

Standards for Commercial Support, 1: Independence

How can non-exempt entities stay involved in CME? (SCS 1.1)

Non-exempt entities must put the control of CME into the hands of those outside of the commercial interest, e.g. by creating an independent education foundation.

The ACCME has said (FAQs published September 2004) that commercial supporters may not direct content. Is it inappropriate for the Provider to ask industry for suggestions regarding topics for CME sessions? Is it unacceptable to ask industry for ideas for speakers or topics? (SCS 1.1)

No, the ACCME Updated Standards do not prohibit the accredited provider from asking about topics or speakers. Providers may seek information about what would constitute a good activity from many sources – including commercial supporters. However SCS 1.1 and 3.2 require that the provider make independent decisions about how this information is used.

Is the following scenario allowed?...A CME provider is hired by a drug company to run an event where a doctor (hired by the same drug company) would present a CME seminar, talk, or author a CME paper. (SCS 1.1)

This should **not** occur as described under either the 1992 Standards for Commercial Support or the Updated SCS. There is a requirement that the provider ensure that critical elements of activity planning be done independently of a commercial interest (SCS1.1). The accredited provider is not ‘hired’ but rather receives commercial support and is required to fulfill SCS Standard 3, in this regard. The teacher or author must be selected and paid by the accredited provider (SCS 1.1, SCS 3.8). No funds can go directly from the commercial supporter to the teacher/author (SCS 3.9).

Why will ACCME not allow commercial interests to act as joint sponsors? (SCS 1.2)

Joint sponsors are educational partners and are expected to routinely have a role in making decisions about the elements specified in SCS 1.1.

Standards for Commercial Support, 2: Resolution of Personal Conflicts of Interest

What financial relationships need to be disclosed to the accredited provider? (SCS 2.1)

Individuals need to disclose relationships with a commercial interest if both (a) the relationship is financial and occurred within the past 12 months and (b) the individual has the opportunity to affect the content of CME about the products or services of that commercial interest.

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities for which remuneration is received or expected. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner. The ACCME has not set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

When do relationships create ‘conflicts of interest?’ (SCS 2.1)

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest **and** the opportunity to affect the content of CME about the products or services of that commercial interest.

Where is the ‘conflict?’ (SCS 2.1)

When the provider’s interests are aligned with those of a commercial interest the interests of the provider are in ‘conflict’ with the interests of the public. The interests of the people controlling CME must always be aligned with what is in the best interests of the public.

How do these circumstances create a conflict of interest? (SCS 2.1)

The potential for increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias. Commercial bias is prohibited in CME.

If at the first planning meeting for a CME activity, all committee members are asked to disclose, and each member responds that he/she has nothing to disclose (or disclose something), and this information is reflected in the minutes of the meeting – is that enough documentation that disclosure was sought? (SCS 2.1)

Yes. That documentation would help verify that the first step of a mechanism for identifying conflicts of interest is in place. That would document for ACCME that the Provider knew the relevant financial relationships of the Committee members.

Following up on that question, do we need committee members to sign a disclosure statement at every meeting while planning

the same activity? (SCS 2.1)

No. Compliance with SCS2.1 requires that disclosure is made. Disclosing the same information repeatedly to the same Provider is not necessary. With the original disclosure information, the Provider is able to implement its mechanism to resolve any conflicts of interest.

What do we do when we appoint a person to speak at the last minute and when the person arrives at the activity they refuse to disclose relationship information? (SCS 2.2)

You must not carry on with the activity under these circumstances. The person cannot participate if they refuse to disclose because conflicts of interest can neither be identified nor resolved.

What do we do when we appoint a person to speak at the last minute and we have not had time to analyze disclosure information – never mind try to resolve any conflicts of interest? (SCS 2.3)

It is reasonable to expect that providers would have plans to manage this contingency as part of their institutional mechanisms for resolving conflicts of interest. Each provider is free to develop the strategy that best suits their circumstances.

What if, based on the disclosure information that we collect, we believe there is a conflict of interest? Does ACCME have any other examples of mechanisms for resolving conflict of interests that go beyond the five examples in “Identifying and Resolving Conflicts of Interest in Continuing Medical Education?” (SCS 2.3)

Yes. Please keep in mind that these are only suggested mechanisms. Each provider will want to design and adopt a mechanism that works best for its structure and type of activities. The intent of the Updated Standards is that any content about products is aligned with the best interest of the physician learners and their patients.

