



Kansas Medical Society Continuing Medical Education Providers Accreditation Manual

***Prepared by the Kansas Medical Society
Continuing Medical Education Committee***

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General Information

What is the KMS?

The Kansas Medical Society (KMS), along with its component medical societies, is the largest, most effective organization representing the interest of all Kansas physicians and their patients. The KMS is nationally **recognized** by the ACCME to accredit intrastate sponsors to offer their own Category 1 CME credit. As a state medical society recognized by the ACCME to accredit intrastate sponsors of CME, the KMS has adopted the ACCME Essential Areas, including the Standards for Commercial Support and Updated Accreditation Criteria. In addition, the KMS CME Committee has also devised policies and procedures for intrastate accreditation.

What is the ACCME?

The Accreditation Council for Continuing Medical Education (ACCME) is the agency responsible for maintaining the quality of continuing medical education (CME) in the United States. The Council is composed of representatives from the following organizations: American Medical Association, American Hospital Association, Associate for Hospital Medical Education, Association of American Medical Colleges, Council of Medical Specialty Societies, and Federation of State Medical Boards. In order to achieve this goal, it has established a set of criteria called the *Essential Areas and Their Elements* which must be met by organizations seeking to provide continuing education for physicians. ACCME sets national standards and guidelines for accreditation of CME sponsors; accredits state medical societies, medical schools, and entities which provide nationally promoted CME activities; and recognizes state medical associations as the accrediting bodies for their states.

National versus Intrastate Accreditation

Organizations intending to provide CME for physicians on an ongoing basis must be individually accredited to perform this function by demonstrating total compliance with the ACCME/KMS Essential Areas. There are two types of accreditation: national and intrastate. National accreditation is controlled and conducted directly by the ACCME. National accreditation is specifically designed for those organizations which consistently advertise and provide CME activities to a national physician audience. For more information, contact the ACCME at 312-464-2500. Those organizations interested in providing CME for physicians within their own organization, their local community, or their state should seek intrastate accreditation, a role which is fulfilled primarily by the state medical society in each state.

What is AMA Category 1 Credit?

AMA Category 1 credit is a type of educational credit that can be applied toward the American Medical Association Physician's Recognition Award (AMA PRA). The award indicates participation in continuing medical education and is a means of recognizing a physician's professional commitment to his or her patients and to the public.

The AMA PRA is a certificate awarded by the AMA to physicians who earn and document 50 credits of continuing medical education for one year (two and three-year certificates are available as well). The PRA was established by the AMA in 1968 to formally recognize and encourage physician participation in CME activities.

The AMA PRA is a voluntary recognition program, however, many licensing or certifying boards, specialty societies, etc. which require CME, accept receipt of the PRA as fulfillment of their respective requirements.

For more information on the AMA PRA credit system, sign up for an e-mail distribution list and other information at cppd@ama-assn.org.

An activity can be designated AMA Category 1 if it is provided or jointly sponsored by an institution or organization accredited for continuing medical education by the ACCME or by a

state medical society or other accredited institution, and if the activity meets or exceeds the following criteria:

- 1) it conforms to the definition of continuing medical education: "Continuing Medical Education consists of educational activities which serve to maintain, develop or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public." (*The Physician's Recognition Award, American Medical Association*);
- 2) it is based on perceived or demonstrated educational need;
- 3) it is designed to meet the continuing medical education needs of an individual physician or a specific group of physicians;
- 4) the educational objectives of the activity are stated;
- 5) the content is appropriate for the specified objectives;
- 6) the teaching/learning methodologies and techniques are suitable for the objectives and format of the activity;
- 7) evaluation mechanisms are defined to assess the quality of the activity and its relevance to the stated needs and objectives;
- 8) there is documentation of physicians' participation;
- 9) commercial support of the activity conforms to the *Standards for Commercial Support for CME* established by the ACCME/KMS.

PRA requirements and materials are revised periodically. Application forms and current information on criteria and requirements may be obtained from the AMA Division of Continuing Professional Development, 515 North State Street, Chicago, IL 60610, (312) 464-4672, or by visiting the AMA web site for a copy of the AMA PRA Information Booklet: <http://www.ama-assn.org/go/prs>.

An accredited organization's authority to designate credit for its CME activities extends only to credit for the AMA PRA. The following credit statement must be used on all promotional pieces that are designated for *AMA PRA Credit*TM:

The (name of the accredited provider) designates this educational activity for a maximum of (number of credits) *AMA PRA Category 1 Credit(s)*TM. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Refer to the AMA PRA information booklet for wording for non-physician certificates or transcripts.

Providers may apply for and grant other types of credit for physicians, i.e. AAFP, ACOG. Providers may also seek continuing education credit for other healthcare professionals as appropriate for the content of the activity. Examples include nurses, physical therapists, and social workers.

Credit for the AMA PRA is determined by the actual clock hours of educational time. Time allotted for registration, breaks, lunch, etc., is not applied toward the number of hours. The time it takes to participate in the activity may be rounded to the nearest quarter hour and credit should be awarded accordingly.

Physicians should be instructed to claim credit equal to their participation in an activity.

Accreditation Information

Eligibility for Accreditation

Hospitals, medical societies, medical professional associations, and other qualified research oriented organizations with professional memberships which are committed to providing continuing medical education for physicians are eligible for accreditation by the KMS provided they meet the following conditions. The organization must exhibit a dedicated interest in and commitment to continuing medical education for physicians, and must demonstrate compliance with the KMS Essential Areas and Elements and the KMS policies. The organization must be incorporated and based in Kansas with a desire to offer CME activities within the state of Kansas for the local physician audience. Those organizations not meeting the established criteria will be directed to seek national accreditation or to engage in joint sponsorship with an accredited provider.

Before an organization is eligible to apply for accreditation, there are certain requirements which the organization must employ during the implementation and organization of its CME program. The organization must be familiar with the process of accreditation and the KMS Essential Areas and Elements and KMS policies. The organization should appoint a CME Committee whose membership is derived from a variety of medical specialties and a CME Coordinator or other staff person who is primarily assigned to execute the details associated with producing CME programs and maintaining the extensive documentation required of accredited providers of Category 1 CME credit. Appropriate individuals from the CME program, such as the CME Committee Chairman, the Director of Medical Education, and the CME Coordinator should make plans to attend at least one accreditation workshop provided by the KMS or the ACCME.

