1 and SCS 3.2 if the provider enters into a commercial support agreement where the commercial supporter specifies the manner in which the provider will fulfill the requirements of the ACCME's Elements, Policies and Standards.*

On July 20, 2007, the ACCME adopted the above statement as ACCME policy applicable to all electronically, digitally, or manually signed written agreements executed after January 1, 2008.

The ACCME believes that if the CME planning process begins with the provider meeting the specifications of industry regarding how the provider fulfills the requirements of the elements of ACCME's requirements - then the provider is agreeing to terms and conditions stipulated by industry for how it will fulfill ACCME requirements. Such CME would not be independent (SCS 1.1) and would not meet the expectations of SCS 3.2 of the 2004 ACCME Standards for Commercial Support. Of course, it would be perfectly appropriate for the commercial supporter to specify that the provider must be in compliance with the ACCME Standards for Commercial Support – and for the provider to agree to this provision.

A *review of the feedback* revealed that most favored the proposed policy. Those that believe that CME is collaboration between themselves and industry, as partners or clients, saw the policy as problematic. Comments mentioned that the proposed policy would interfere or prevent (or force 'underground') interaction and dialogue between accredited providers and commercial supporters where the commercial supporter could suggest, for example, speakers or methods of evaluation.

Some of the comments suggested that the ACCME could not really stop commercial supporters from specifying "the manner in which the provider will fulfill the requirements of the ACCME's Elements, Policies and Standards" because they could do so through their own internal specifications for what they would or would not fund – and leave such specifications out of the ACCME's required written agreement. Others said that because the accredited provider is ultimately responsible for the content of the CME activity, this policy and these safeguards are not required.

The ACCME believes that CME can receive commercial support from industry without receiving any advice or guidance, either nuanced or direct, on the content of the activity or on who should deliver that content. In CME, the terms '*industry partners*' and '*collaboration with industry*' imply a relationship that is not consistent with the spirit of independence as articulated in the ACCME Standards for Commercial Support.

### **Related Questions and Answers**

**As more 'commercial interests' are moving to online and electronic commercial support application processes, is there any type of confirmation or verification regarding the written agreement for commercial support that can be used as a surrogate for a signature?**

Yes. The ACCME accepts electronic signatures as evidence that written agreements are signed. In addition, the ACCME has received a few examples of online and electronic commercial support application processes that provide a structure and specific terms that meet ACCME's expectations for written agreements. The ACCME is continuing to review the online and electronic application processes of 'commercial interests' and requests that providers contact the ACCME if the need arises for affirmation of the adequacy of a specific online system

in fulfilling ACCME's requirements for a written agreement and/or signature(s) on the agreement.



However, a provider will be found in Noncompliance with SCS 1.1 and SCS 3.2 if the provider enters into a commercial support agreement where the commercial supporter specifies the manner in which the provider will fulfill the requirements of the ACCME's Elements, Policies and Standards. (Applicable to all electronically, digitally or manually signed written agreements executed after January 1, 2008.)



**Can an accredited provider be added as a party to a written agreement for commercial support after the original agreement was executed?**

Yes. An accredited provider can fulfill the expectations of SCS 3.4 to 3.6 by adopting a previously executed agreement between an accredited provider and a commercial supporter and indicating in writing their acceptance of the terms and conditions specified and the amount of commercial support they will receive.

**What does the ACCME mean by 'control' in its expectation that a provider make certain decisions free from the 'control' of a 'commercial interest'?**

The ACCME expects that the provider makes decisions related to the planning and implementation of CME activities without being directed or influenced by 'commercial interests.'



A provider will be found in Noncompliance with SCS 1.1 and SCS 3.2 if the provider enters into a commercial support agreement where the commercial supporter specifies the manner in which the provider will fulfill the requirements of the ACCME's Elements, Policies and Standards. (Applicable to all electronically, digitally or manually signed written agreements executed after January 1, 2008.)

## Specific information communicated to learners...

ACCME policy requires that specific information be communicated to learners prior to the start of the activity – the learners can integrate this important information into their decisions about participating in the activity and about how to use the information they are receiving. Although formats for the delivery of education might vary, the requirement that this information be communicated is consistent across formats. For a decade, the ACCME has required that providers communicate the following specific information to learners before the learners start engaging with CME.