1. **“Peer review” of CME is often already in place and is a mechanism to resolve conflict of interest:** Scientific abstracts or free-standing papers or articles in enduring materials are often already peer reviewed or judged against predetermined criteria to ensure the data supports the conclusions before they are accepted for presentation or publication. When people have relationships but are presenting the abstract or paper within a peer review process, the conflict may well be resolved by that peer review process. Similarly, groups of people working together to do reviews of activity content prior to publication can resolve conflicts of interest by ensuring the content is valid and aligned with the interest of the public. Multiple levels of peer review to validate content are also effective mechanisms for resolving conflict of interest.
2. In the presence of some form of oversight by the provider, **referencing the ‘best available evidence’ is also an important mechanism for resolving conflict of interest.** Consider the situation where a person who does promotional education on a particular drug for a commercial interest is asked to analyze an important, very new, clinical trial report on that drug and present recommendations for how to use that drug in clinical practice. The content of the activity (in this case the teacher’s recommendations) can be aligned with what is in the best interests of the public by the teacher referencing the best available evidence in the literature, the grade or level of that evidence and by identifying the conclusions that the evidence support. Through integrating what this best available evidence supports with what the new study has revealed the person can go on to draw conclusions or formulate recommendations. When nested within some form of peer-review or oversight process there is even external validation of the conclusions.

How does a provider implement a mechanism for resolving conflicts of interest? It all seems very abstract and daunting, and seems to imply that experts with financial relationships must be excluded. (SCS 2.3)

What follows is an example of how several tactics can be tied together by the Provider into a mechanism to resolve conflicts of interest that could demonstrate the Provider’s compliance with the ACCME requirements, and preserve participation of experts with financial relationships.

1. Determine through disclosure mechanisms if those involved in planning or presenting content within a CME activity have financial relationships related to that content.
2. If planners, presenters or authors have financial relationships that create conflict of interest,
 - a. The conflict can be resolved by an **effective peer review of content** prior to presentation or publication to ensure the content is valid and aligned with the interest of the public. Various methods of peer review to validate content can be effective mechanisms for resolving conflict of interest. One way to resolve the conflict of interest is to have scientific abstracts or free-standing papers or articles, peer reviewed or judged by commercially disinterested peers before they are accepted for presentation or publication.
 - b. In addition, requiring that all financial relationships be disclosed prior to an activity will alert participants (audience, readers) of the potential for conflict of interest and commercial bias. **Participants could be asked to evaluate the objectivity of the presentation or publication, and to identify any perceived commercial bias.**
 - c. Also, presenters, authors, planners and reviewers could be **instructed to reference the best available evidence.**

If disclosure information cannot be analyzed in a timely fashion, is it appropriate for the activity or presentation to go on without formal CME credit? (SCS 2.3)

ACCME has never recommended withholding CME credit at the last minute as an alternative to producing CME that is in compliance with accreditation requirements. It does not seem fair to the physician learners. Assuming that in this scenario there is financial relationship information to disclose to the learners, a mechanism to resolve conflicts of interest could still be put in place. For example, the participants could be asked to evaluate the objectivity of the presentation **and** the Provider could make it clear to the teacher that there is an expectation that the presentation would be compliant with the ACCME content validation statements, which state that...

(a) All the recommendations involving clinical medicine in a CME activity [are] based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.

(b) All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation [conforms] to the generally accepted standards of experimental design, data collection and analysis. Providers are not eligible for accreditation if they present activities that promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits, or known to be ineffective in the treatment of patients.

Standards for Commercial Support, 3: Appropriate Use of Commercial Support

What is ‘commercial support?’ (SCS 3.1)

Commercial Support is financial, or in-kind, contributions given by a *commercial interest*, which is used to pay all or part of the costs of a CME activity.

Can the commercial support be spent directly by the commercial supporter on costs related to the CME activity? (SCS 3.1)

No. The commercial support must go first to the provider or a provider’s joint sponsor or a provider’s educational partner.

Can a commercial supporter direct the content of CME? (SCS 3.2)

No. The provider must ensure that the content of the CME truly remains beyond the control of the commercial supporter. The process to develop the CME must be independent of the commercial interest. Providers must not allow commercial supporters to directly (SCS 1.1) or indirectly (SCS3.2) control the content of CME.