A new CME program must be organized in such a fashion as to demonstrate that it has the capabilities and resources to adhere to the KMS Essentials and Elements and the KMS policies. Proper administration of the program must be implemented with a mechanism established to utilize all appropriate organizational resources relating to CME functions.

The new program, once organized, should begin to develop CME activities appropriate for the designation of AMA Category 1 credit. The program should then engage in joint sponsorship of CME activities with a sponsor already accredited to offer Category 1 CME credit. Joint sponsorship is an important component of the initial process since this enables the organization to work within the confines of an accredited program and establish a track record. The KMS CME Committee requires interested organizations to jointly sponsor approximately 15-20 hours of Category 1 CME with another accredited organization before applying for intra-state accreditation.

Once the program establishes an adequate track record and can demonstrate compliance with all KMS Essentials and Elements, the organization should then apply for intra-state accreditation through the KMS.

The Accreditation Application Process

The first step in the accreditation process is the submission of an original accreditation application **and three copies**. Upon submission, the application is comprehensively reviewed by one member of the CME Committee before any further action is taken. In the event that the

organization is deemed ill-prepared for accreditation, the application will be returned to the applying organization with recommendations and suggestions for future submission.

Site Survey of the Applying Organization

Once the application is deemed acceptable, a date for an on-site survey of the organization is scheduled. A survey team is assembled consisting of KMS staff and physician committee members. During the survey, the survey team will discuss the entire application with the CME chairman, any available CME Committee members, and the CME Coordinator of the organization. In addition, the surveyors will also review the policies and procedures of the CME unit, as well as its methods of documentation. Finally, the surveyors will tour the actual facility and become familiar with the infrastructure of the organization.

Once the survey has been conducted, the survey team will prepare a report and make recommendations to the KMS CME Committee at their next available meeting. The full committee will make the final decision regarding accreditation status. The initial accreditation process can take anywhere from six to eight months, and applying organizations are reminded to plan accordingly.

Accreditation Fees and Associated Expenses

The application for initial accreditation is \$2,850 and for re-accreditation is \$2,500. Additionally, an annual review fee of \$500 is collected with the submission of an annual report of activity.

Types and Length of Accreditation

Accreditation with Commendation - Awarded to an accredited organization following formal review, a site survey, and favorable action with exemplary commendations by the Committee on Continuing Education.

Term: 6 years

Criteria for 6-year Term of Accreditation with Commendation – The provider: 1) demonstrates compliance in criteria 1 through 22; **and** 2) previous accreditation was a four-year term with all Elements in compliance, or brought into compliance before end of term. If, during a six-year accreditation term, an organization reports a change in primary CME staff, the committee may request a sample of activity documentation to ensure continued compliance with the accreditation elements.

Full Accreditation – Awarded to an accredited organization following formal review, a site survey, and favorable action by the committee.

Term: 4 years (Standard Accreditation Term)

Provisional Accreditation – Awarded to an initial applicant following formal review, a site survey, and favorable action by the committee.

Term: 2 years

Extension: May be extended once for a maximum of 2 years.

Restrictions: May not jointly sponsor with non-accredited entities. Upon first resurvey, provisionally accredited organizations must be given full accreditation, non-accreditation or an extension. They may NOT be placed on probation.

Probationary Accreditation – An accredited program that seriously deviates from compliance with the accreditation requirements may be placed on Probation. Probation may also result from a provider's failure to demonstrate compliance in a progress report.

Term: Standard 4 year term for 2 years. Accreditation status, and the ability for a provider to complete its four-year term, will resume when a Progress Report is received, validated, and accepted by the KMS CME Committee.

Extension: May **not** be extended.

Restrictions: May **not** jointly sponsor with non-accredited entities; no more than 4 years full accreditation following probation.

Non-Accreditation

- Given to an initial applicant following formal review and a site survey when the committee determines that an organization is not in substantial compliance with the Essential Areas and Their Elements. Non-accreditation may also be given at the First Level Review prior to a site survey.
- Given to a probationary accredited organization following formal review and a site survey when the committee determines that the organization is not in substantial compliance with the Essential Areas and Their Elements.
- After a Progress Report of accredited provider on Probation. Noncompliance with any one of the Elements will be cause for Non-Accreditation.

Term: Indeterminate. An organization may later re-apply for accreditation under status as an initial applicant.

Restrictions: A period of probationary accreditation must be granted before a fully accredited organization can be given non-accreditation.

Progress Report Decisions

Upon review and site survey, some providers are required to submit Progress Reports to KMS. A decision regarding a provider's Progress Report could be one of three options:

- 1) **Accept:** Evidence that the area(s) of Accreditation Requirements in non-compliance has been corrected and brought into compliance.
- 2) **Clarification Required:** Information in the Progress Report indicates the area of non-compliance is mostly resolved, but some additional information is required to be certain the provider is in compliance. An additional Progress Report may be required.
- 3) **Reject:** The Progress Report does not provide evidence that the areas in non-compliance have been corrected. Either a second Progress Report or a focused accreditation survey may be required. KMS can place a provider on Probation or Non-Accreditation as the result of findings on a Progress Report.

Reconsideration and Appeals

A provider that receives a decision of Probation or Non-Accreditation may request Reconsideration when it feels that the evidence it presented to KMS justifies a different decision. Only material which was considered at the time of the review and site survey may be reviewed upon Reconsideration. If, following the Reconsideration, KMS sustains its original action, the organization may request a hearing before an Appeals process.

KMS Essential Areas and Their Elements

The KMS recognizes that the professional responsibility of physicians requires continuous learning throughout their careers, appropriate to the individual physician's needs. The KMS also recognizes that physicians are responsible for choosing their CME activities in accordance with their perceived and documented needs, individual learning styles, and practice setting requirements and for evaluating their own learning achievements. The Essential Areas and policies¹, therefore, are designed to encourage providers to consider the needs and interests of potential physician participants in planning their CME activities and to encourage the physicians to assume active roles in the planning process.

In the Essential Areas and policies, the KMS has identified certain elements of structure, method, and organization that contribute to the development of effective continuing medical education. The Essential Areas and policies are the practices that a provider must implement for accreditation.

With the Updated Accreditation Criteria the focus of CME is now on contributing to the physician's strategies for patient care (**competence**), their actual **performance** in practice, and/or their **patient outcomes**. Providers must now establish a specific mission, provide education interventions to meet that mission, and then assess their program's impact at meeting that mission and improving their program.