<p><i>For all CME activities (e.g., journal-based CME, live activities, web-based activities)</i></p> <ul style="list-style-type: none"><li>▪ ACCME accreditation statement</li><li>▪ Purpose or Objectives</li><li>▪ Financial relationship information</li><li>▪ Name of Commercial supporter(s)</li></ul>	<p><i>And <u>in addition</u>, in enduring materials</i></p> <ul style="list-style-type: none"><li>▪ Principal faculty and their credentials</li><li>▪ Medium or combination of media used;</li><li>▪ Method of physician participation in the learning process;</li><li>▪ Estimated time to complete the educational activity (same as number of designated credit hours);</li><li>▪ Dates of original release and most recent review or update; and</li><li>▪ Termination date (date after which enduring material is no longer certified for credit).</li></ul>
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It is the intention of the ACCME that all this information be transmitted (not just be accessible) to the learner prior to the learner engaging in the CME activity. Modern formats of CME provide the opportunity to make the information accessible, but also avoidable, by the learner. For example, on the Internet a learner can be at the first screen of an activity with all of the information accessible by clicking a 'tab' – but at the same time the learner can avoid the information by clicking 'next' to proceed through the CME activity – without ever seeing the information.

The ACCME has addressed this issue in the past in other formats. The ACCME has said that providers are out of compliance with the disclosure requirements if they simply tell learners, "Disclosure information is available at the registration desk if you want to review it." It is the ACCME's intent that the learner actually be presented with the information and that reasonable opportunity (ex., time) be afforded to the learner to review the information.


The ACCME has adopted the following policy to ensure that the required information is also transmitted to the learners in activities in which the learner participates electronically.

*For CME activities in which the learner participates electronically (e.g., via Internet, CD-ROM, satellite broadcasts), all required ACCME information must be transmitted to the learner prior to the learner beginning the CME activity. (All new CME activities released on or after January 1, 2008 must conform to this policy. Existing CME activities that are reviewed and re-released after January 1, 2008 must conform to this policy.)*

### Related Question and Answer

#### **If a live activity is turned into an enduring material, do faculty disclosure and acknowledgement of commercial support still need to be made?**

The enduring material, the new CME activity, must demonstrate compliance with all applicable ACCME requirements, including faculty disclosure and acknowledgement of any commercial support.

 For CME activities including those in which the learner participates electronically (e.g., via Internet, CD-ROM, satellite broadcasts), all required ACCME information must be transmitted to the learner prior to the learner beginning the CME activity. All new CME activities released on or after January 1, 2008 must conform to this policy. Existing CME activities that are reviewed and re-released after January 1, 2008 must conform to this policy.

## CME Activity Location...

Some accredited providers are using the information technology resources of 'commercial interests' as the delivery mechanisms for accredited CME. Some accredited providers are contracting with 'commercial interests' as vendors of CME distribution services (e.g., web sites) and are accepting these services as 'in-kind' commercial support. Under these circumstances, the CME content is in the control of 'commercial interests,' is being distributed by 'commercial interests,' and is not separated from promotional and product materials of the commercial website.

These circumstances are contrary to the spirit, and the requirements, of the ACCME Standards for Commercial Support as "the CME content is in the control of 'commercial interests'" (SCS 1.1) or "is being distributed by the 'commercial interest'" (SCS 4.5).

The ACCME has taken action to modify ACCME policy regarding CME delivered electronically. The ACCME has changed the section on activity location within its "Internet CME Policy."

*Accredited providers may not place their CME activities on a website owned or controlled by a 'commercial interest'. (All new CME activities released on or after January 1, 2008 must conform to this policy. Existing CME activities that are reviewed and re-released after January 1, 2008 must conform to this policy.)*

## Regarding journal-based CME...

Earlier in 2007, ACCME released the following proposed policy for comment:

*“The ACCME considers the following to be elements of a journal-based CME activity: information required to be communicated before an activity; CME content; content-specific post-tests; education evaluation. Therefore, there cannot be any product-promotion material or product-specific advertisement of any type within, or between, these elements of a CME activity.”*

This proposal supplemented ACCME policies already in place for several years that state,

*“A journal-based CME activity includes the reading of an article (or adapted formats for special needs), a provider stipulated/learner directed phase (that may include reflection, discussion, or debate about the material contained in the article(s)) and a requirement for the completion by the learner of a pre-determined set of questions or tasks relating to the content of the material as part of the learning process. The educational content of journal CME must be within the ACCME's [Definition of CME](#). Journal CME activities must comply with all [ACCME Essential Areas and Elements](#) (including the Standards for Commercial Support) and [Accreditation Policies](#). Because of the nature of the activity, there are two additional requirements that journal CME must meet: 1) The ACCME does not consider a journal-based CME activity to have been completed until the learner documents participation in that activity to the provider. 2) The learner should not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials. (ACCME, 1992)”*

*“...for print [CME], advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity ( ACCME Standards for Commercial Support, 2004.)”*

On July 20, 2007, after consideration of feedback received through the call-for-comment, the ACCME decided not to change or add to current policy. The ACCME has chosen instead to clarify current policy.