What is the Provider to do if the commercial supporter says the content of the activity is not accurate – or unreasonably favors their product? (SCS 3.2)

The ACCME recognizes that commercial supporters may be held accountable to the U.S. Government for the claims or recommendations made in a CME activity they support. As a result the commercial supporter may feel compelled to raise issues with the provider about content. There is nothing wrong with the Provider receiving these comments in the spirit of patient safety and quality healthcare. However, the validity of the content of the CME should then be established **by the Provider** and through a process that reflects compliance with ACCME’s Content Validation Statements.

Can there be commercial support that the Provider does not know about? (SCS 3.3)

No. The Provider or its agents (e.g., staff, managers, educational partners or joint sponsors) must decide what commercial support will be accepted and how it will be spent or used.

How does the CME provider pay for its services in the production and distribution of a CME activity? Can they take a portion of the grant monies to pay for their activity-related expenses, e.g., certificates, mailings? (SCS 3.3)

Yes. The funds from commercial support may be used by the Provider to pay for the cost of the activity including for example, the distribution of certificates and other mailings, as required.

Must the commercial support be given as a single lump sum grant or payment? (SCS 3.4, 3.5, 3.6)

No – commercial support does not have to be in a single payment or grant.

Can you tell us what elements must be included in the written agreement? (SCS 3.4, 3.5, 3.6)

When there is commercial support there must be a written agreement that,

- Itemizes how the Provider will use the commercial support in the development and presentation of the CME activity;
- Itemizes the organizations involved in the activity (e.g., joint sponsors, education partners, managers); Specifies the organizational name of the commercial interest(s) that supplied the funds;
- Specifies what funds or in-kind services will be given by the commercial supporter to support the provider’s activity; and
- Is signed by the commercial interest and the accredited provider.

Can the commercial supporter require that the payment of the funds to the provider be conditional upon the provider delivering the activity, as promised? (SCS 3.4, 3.5, 3.6)

Yes.

Can a commercial supporter require in the written agreement that unexpended funds be returned to the commercial supporter? (SCS 3.4, 3.5, 3.6)

Yes.

Can we use a letter of agreement written by a commercial supporter? (SCS 3.4, 3.5, 3.6)

Yes. The agreement must describe the terms, conditions and purposes of the commercial support grant and be signed by the commercial supporter and the accredited provider.

Can a commercial supporter stipulate that if they do not approve of what was said -- or what will be said – that they will not pay the commercial support? (SCS 3.4, 3.5, 3.6)

No. This stipulation implies a control of content and acts as a disincentive to professional autonomy that is unacceptable in continuing medical education.

Why is ACCME requiring that providers have their own policies and procedures governing honoraria? (SCS 3.7, 3.8)

The ACCME intends for the CME Provider to be the one to decide how much people are paid for their services as planners, faculty, and authors in CME activities.

Can a commercial supporter supplement their contributions to the activity by additional direct payments to people involved in the activity? (SCS 3.9)

No. All commercial support must be stipulated by a written agreement and must flow through the Provider and/or its educational partner. Only the Provider and/or its educational partner can make payments to people for their role(s) in the activity.

Can providers pay some of the expenses of people who are both faculty and learners? (SCS 3.10)

Yes – but CME providers need to be sure that these people have bona fide teaching roles. In the United States, physician learners are not to be given compensation or reimbursement for attending CME activities (see Opinion 8.061 of the Council on Ethical and Judicial Affairs of the American Medical Association). It is unacceptable for anyone other than the Provider, or its agents, to receive direct financial benefit from commercial support.

How can meals or social events compete with educational events? (SCS 3.11)

Meals or social events compete with educational events when they happen at the same time in a different location or when they are the main attraction at the educational activity.

Are meal-time speakers prohibited? (SCS 3.11)

No they are not prohibited. Working and learning through meal time is an efficiency often included in bona fide CME activities.

How can meals or social events take precedence over educational events? (SCS 3.11)

Using commercial support to pay for modest meals and social events at CME activities has been allowed for years. However, providers must avoid making meals or social events longer or more important or more costly than the educational activity, for example.

Whose expenses can be paid for out of the commercial support? (SCS 3.12)

Commercial support underwrites the Provider's expenses for developing and presenting an activity. Commercial support can be used to pay for the expenses of teachers and authors as well others who are working for the Provider on the activity.