The three Essential Areas are Purpose and Mission, Educational Planning, and Evaluation and Improvement:

- The **Purpose and Mission Area** describes *why* the organization is providing CME.
- The **Educational Planning Area** explains *how* the organization plans and provides CME activities, incorporating the Standards for Commercial Support to ensure independence.
- The **Evaluation and Improvement Area** evaluates *how well* the organization is accomplishing its purpose in providing CME activities and identifies opportunities for change and improvement in the CME program.
- The **Elements** describe performance in the Essential Area.
- The **Criteria** have been developed for each Element to determine a provider's compliance with the Element. Satisfactory compliance of various criteria will indicate a provider's level of accreditation:
 - 1) Level 1 – Provisional Accreditation – Initial Applicants Only: Meet or Exceed Criteria #1-3 and 7-12
 - 2) Level 2 – Full Accreditation: Meet or Exceed Criteria #1-15
 - 3) Level 3 – Accreditation with Commendation: Meet or Exceed Criteria 1-22

To make accreditation decisions, KMS will review the data collected for the three Essential Areas and their criteria to determine the level of accreditation. This process is repeated at the end of every term for accredited providers and more frequently where monitoring suggests possible areas for improvement.

Updated Criteria for Compliance with Accreditation Elements

		Level 1 Provider Provisional Accreditation	Level 2 Provider Full Accreditation	Level 3 Provider Accreditation with Commendation	
Element					
1.	The provider has a CME mission statement that includes all of the basic components (CME purpose, content areas, target audience, type of activities, expected results) with expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.	1.1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2.	The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.	2.1 2.2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3.	The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.	2.1 2.3	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4.	The provider generates activities/educational interventions around content that matches the learners' current or potential scope of professional activities.	2.1		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
5.	The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives and desired results of the activity.	2.1		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6.	The provider develops activities/educational interventions in the context of desirable physician attributes (e.g., IOM competencies, ACGME Competencies).	2.1		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
7.	The provider develops activities/educational interventions independent of commercial interests (SCS 1, 2 and 6).	SCS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
8.	The provider appropriately manages commercial support (if applicable, SCS 3).		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
9.	The provider maintains a separation of promotion from education (SCS 4).		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
10.	The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
11.	The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions.	2.4	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
12.	The provider gathers data or information and conducts a program-based analysis on the degree to which the CME mission of the provider has been met through the conduct of CME activities/educational interventions.	2.5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
13.	The provider identifies, plans and implements the needed or desired changes in the overall program (e.g., planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on ability to meet the CME mission.			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
14.	The provider demonstrates that identified program changes or improvements, that are required to improve on the provider's ability to meet the CME mission, are underway or completed.			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
15.	The provider demonstrates that the impacts of program improvements, that are required to improve on the provider's ability to meet the CME mission, are measured.			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
16.	The provider operates in a manner that integrates CME into the process for improving professional practice.				<input checked="" type="checkbox"/>
17.	The provider utilizes non-education strategies to enhance change as an adjunct to its activities/educational interventions (e.g., reminders, patient feedback).				<input checked="" type="checkbox"/>
18.	The provider identifies factors outside the provider's control that impact on patient outcomes.				<input checked="" type="checkbox"/>
19.	The provider implements educational strategies to remove, overcome or address barriers to physician change.				<input checked="" type="checkbox"/>
20.	The provider builds bridges with other stakeholders through collaboration and cooperation.				<input checked="" type="checkbox"/>

21. The provider participates within an institutional or system framework for quality improvement.	
22. The provider is positioned to influence the scope and content of activities/educational interventions.	



KMS ESSENTIAL AREAS AND THEIR ELEMENTS

Essential Area 1: Purpose and Mission

The provider must:

- Element 1 Have a written statement of its CME mission, which includes the CME purpose, content areas, target audience, type of activities provided, and expected results of the program.

Essential Area 2: Educational Planning

The provider must,

- Element 2.1 Use a planning process(es) that links identified educational needs with a desired result in its provision of all CME activities.
- Element 2.2 Use needs assessment data to plan CME activities.
- Element 2.3 Communicate the purpose or objectives of the activity so the learner is informed before participating in the activity.
- Element 3.3 Present CME activities in compliance with the KMS's policies for disclosure and commercial support.

Essential Area 3: Evaluation and Improvement

The provider must,

- Element 2.4 Evaluate the effectiveness of its CME activities in meeting identified educational needs.
- Element 2.5 Evaluate the effectiveness of its overall CME program and make improvements to the program.

Administration Policy

The provided must,

- Have an organizational framework for the CME unit that provides the necessary resources to support its mission including financial support, appropriate staff, and a CME committee composed of representatives of the target audience.

KMS UPDATED ACCREDITATION DECISION-MAKING CRITERIA

Measurement criteria have been developed for each *Element* in the *Essential Areas* to measure whether the accredited provider meets the basic level of accreditation. **A provider's documentation of the measurement criteria will be the KMS's primary source of information for determining compliance with the Elements.**

ESSENTIAL AREA 1 – PURPOSE AND MISSION

- E1 The provider must have a written statement of its CME mission, which includes the CME purpose, content areas, target audience, type of activities provided, and expected results of the program.

CRITERIA FOR COMPLIANCE

- C1 The provider has a CME mission statement that includes all of the basic components (CME purpose, content areas, target audience, type of activities, expected results) with expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.

ESSENTIAL AREA 2 – EDUCATIONAL PLANNING

- E2.1 The provider must use a planning process(es) that links identified educational needs with a desired result in its provision of all CME activities.
- E2.2 The provider must use needs assessment data to plan CME activities.
- E2.3 The provider must communicate the purpose or objectives of the activity so the learner is informed before participating in the activity.
- E3.3 The provider must present CME activities in compliance with the KMS's policies for disclosure and commercial support.

CRITERIA FOR COMPLIANCE

- C2 The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.
- C3 The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.
- C4 The provider generates activities/educational interventions around content that matches the learners' current or potential scope of professional activities.
- C5 The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives and desired results of the activity.
- C6 The provider develops activities/educational interventions in the context of desirable physician attributes (e.g., IOM competencies, ACGME competencies).

- C7 The provider develops activities/educational interventions independent of commercial interests (SCS 1, 2 and 6).
- C8 The provider appropriately manages commercial support (if applicable, SCS 3).
- C9 The provider maintains a separation of promotion from education (SCS 4).
- C10 The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).