*The ACCME considers information required to be communicated before an activity (e.g., disclosure information, disclosure of commercial support, objectives), CME content (e.g., articles, lectures, handouts, and slide copies), content-specific post-tests, and education evaluation all to be elements of a journal-based CME activity. (Effective immediately.)*

The ACCME will ensure, through the ACCME accreditation process and education initiatives, that these elements of a CME activity do not contain any advertising, trade names or product group messages. The juxtaposition of some advertising between components (or elements) continues to be permitted. Providers should review the ACCME Standards for Commercial Support in this regard.

Feedback to the call-for-comment on journal-based CME predominately focused on the statement *“...there cannot be any product-promotion material or product-specific advertisement of any type within, or between, these elements of a CME activity.”*

Feedback speaking against the proposed policy was submitted by a limited number of CME staff of accredited providers, publishers of accredited providers, and editors of journals published by accredited providers. The ACCME was challenged on the necessity, negative impact and value of the proposed policy by these respondents. The ACCME was told that, “[ACCME policy] would cause the journals to be assessed with penalties by third-party organizations that survey journal readership and form the basis on which advertising is sold.” Publishers asserted that it would be technically difficult to fulfill the requirement. Editors suggested it was unnecessary as individual publisher-based policy and the policies of the

“International Committee of Medical Editors” are thought to be sufficient safeguards in separating promotion from education. Written responses expressed the belief that no problem exists in any publications that follow the standards of the “International Committee of Medical Editors” because a) the content is validated through the review process; b) juxtaposed advertisements cannot be on a related topic and; c) no ads can be interleaved within the pages of articles.

Many other respondents saw added value in the proposed ACCME policy and how it was consistent with current practice and expectations in other formats of CME.

## Definition of a ‘commercial interest’...

In 2007, the ACCME released the following proposed modification to the 2004 ACCME definition of a ‘commercial interest’ for comment:

A ‘commercial interest’ is any proprietary entity producing, marketing, re-selling, distributing or otherwise participating in or profiting from the distribution, promotion or sale of health care goods or services consumed by, or used on, patients.

Comments that were submitted addressed several areas. Some respondents thought that ACCME was intending to stop medical education companies from being accredited providers, which was not the case.

The continuing need for ‘exemptions’ for health care providers was seen as a weakness of the policy by some and as a strength of the policy for others. Some of the respondents said that physician organizations, groups, and academic medical centers have significant enough financial relationships with ‘commercial interests’ to cause them NOT to be independent of those interests, similar to some medical education and communication companies – so at the least they could have relevant financial relationships causing conflicts of interest in CME.

In this context, it was observed that the phrase “...*participating in or profiting from the promotion or sale of health care goods or services consumed by, or used on, patients*” encompasses organizations, or persons within accredited providers, with financial relationships that may cause conflicts of interest in CME (e.g., executives, publishers, development officers). Respondents provided information and opinion on how some of these secondary relationships (i.e., *participating in or profiting from*) could be separated from continuing medical education through corporate firewalls and the identification and resolution of conflicts of interest.

Keeping intact all the previous exemptions, the ACCME adopted the following modified definition of a ‘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. (Effective immediately.)*

‘Commercial interests’ are excluded from being an accredited provider of CME because these organizations cannot be compliant with Standard 1.1 or 1.2 of the ACCME Standards for Commercial Support. No entity owned or controlled by a ‘commercial interest’ can be accredited by the ACCME system. There are no structural and organizational safeguards that could be put into place in order for an entity owned or controlled by a ‘commercial interest’ to be accredited by the ACCME system. The ACCME will work individually with accredited providers that might be affected by this definition as they transition to an independent corporate structure that is acceptable in the context of the ACCME’s Standards for Commercial Support.

The definition allows an accredited provider to be owned by a firm that is not a commercial interest. It also allows a provider to have a “sister company” that is a commercial interest. In this case, the ACCME would expect that the accredited provider would have an adequate corporate firewall in place to prohibit any influence or control by the “sister company” over the CME program.

## Related Question and Answer



**How will the change in the definition of a commercial interest (effective immediately) affect already accredited providers that might be owned by a commercial interest?**

The ACCME will work individually with accredited providers that might be affected by this definition as they transition to an independent corporate structure that is acceptable in the context of the ACCME's Standards for Commercial Support. It is ACCME's expectation that any accredited provider that is, or is currently owned by, a commercial interest will transition to a different corporate structure (or will withdraw from accreditation) by August 2009.

## Accreditation and credit...

ACCME accreditation and AMA PRA Category 1 Credit™ have long been linked as markers of quality continuing medical education. The AMA credit system requires that providers be accredited by the ACCME, or an ACCME Recognized entity, in order to designate activities for credit. The ACCME's accreditation process reviews activities, designated for credit, in order to determine a provider's level of compliance and therefore award initial or reaccreditation.