In the past we have provided scholarships to residents and fellows after a nomination and selection process in compliance with the 1992 SCS. According to the Updated 2004 Standard 3.12, is this still permissible?

Yes. Scholarships for Residents and Fellows fall under the purview of other organizations' guidelines and standards (e.g., See the Ethical Opinion 8.061 of the Council of Ethical and Judicial Affairs of the AMA). It is not a topic addressed by the ACCME in the Updated Standards for Commercial Support. The existence of such scholarships and/or the compliance by the provider in the administration of such scholarships will not be reviewed by the ACCME's accreditation process. ACCME will **not** be finding Providers out of compliance with SCS 3.12 for providing scholarships to Residents and Fellows.

Many providers produce CME activities paid for entirely by commercial support with no charge to the participants. Typically these activities include a modest meal. Commercial support has been used to pay for this meal as part of the activity. Are meals still allowed as part of CME activities in light of SCS3.12?

Yes. ACCME considers meals arranged by the Provider in conjunction with an activity to be an appropriate part of the expenses of a

meeting and can be paid for out of the commercial support.

What kind of documentation of commercial support is expected? (SCS 3.13)

ACCME expects to be able to review income and expense statements for all CME activities. These statements must reflect:

- *Significant sources of income:* Including income from commercial support, advertising and exhibit fees, tuition and registration fees, internal budget allocations and any other source that represents greater than 20% of total income.
- *Significant expenses:* Including staff salaries, meeting costs, honoraria, faculty travel expenses and any other item that represents greater than 20% of total expense.

Can a commercial supporter ask for an accounting of how their commercial support has been spent? (SCS 3.13)

Yes. It is appropriate for an accounting of how the commercial support has been spent to be included in the written agreement between the Provider and the commercial supporter.

Does an accredited provider have to give a list of its participants to its commercial supporters? (SCS 3)

No. The ACCME has no specific policy on this matter. The decision is an organizational one for the provider.

Standards for Commercial Support, 4: Appropriate Management of Associated Commercial Promotion

Are advertising and exhibit opportunities always to be offered to commercial supporters? (SCS 4.1)

No. Payment and arrangements for advertising and exhibits are separate, business transactions. They are payment for the sale of promotional space.

Is the provider responsible for the content of advertising and exhibits? (SCS 4.1)

No. The Provider is not accountable to the ACCME for the content of advertising and exhibits. The information transferred in an advertisement or exhibit is not part of the Provider's program of continuing medical education activities.

Does SCS 4.2 represent a change for enduring materials?

This is a more detailed description of the requirements that must be followed if there is advertising in enduring materials. There can be advertising before and after the CME content of an enduring material but those advertisements cannot be related to the content of the CME and cannot have been paid for by the commercial supporter.

Where can providers put advertisements in printed enduring materials and printed journal-based CME and still be in compliance with SCS4.2?

- In **journal-based CME** there cannot be an advertisement within the pages of the article on which the activity is based. There can be advertisements between articles.
- In a **print enduring material** there can be advertisement at the end and the beginning of the CME content but nowhere else in the enduring material.

What does ACCME mean by 'space or place?' (SCS 4.2)

Twenty years ago, most CME occurred in a lecture hall. Now, learning activities occur in many different environments including electronic media, and ACCME intends that all of these places and spaces of CME activity need to be protected from encroachment by advertising, sales or promotional activity.

What can and what cannot have advertising? (SCS 4.3)

ACCME insists on the separation of education from all promotional activities, materials and messages. Many providers create a print or text based document that goes along with an activity and provides information that is supplementary to the education content – like reproductions of slides, graphics or other handouts. These documents, in print or electronic, are an integral part of the education and as such cannot have any advertising, trade name or a product-group message associated with them.

Our program book has abstracts in it but we give no CME credit for the abstracts – there is no problem having advertising in the program book – correct? (SCS 4.3)

The Updated SCS do not represent a change from what has been ACCME policy for many years. It depends on what the Program Book, with abstracts, is used for in relation to the CME activity. If the abstracts are referenced during the activity or serve as a component of the content, then there can be no advertising in the Program Book. If the abstracts are not referenced as part of the CME content, and appear in the Program Book with all other logistical information about the activity, then there can be advertising.

Does SCS 4.4 refer to what we call a ‘program book?’

Yes. It contains logistical and organizational information and not education materials. It contains maps and floor plans but not slides and not abstracts.