[NOTE: Regarding E3.3 and C7 to C10 – The KMS’s policies for disclosure and commercial support are articulated in: (1) The Standards For Commercial Support: Standards to Ensure Independence in CME Activities, as adopted by the KMS in April 2005; and (2) KMS policies applicable to commercial support and disclosure.]

ESSENTIAL AREA 3 – EVALUATION AND IMPROVEMENT

- E2.4 The provider must evaluate the effectiveness of its CME activities in meeting identified educational needs.
- E2.5 The provider must evaluate the effectiveness of its overall CME program and make improvements to the program.

CRITERIA FOR COMPLIANCE

- C11 The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program’s activities/educational interventions.
- C12 The provider gathers data or information and conducts a program-based analysis on the degree to which the CME mission of the provider has been met through the conduct of CME activities/educational interventions.
- C13 The provider identifies, plans and implements the needed or desired changes in the overall program (e.g., planners, teachers, infrastructure, methods, resources, facilities, interventions) that are required to improve on ability to meet the CME mission.
- C14 The provider demonstrates that identified program changes or improvements, that are required to improve on the provider’s ability to meet the CME mission, are underway or completed.
- C15 The provider demonstrates that the impacts of program improvements, that are required to improve on the provider’s ability to meet the CME mission, are measured.

ACCREDITATION WITH COMMENDATION

In order for an organization to achieve the status Accreditation with Commendation, the provider must demonstrate that it fulfills the following Criteria 16-22, in addition to Criteria 1-15.

CRITERIA FOR COMPLIANCE

- C16 The provider operates in a manner that integrates CME into the process for improving professional practice.

- C17 The provider utilizes non-educational strategies to enhance change as an adjunct to its activities/educational interventions (e.g., reminders, patient feedback).
- C18 The provider identifies factors outside the provider's control that impact on patient outcomes.
- C19 The provider implements educational strategies to remove, overcome or address barriers to physician change.
- C20 The provider builds bridges with other stakeholders through collaboration and cooperation.
- C21 The provider participates within an institutional or system framework for quality improvement.
- C22 The provider is positioned to influence the scope and content of activities/educational interventions.

Levels of Accreditation

PROVISIONAL ACCREDITATION requires compliance with Criteria 1 to 3 and 7 to 12.

CONTINUED ACCREDITATION requires compliance with Criteria 1 to 3 and 7 to 12 (*Provisional Accreditation*) **plus** six additional criteria; Criteria 4 to 6 and 13 to 15.

ACCREDITATION WITH COMMENDATION requires compliance with Criteria 1 to 15 (*Continued Accreditation*) **plus** seven additional criteria; Criteria 16 to 22.



KMS STANDARDS FOR COMMERCIAL SUPPORT OF CME

Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The KMS defines a “commercial interest” as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.

- (a) Identification of CME needs;
- (b) Determination of educational objectives;
- (c) Selection and presentation of content;
- (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
- (e) Selection of educational methods;
- (f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The KMS defines “relevant” financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider’s educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider’s written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

STANDARD 4. Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For **print**, 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.

- For **computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content.

- For **audio and video recording**, advertisements and promotional materials will not be included within the CME.

There will be no 'commercial breaks.'

- For **live, face-to-face CME**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

STANDARD 5. Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

STANDARD 6. Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.

Adopted by KMS, 2005

Accreditation Policies

KMS policies supplement the Essential Areas and Elements, and result from actions taken by the KMS Continuing Medical Education Committee. Committee actions are based on a review and discussion of relevant research as well as feedback obtained from multiple constituents, including the Accreditation Council on Continuing Medical Education and accredited providers.

KMS has organized its accreditation policies according to topic, and presents them in a format intended to assist providers in understanding the policies, as well as KMS's expectations for their implementation.

Accreditation Statement

The accreditation statement identifies which KMS accredited organization is responsible for demonstrating the CME activity's compliance with all **KMS Essential Areas and Elements** (including the Standards for Commercial Support) and **Accreditation Policies**. The accreditation statement must appear on all CME activity materials and brochures distributed by accredited organizations, except that the accreditation statement does not need to be included on initial save-the-date type activity announcements. Such announcements contain only general, preliminary information about the activity like the date, location, and title. If more specific information is included, like faculty and objectives, the accreditation statement must be included.

The KMS accreditation statement is as follows:

For directly sponsored activities: "The (name of accredited provider) is accredited by the Kansas Medical Society to provide continuing medical education for physicians."

For jointly sponsored activities: "This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Kansas Medical Society through the joint sponsorship of (name of accredited provider) and (name of non-accredited provider). The (name of accredited provider) is accredited by the KMS to provide continuing medical education for physicians."

Providers who designate activities for *AMA PRA Category 1 Credit™* must use the following language in both announcement and activity materials:

AMA/PRA Designation Statement for Category I Credit: "The (name of accredited provider) designates this educational activity for a maximum of (number of credits) AMA PRA Category 1

Credit(s)TM. Physicians should claim credit commensurate with the extent of their participation in the activity.

AMA PRA Category 1 Credit is a trademark of the American Medical Association. Accredited providers are required to use “*AMA PRA Category 1 CreditTM*” whenever the phrase is first used in any publication, and periodically through the publication. This standard language, along with the Designation Statement, benefits both providers and physicians by clearly communicating the provider’s privilege to award AMA PRA Category 1 Credit on behalf of the AMA.

For co-sponsored activities: There is no “co-sponsorship” accreditation statement. If two or more accredited providers are working in collaboration on a CME activity, one provider must take responsibility for the compliance of that activity. Co-sponsored CME activities should use the directly sponsored activity statement, naming the one accredited provider that is responsible for the activity. KMS has no policy regarding specific ways in which providers may acknowledge the involvement of other KMS accredited providers in their CME activities.

CME Content

KMS’s definition of CME describes what content is accepted for activities that are certified for credit:

Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

A broad definition of CME, such as the one found above, recognizes that all continuing educational activities which assist physicians in carrying out their professional responsibilities more effectively and efficiently are CME. A course in management would be appropriate CME for physicians responsible for managing a health care facility; a course in educational methodology would be appropriate CME for physicians teaching in a medical school; a course in practice management would be appropriate CME for practitioners interested in providing better service to patients.