Over the years, what is recognized as a CME activity has broadened in format and method of learner participation, first due to the incorporation into CME of regularly scheduled conferences, enduring materials and the Internet, and more recently due to the actions of the AMA credit system with its new definitions of activities (e.g., test-item writing, manuscript review, and committee learning).

At the same time, the AMA was directly granting AMA PRA Category 1 Credit™ for certain professional activities (as described in the 2005 AMA PRA Booklet, "Physicians may claim *AMA PRA Category 1 Credit™* directly from the AMA for learning that occurs as a result of teaching in live CME activities, poster presentations, published articles, medically related advanced degree or American Board of Medical Specialties (ABMS) member board certification, recertification and Maintenance of Certification (MOC)").

In March 2006, the AMA issued a revision to its Physician's Recognition Award Booklet. In it, the AMA allowed "*assigning credit for teaching at Category 1 live activities*" from a direct credit awarded by the AMA to one involving ACCME accredited providers who would be able to award credit to their faculty for the learning involved in preparing to teach in live CME activities. The AMA wrote,

*Providers may also award AMA PRA Category 1 Credit to their faculty for teaching at the provider's designated live activities. This credit acknowledges the learning associated with the preparation for an original presentation.*

*Assigning credit for teaching at Category 1 live activities*

- *Faculty may be awarded two (2) AMA PRA Category 1 Credits for each hour they present at a live activity designated for such credit.*
- *Faculty may not claim simultaneous credit as physician learners for sessions at which they present; however, they may claim participant credit for other sessions they attend as learners at a designated live activity.*
- *Credit may only be claimed once for repeated presentations.*

The ACCME has taken formal action to affirm the linkage between accreditation and credit.

*All CME educational activities developed and presented by a provider accredited by the ACCME system and associated with AMA PRA Category 1 Credit™ must be developed and presented in compliance with all ACCME accreditation requirements - in addition to all the requirements of the AMA PRA program. All activities so designated for, or awarded, credit will be subject to review by the ACCME accreditation process as verification of fulfillment of the ACCME accreditation requirements. (Effective immediately.)*

## Related Questions and Answers

New

### **What does the ACCME expect from Providers who award credit for teaching in CME activities?**

Providers who award credit for teaching in CME activities must recognize that they are now building an educational activity that must meet the requirements of the ACCME. Every activity needs to be in compliance with all applicable ACCME requirements. ACCME accredited providers have the ability to designate CME activities for AMA PRA Category 1 credit™. The American Medical Association (AMA) defines what kinds of activities are eligible for credit. ACCME accredited providers add value for participants by the facilitation and measurement of learning through the application of the ACCME Essential Areas, Elements and Policies. Accredited CME providers can now designate credit for teaching in CME, internet searching and learning, test item writing, manuscript review and performance improvement activities, in addition to live activities (including some committee learning), enduring materials and journal-based continuing medical education. The ACCME supports AMA efforts which address the need for a continuing medical education credit and accreditation system that recognizes a) the variety of formats in which physicians learn and b) the added value of the delivery of these educational interventions through accredited CME providers. The ACCME's educational and organizational requirements, including the Standards for Commercial Support, can be applied to all formats of CME activities. When an ACCME accredited provider designates an educational activity for AMA PRA Category 1 credit™, it does so under the umbrella of the ACCME accreditation statement.

“Learning from Teaching” is a new activity format. The ACCME expects that all the new formats of continuing medical education will be implemented, and compliance demonstrated, within the current framework of the ACCME's accreditation requirements and process. An accredited provider might choose to make one activity for all faculty throughout the year, thus making the documentation for the activity more centralized. Whatever the manner of record-keeping, it is ACCME's expectation that these activities will be in compliance with the accreditation requirements, equal to any other format of activity offered by an accredited provider.

New

### **Why can't we just award credit to faculty for teaching or writing in an activity certified for credit?**

Teachers and authors provide the link between learner needs and expected results. Faculty are chosen for their ability to facilitate learning in order to achieve the expected result of the activity. Implicit in one's role as faculty is the expectation that the teacher/author's expertise and skill is the same as the purpose or objective of the activity. In other words, the teacher's starting point is the learner's end point. CME is about learning and change. It is about improvements in competence, or performance, or patient outcomes. Accredited providers, therefore, need to find a way to facilitate improvements of the teachers and authors who receive credit. This is applicable to all formats of CME.

New

### **How does the designation of AMA PRA Category 1 Credit™ relate to what part of our CME program is reviewed by ACCME?**

All CME educational activities developed and presented by a provider accredited by the ACCME system and associated with AMA PRA Category 1 Credit™ must be developed and presented in compliance with all ACCME accreditation requirements - in addition to all the requirements of the AMA PRA program. All activities so designated for, or awarded, credit will be subject to review by the ACCME accreditation process as verification of fulfillment of the ACCME accreditation requirements.