Does this mean that ACCME is prohibiting commercial supporters and other commercial interests from distributing CME enduring materials to physicians? (SCS 4.5)

No. The regulation of commercial interests’ promotional activities is not within the scope of ACCME’s responsibility. SCS4.5 is about the **providers’** role in separating promotion from education. ACCME is asking accredited providers to use their own distribution channels for CME activities. For example, having a CME enduring material created so as to be used in promotional visits to physicians’ offices is **not** in keeping with the concept of separating CME from promotion.

Can the Provider use a commercial supporter to distribute promotional materials for CME activities, e.g., “save the date cards, brochures?” (SCS 4.5)

Yes.

What if a commercial entity is interested in buying a CME product and approaches the CME provider – is it acceptable to sell the product to it? (SCS 4.5)

Yes. A Provider would not be out of compliance with the Standards for Commercial Support.

Standards for Commercial Support, 5: Content and Format Without Commercial Bias

What if an activity does in fact imply that a certain product or service is better than another? (SCS 5.1)

CME exists to support the physician change and learning -- so as to increase their ability to participate in providing quality healthcare or improved healthcare. ACCME expects that providers will always be able to demonstrate how each activity contributes to quality and/or improvement in healthcare, and is, therefore, aligned with what is in the best interest of the public.

Since the updated SCS do not mention off-label usage, does that mean that disclosure for off-label uses is no longer required or that discussion of off-label uses is not allowed in a CME activity? (SCS 5.1)

Discussion of off-label uses are certainly allowed in CME activities. However, providers are no longer required to have a mechanism in place to ensure that off-label or investigational uses are disclosed as such. The ACCME adopted content validation statements in 2002 that are expectations of providers with regard to any recommendations for clinical care. Specifically, ‘all the recommendations involving clinical medicine in a CME activity [are] based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation [conforms] to the generally accepted standards of experimental design, data collection and analysis.’

Does CME have to give ‘equal time’ to all modalities of therapy (e.g., surgical vs. medical)? Does CME have to give ‘equal time’ to all formulations of a drug or all products in a class of products? (SCS 5.2)

CME must be free of commercial bias. CME must not promote products or services. CME must promote improvements in healthcare. A ‘balanced view’ means that recommendations or emphasis must fairly represent, and be based on, a reasonable and valid interpretation of the information available on the subject (e.g., “On balance the data support the following ...”). A ‘balanced view of therapeutic options’ also means that no single product or service is over represented in the education activity when other equal but competing products or services are available for inclusion.

Standards for Commercial Support, 6: Disclosures Relevant to Potential Commercial Bias

If we have taken appropriate steps to resolve conflicts of interest what is there left to disclose? (SCS 6.1)

Informed learners are the final safeguards in assuring that a CME activity is independent from commercial influence. Regarding personal conflicts of interest, CME providers are to have in place mechanisms to identify and resolve conflicts of interest. While these mechanisms should greatly reduce the potential for conflicts of interest to affect CME content, a potential for influence remains. Disclosing to learners the relevant financial relationships that were present and resolved assists learners in assessing the potential for bias in information that is presented. ACCME believes this disclosure contributes to the transparency and accountability of the system.

What does ACCME mean by ‘nature of relationship? (SCS 6.1)

The ‘nature of the relationship’ means the role they play or service they provide in exchange for some form of compensation (e.g., employment, management position, independent contractor including contracted research, consulting, speaking and teaching, membership on advisory committees or review panels and board membership).ACCME has **not** set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship therefore the dollar value of the relationship does **not** need to be disclosed.

What does SCS 6.2 add to the system?

This allows the learners to distinguish between missing disclosure information and the circumstances where there is nothing to disclose.

Is disclosure of commercial support different than disclosure of financial relationships? (SCS 6.3)

Yes. Commercial support is given to the accredited Provider and the accredited Provider must disclose its existence to the learner. The presence of commercial support is critical information. The disclosure of commercial support is not an opportunity for product advertising but rather it must be restricted to the name of the corporate entity that provided the financial or specified in-kind support.

Can a commercial supporter's logo be used to acknowledge support? (SCS 6.3, 6.4, 6.5)

While the logo can appear, the provider cannot acknowledge support only by showing the commercial supporter's logo. The acknowledgement needs to specifically tell the learner that the commercial supporter gave support for the activity. The acknowledgment of commercial support cannot contain any product promotion.