Not all continuing educational activities which physicians may engage in however are CME. Physicians may participate in worthwhile continuing educational activities which are not related directly to their professional work and these activities are not CME. Continuing educational activities which respond to a physician’s non-professional educational need or interest, such as personal financial planning or appreciation of literature or music, are not CME.

CME that discusses issues related to coding and reimbursement in a medical practice falls within KMS’s definition of CME.

Providers are not eligible for KMS accreditation or reaccreditation 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. An organization whose program of CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for KMS accreditation.

Content Validation

Accredited providers are responsible for validating the clinical content of CME activities that they provide. Specially:

1. All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
2. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
3. Providers are not eligible for KMS accreditation or re-accreditation if they present activities that promote recommendations, treatment, or manners of practicing medicine that are not within the definition of CME; that are known to have risks or dangers that outweigh the benefits; or are known to be ineffective in the treatment of patients.

Commercial Support and Disclosure

These policies and definitions supplement the **Standards for Commercial Support: Standards to Ensure the Independent of CME Activities (SCS)**.

Relevant to SCS 1 (Ensuring Independence in Planning CME Activities)

A **commercial interest** is any proprietary entity producing health care goods or services consumed by, or used on patients.

The KMS does not consider providers of clinical service directly to patients to be commercial interests.

A commercial interest is not eligible for KMS accreditation. Within the context of this definition and limitation, the KMS considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

- 501c non-profit organizations
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For-profit rehabilitation centers
- For-profit nursing homes

KMS reserves the right to modify this definition and this list of eligible organizations from time to time without notice.

Relevant to SCS 2 (Identifying and Resolving Conflicts of Interest)

Financial Relationships: 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 from which remuneration is received, or expected.

With respect to personal **financial relationships**, 'contracted research' includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

Conflict of Interest: Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.

The KMS 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. The KMS considers “content of CME about the products or services of that commercial interest” to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

With respect to **financial relationships** with commercial interests, when a person divests themselves of a relationship it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.

Relevant to SCS 3 (Appropriate Use of Commercial Support)

Commercial Support is financial, or in-kind, contributions given by a commercial interest (see Policies relevant to SCS 1), which is used to pay all or part of the costs of a CME activity.

Element 3.12 of the KMS’s Updated Standards for Commercial Support applies only to physicians whose official residence is in the United States.

Relevant to SCS 4 (Appropriate Management of Commercial Promotion)

Commercial exhibits and advertisements are promotional activities and not continuing medical education. Therefore, monies paid by commercial interests to providers for these promotional activities are not considered to be ‘commercial support’. However, accredited providers are expected to fulfill the requirements of SCS 4 and to use sound fiscal and business practices with respect to promotional activities.

Relevant to SCS 6 (Disclosure to Learners)

Disclosure of information about provider and faculty relationships may be disclosed verbally to participants at a CME activity. When such information is disclosed verbally at a CME activity, providers must be able to supply KMS with written verification that appropriate verbal disclosure occurred at the activity. With respect to this written verification:

1. A representative of the provider who was in attendance at the time of the verbal disclosure must attest, in writing:
 - a) that verbal disclosure did occur; and
 - b) itemize the content of the disclosed information (SCS 6.1); or
 - c) itemize that there was nothing to disclose (SCS 6.2).
2. The documentation that verifies that adequate verbal disclosure did occur must be completed within one month of the activity.

The provider’s acknowledgment of commercial support as required by SCS 6.3 and 6.4 may state the name, mission, and areas of clinical involvement of the company or institution and may include corporate logos and slogans, if they are not product promotional in nature.

Enduring Materials

An enduring material is a non-live CME activity that “endures” over time. It is most typically a videotape, monograph, or CD rom. Enduring materials can also be delivered via the Internet. The

learning experience by the physician can take place at any time in any place, rather than only at one time, and one place, like a live CME activity.

Enduring materials must comply with all KMS Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies. However, there are special communication requirements for enduring materials because of the nature of the activities. Because there is no direct interaction between the provider and/or faculty and the learner, the provider must communicate the following information to participants so that they are aware of this information prior to starting the educational activity:

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

Providers that produce enduring materials must review each enduring material at least once every three years or more frequently if indicated by new scientific developments. So, while providers can review and re-release an enduring material every three years (or more frequently), the enduring material cannot be certified for credit for more than three years without some review on the part of the provider to ensure that the content is still up-to-date and accurate. That review date must be included on the enduring material, along with the original release date and a termination date.

Accredited providers may not enlist the assistance of commercial interests to provide or distribute enduring materials to learners.

KMS policy does not require 'post-tests' for enduring materials. KMS records retention policies do, however, require participants to verify learner participation and evaluate all CME activities. So, accredited providers often choose to include a post-test in their enduring material activities as a way to comply with those two requirements.

Sometimes providers will create an enduring material from a live CME activity. When this occurs, KMS considers the provider to have created two separate activities – one live activity and one enduring material activity. Both activities must comply with all KMS requirements, and the enduring material activity must comply additionally with all KMS policies that relate specifically to enduring materials.

Fees

KMS accredited providers are accountable for timely submission of fees that are required either to attain or maintain accreditation.

- \$2,850 Initial Accreditation Fee (New Programs)
- \$2,500 Reaccreditation Fee
- \$500 Annual Fee

Internet CME

Live or enduring material activities that are provided via the Internet are considered to be "Internet CME." Internet CME must comply with all KMS Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies. However, there are special requirements for Internet CME because of the nature of the activities:

Activity Location: KMS accredited providers may not place their CME activities on a pharmaceutical or device manufacturers' product website.

Links to Product Websites: With clear notification that the learner is leaving the educational website, links from the website of an KMS accredited provider 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: 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 not interleaved between computer 'windows' or screens of the CME content.

Hardware/Software Requirements: The accredited provider must indicate, at the start of each Internet CME activity, the hardware and software required for the learner to participate.

Provider Contact Information: The accredited provider must have a mechanism in place for the learner to be able to contact the provider if there are questions about the Internet CME activity.

Policy on Privacy and Confidentiality: The accredited provider must have, adhere to, and inform the learner about its policy on privacy and confidentiality that relates to the CME activities it provides on the Internet.

Copyright: The accredited provider must be able to document that it owns the copyright for, or has received permission for use of, or is otherwise permitted to use copyrights materials within a CME activity on the Internet.

Joint Sponsorship

KMS accredited providers that plan and present one or more activities with non-KMS accredited providers are engaging in "joint sponsorship."

Intent: The accredited provider shall accept responsibility that the KMS accreditation policies and procedures are met and that it participates integrally in the planning and implementation of educational activities planned and presented in joint sponsorship with non-accredited providers.

A commercial interest cannot take the role of non-accredited provider in a joint sponsorship relationship.

The KMS expects all CME activities to be in compliance with the Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies. In cases of joint sponsorship, it is the KMS accredited provider's responsibility to be able to demonstrate through written documentation this compliance to the KMS. Materials submitted that demonstrate compliance may be from either the KMS accredited provider's files or those of the non-accredited provider.

Note, that if a jointly sponsored activity is found to be in Non-Compliance with KMS's content validation policies or policies for disclosure and commercial support, the accredited provider in the relationship may be asked to provide one or more Monitoring Progress Reports related to the issue. Similarly, special requirements exist for accredited providers that jointly-sponsor activities with non-accredited organizations that have a history of joint-sponsoring activities that do not comply with KMS's content validation policies or policies for disclosure and commercial support.

The accredited provider must inform the learner of the joint sponsorship relationship through the use of the appropriate accreditation statement. All printed materials for jointly sponsored activities must carry the appropriate accreditation statement.

All KMS accredited providers that choose to initiate joint sponsorship subsequent to achieving accreditation must notify the KMS of their intention to do so. This will assist the KMS in ensuring that all activity formats are identified and reviewed at the time of reaccreditation.

If a provider is placed on probation, it may not jointly sponsor CME activities with non-accredited providers, with the exception of those activities that were contracted prior to the probation decision. A provider that is placed on probation must inform the KMS of all existing joint sponsorship relationships, and must notify its current contracted joint sponsors of its probationary status.

The KMS maintains no policy that requires or precludes accredited providers from charging a joint sponsorship fee.

Journal CME

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 KMS's Definition of CME.

Journal CME activities must comply with all KMS 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 KMS 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.

Records Retention

Specific CME activity records must be maintained by all accredited providers. Records retention requirements relate to the following two topics: **Attendance Records** and **Activity Documentation**.

1. **Attendance Records:** An accredited provider must have mechanisms in place to record and, when authorized by the participating physician, verify participation for six years from the date of the CME activity. The accredited provider is free to choose whatever registration method works best for their organization and learners. The KMS does not require sign-in sheets.

2. **Activity Documentation:** An accredited provider is required to retain activity files/records of CME activity planning and presentation during the current accreditation term or for the last twelve months, whichever is longer. Maintenance of this documentation enables the provider to, at the time of re-accreditation; show KMS how the activities it provided during its current term of accreditation were compliant with all KMS Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies.

Additionally, if KMS receives a complaint about an accredited provider, and the complaint relates to the provider's implementation of one or more KMS Essential Areas or Elements or

Accreditation Policies, KMS may ask the provider to respond to the complaint according to KMS's Procedure for Handling Complaints/Inquiries Regarding KMS Accredited Providers ("the Procedure"). The length of time during which an accredited provider must be accountable for any complaints/inquiries received by KMS is limited to twelve months from the date of the activity, or in the case of a series, twelve months from the date of the activity which is in question. Information and correspondence generated via the Procedure is maintained as confidential.

Regularly Scheduled Series (RSS's)

KMS defines "regularly scheduled series", as weekly or monthly CME activities that are primarily planned by and presented to the provider's professional staff. Providers that furnish these types of activities must describe and verify that they have a system in place to monitor these activities' compliance with KMS Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies. The monitoring system must:

1. Be based on real performance data and information derived from the RSCs that describes compliance (in support of KMS Elements 2.1, 2.5 and 3.1 – 3.3), and
2. Result in improvements when called for by this compliance data (in support of KMS Elements 2.4, 2.5 and 3.1), and
3. Ensure that appropriate KMS Letters of Agreement are in place whenever funds are contributed in support of CME (in support of KMS Element 3.3).

Also, the provider is required to make available and accessible to the learners a system through which data and information on a learner's participation can be recorded and retrieved. The critical data and information elements include: learner identifier, name/topic of activity, date of activity, hours of credit designated or actually claimed. The KMS limits the provider's responsibility in this regard to "access, availability and retrieval." Learners are free to choose not to use this available and accessible system.

Compliance with AMA Ethical Guidelines

Continuing medical education providers accredited by the Kansas Medical Society are expected to operate their programs in compliance with AMA opinion 8.061 (Gifts to Physicians from Industry) and opinion 9.011 (Ethical Issues in CME). Enforcement of those guidelines is carried out by the American Medical Association, not the Kansas Medical Society (non-compliance can result in the AMA's action to withdraw a provider's ability to award Category 1 credit).

AMA Opinion 8.061 and Opinion 9.011 are attached.

E-8.061 Gifts to Physicians from Industry

Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines: (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members. (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads). (3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made. (4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference. (5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses. (6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional, or specialty medical associations. (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures. (II)

Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990 (JAMA. 1991; 265: 501); Updated June 1996 and June 1998.

Clarification of Opinion 8.061

Scope Opinion 8.061, "Gifts to Physicians from Industry," is intended to provide ethical guidance to physicians. Other parties involved in the health care sector, including the pharmaceutical, devices, and medical equipment industries and related entities or business partners, should view the guidelines as indicative of standards of conduct for the medical profession. Ultimately, it is the responsibility of individual physicians to minimize conflicts of interest that may be at odds with the best interest of patients and to access the necessary information to inform medical recommendations.

The guidelines apply to all forms of gifts, whether they are offered in person, through intermediaries, or through the Internet. Similarly, limitations on subsidies for educational activities should apply regardless of the setting in which, or the medium through which, the educational activity is offered.

General Questions (a) Do the guidelines apply only to pharmaceutical, device, and equipment manufacturers?

"Industry" includes all "proprietary health-related entities that might create a conflict of interest."

Guideline 1 Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or for use by family members.

(a) May physicians accept gram stain test kits, stethoscopes, or other diagnostic equipment?

Diagnostic equipment primarily benefits the patient. Hence, such gifts are permissible as long as they are not of substantial value. In considering the value of the gift, the relevant measure is not the cost to the company of providing the gift. Rather, the relevant measure is the cost to the physician if the physician purchased the gift on the open market.

(b) May companies invite physicians to a dinner with a speaker and donate \$100 to a charity or medical school on behalf of the physician?

There are positive aspects to the proposal. The donations would be used for a worthy cause, and the physicians would receive important information about patient care. There is a direct personal benefit to the physician as well, however. An organization that is important to the physician-and one that the physician might have ordinarily felt obligated to make a contribution to-receives financial support as a result of the physician's decision to attend the meeting. On balance, physicians should make their own judgment about these inducements. If the charity is predetermined without the physician's input, there would seem to be little problem with the arrangement.

(c) May contributions to a professional society's general fund be accepted from industry?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(d) When companies invite physicians to a dinner with a speaker, what are the relevant guidelines?

First, the dinner must be a modest meal. Second, the guideline does allow gifts that primarily benefit patients and that are not of substantial value. Accordingly, textbooks and other gifts that primarily benefit patient care and that have a value to the physician in the general range of \$100 are permissible. When educational meetings occur in conjunction with a social event such as a meal, the educational component must have independent value, such as a presentation by an authoritative speaker other than a sales representative of the company. Also, the meal should be a modest one similar to what a physician routinely might have when dining at his or her own expense. In an office or hospital encounter with a company representative, it is permissible to accept a meal of nominal value, such as a sandwich or snack.

(e) May physicians accept vouchers that reimburse them for uncompensated care they have provided?

No. Such a voucher would result directly in increased income for the physician.

(f) May physicians accumulate "points" by attending several educational or promotional meetings and then choose a gift from a catalogue of education options?

This guideline permits gifts only if they are not of substantial value. If accumulation of points would result in physicians receiving a substantial gift by combining insubstantial gifts over a relatively short period of time, it would be inappropriate.

(g) May physicians accept gift certificates for educational materials when attending promotional or educational events?

The Council views gift certificates as a grey area which is not per se prohibited by the guidelines. Medical textbooks are explicitly approved as gifts under the guidelines. A gift certificate for educational materials, ie, for the selection by the physician from an exclusively medical textbook catalogue, would not seem to be materially different. The issue is whether the gift certificate gives the recipient such control as to make the certificate similar to cash. As with charitable donations, preselection by the sponsor removes any question. It is up to the individual physician to make the final judgment.

(h) May physicians accept drug samples or other free pharmaceuticals for personal use or use by family members?

The Council's guidelines permit personal or family use of free pharmaceuticals (i) in emergencies and other cases where the immediate use of a drug is indicated, (ii) on a trial basis to assess tolerance, and (iii) for the treatment of acute conditions requiring short courses of inexpensive therapy, as permitted by Opinion 8.19, "Self-Treatment or Treatment of Immediate Family Members." It would not be acceptable for physicians to accept free pharmaceuticals for the long-term treatment of chronic conditions.

(i) May companies invite physicians to a dinner with a speaker and offer them a large number of gifts from which to choose one?

In general, the greater the freedom of choice given to the physician, the more the offer seems like cash. A large number of gifts presented to physicians who attend a dinner would therefore be inappropriate.

There is no precise way of deciding an appropriate upper limit on the amount of choice that is acceptable. However, it is important that a specific limit be chosen to ensure clarity in the guidelines. A limit of eight has been chosen because it permits flexibility but prevents undue freedom of choice. Each of the choices must have a value to the physicians of no more than \$100.

(j) May physicians charge for their time with industry representatives or otherwise receive material compensation for participation in a detail visit?

Guideline 1 states that gifts in the form of cash payments should not be accepted. Also, Guideline 6 makes clear that, in the context of the industry-physician relationship, only physicians who provide genuine services may receive reasonable compensation. When considering the time a physician spends with an industry representative, it is the representative who offers a service, namely the presentation of information. The physician is a beneficiary of the service. Overall, these guidelines do not view that physicians should be compensated for the time spent participating in educational activities, nor for time spent receiving detail information from an industry representative.

Guideline 2 Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads).

(a) May physicians, individually or through their practice group, accept electronic equipment, such as hand held devices or computers, intended to facilitate their ability to receive detail information electronically?

Although Guideline 2 recognizes that gifts related to a physician's practice may be appropriate, it also makes clear that these gifts must remain of minimal value. It is not appropriate for physicians to accept expensive hardware or software equipment even though one purpose only may pertain to industry-related activities of a modest value.

Guideline 3 The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

Guideline 4 Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's sales representative may create a relationship which could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(a) Are conference subsidies from the educational division of a company covered by the guidelines?

Yes. When the Council says "any subsidy," it would not matter whether the subsidy comes from the sales division, the educational division, or some other section of the company.

(b) May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?

Physicians should not directly accept checks or certificates which would be used to offset registration fees. The gift of a reduced registration should be made across the board and through the accredited sponsor.

Guideline 5 Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(a) If a company invites physicians to visit its facilities for a tour or to become educated about one of its products, may the company pay travel expenses and honoraria?

This question has come up in the context of a rehabilitation facility that wants physicians to know of its existence so that they may refer their patients to the facility. It has also come up in the context of surgical device or equipment manufacturers who want physicians to become familiar with their products.

In general, travel expenses should not be reimbursed, nor should honoraria be paid for the visiting physician's time since the presentations are analogous to a pharmaceutical company's educational or promotional meetings. The Council recognizes that medical devices, equipment, and other technologies may require, in some circumstances, special evaluation or training in proper usage which can not practicably be provided except on site. Medical specialties are in a better position to advise physicians regarding the appropriateness of reimbursement with regard to these trips. In cases where the company insists on such visits as a means of protection from liability for improper usage, physicians and their specialties should make the judgment. In no case would honoraria be appropriate and any travel expenses should be only those strictly necessary.

(b) If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects, or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?

If the physician is providing genuine services, reasonable compensation for time and travel expenses can be given. However, token advisory or consulting arrangements cannot be used to justify compensation.

(c) May a company hold a sweepstakes for physicians in which five entrants receive a trip to the Virgin Islands or airfare to the medical meeting of their choice?

No. The use of a sweepstakes or raffle to deliver a gift does not affect the permissibility of the gift. Since the sweepstakes is not open to the public, the guidelines apply in full force.

(d) If a company convenes a group of physicians to recruit clinical investigators or convenes a group of clinical investigators for a meeting to discuss their results, may the company pay for their

travel expenses?

Expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the National Institute of Health (NIH) conducts similar meetings when it sponsors multi-center clinical trials. When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for "reasonable" expenses. The reasonableness of expenses would depend on a number of considerations. For example, meetings are likely to be problematic if overseas locations are used for exclusively domestic investigators. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in this guideline.

(e) How can a physician tell whether there is a "genuine research purpose?"

A number of factors can be considered. Signs that a genuine research purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of physicians with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of physicians in light of the number of study participants needed for statistical evaluation.

(f) May a company compensate physicians for their time and travel expenses when they participate in focus groups?

Yes. As long as the focus groups serve a genuine and exclusive research purpose and are not used for promotional purposes, physicians may be compensated for time and travel expenses. The number of physicians used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the research purpose, but no larger.

(g) Do the restrictions on travel, lodging, and meals apply to educational programs run by medical schools, professional societies, or other accredited organizations which are funded by industry, or do they apply only to programs developed and run by industry?

The restrictions apply to all conferences or meetings which are funded by industry. The Council drew no distinction on the basis of the organizer of the conference or meeting. The Council felt that the gift of travel expenses is too substantial even when the conference is run by a non-industry sponsor. (Industry includes all "proprietary health-related entities that might create a conflict of interest.")

(h) May company funds be used for travel expenses and honoraria for bona fide faculty at educational meetings?

This guideline draws a distinction between attendees and faculty. As was stated, "[i]t is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses."

Companies need to be mindful of the guidelines of the Accreditation Council on Continuing Medical Education. According to those guidelines, "[f]unds from a commercial source should be in the form of an educational grant made payable to the CME sponsor for the support of programming."

(i) May travel expenses be reimbursed for physicians presenting a poster or a "free paper" at a scientific conference?

Reimbursement may be accepted only by bona fide faculty. The presentation of a poster or a free paper does not by itself qualify a person as a member of the conference faculty for purposes of

these guidelines.

(j) When a professional association schedules a long-range planning meeting, is it appropriate for industry to subsidize the travel expenses of the meeting participants?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

(k) May continuing medical education conferences be held in the Bahamas, Europe, or South America?

There are no restrictions on the location of conferences as long as the attendees are paying their own travel expenses.

(l) May travel expenses be accepted by physicians who are being trained as speakers or faculty for educational conferences and meetings?

In general, no. If a physician is presenting as an independent expert at a CME event, both the training and its reimbursement raise questions about independence. In addition, the training is a gift because the physician's role is generally more analogous to that of an attendee than a participant. Speaker training sessions can be distinguished from meetings (See 5d) with leading researchers, sponsored by a company, designed primarily for an exchange of information about important developments or treatments, including the sponsor's own research, for which reimbursement for travel may be appropriate.

(m) What kinds of social events during conferences and meetings may be subsidized by industry?

Social events should satisfy three criteria. First, the value of the event to the physician should be modest. Second, the event should facilitate discussion among attendees and/or discussion between attendees and faculty. Third, the educational part of the conference should account for a substantial majority of the total time accounted for by the educational activities and social events together. Events that would be viewed (as in the succeeding question) as lavish or expensive should be avoided. But modest social activities that are not elaborate or unusual are permissible, eg, inexpensive boat rides, barbecues, entertainment that draws on the local performers. In general, any such events which are a part of the conference program should be open to all registrants.

(n) May a company rent an expensive entertainment complex for an evening during a medical conference and invite the physicians attending the conference?

No. The guidelines permit only modest hospitality.

(o) If physicians attending a conference engage in interactive exchange, may their travel expenses be paid by industry?

No. Mere interactive exchange would not constitute genuine consulting services.

(p) If a company schedules a conference and provides meals for the attendees that fall within the guidelines, may the company also pay for the costs of the meals for spouses?

If a meal falls within the guidelines, then the physician's spouse may be included.

(q) May companies donate funds to sponsor a professional society's charity golf tournament?

Yes. But it is sensible if physicians who play in the tournament make some contribution themselves to the event.

(r) If a company invites a group of consultants to a meeting and a consultant brings a spouse, may the company pay the costs of lodging or meals of the spouse? Does it matter if the meal is part of the program for the consultants?

Since the costs of having a spouse share a hotel room or join a modest meal are nominal, it is permissible for the company to subsidize those costs. However, if the total subsidies become substantial, then they become unacceptable.

Guideline 6 Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

(a) When a company subsidizes the travel expenses of residents to an appropriately selected conference, may the residents receive the subsidy directly from the company?

Funds for scholarships or other special funds should be given to the academic departments or the accredited sponsor of the conference. The disbursement of funds can then be made by the departments or the conference sponsor.

(b) What is meant by "carefully selected educational conferences?"

The intent of Guideline 6 is to ensure that financial hardship does not prevent students, residents, and fellows from attending major educational conferences. For example, we did not want to deny cardiology fellows the opportunity to attend the annual scientific meeting of the American College of Cardiology or orthopedic surgery residents the opportunity to attend the annual scientific meeting of the American Academy of Orthopedic Surgeons. However, it was not the intent of the guideline to permit reimbursement of travel expenses in other circumstances, such as when conferences or symposia are designed specifically for students, residents, or fellows.

Funds are limited to travel and lodging expenses for attendance at major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

Guideline 7 No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

(a) May companies send their top prescribers, purchasers, or referrers on cruises?

No. There can be no link between prescribing or referring patterns and gifts. In addition, travel

expenses, including cruises, are not permissible.

(b) May the funding company itself develop the complete educational program that is sponsored by an accredited continuing medical education sponsor?

No. The funding company may finance the development of the program through its grant to the sponsor, but the accredited sponsor must have responsibility and control over the content and faculty of conferences, meetings, or lectures. Neither the funding company nor an independent consulting firm should develop the complete educational program for approval by the accredited sponsor.

(c) How much input may a funding company have in the development of a conference, meeting, or lectures?

The guidelines of the Accreditation Council on Continuing Medical Education on commercial support of continuing medical education address this question.

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E-9.011 Continuing Medical Education

Physicians should strive to further their medical education throughout their careers, for only by participating in continuing medical education (CME) can they continue to serve patients to the best of their abilities and live up to professional standards of excellence. Fulfillment of mandatory state CME requirements does not necessarily fulfill the physician's ethical obligation to maintain his or her medical expertise.

Attendees. Guidelines for physicians attending a CME conference or activity are as follows: (1) The physician choosing among CME activities should assess their educational value and select only those activities which are of high quality and appropriate for the physician's educational needs. When selecting formal CME activities, the physician should, at a minimum, choose only those activities that (a) are offered by sponsors accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), or a state medical society; (b) contain information on subjects relevant to the physician's needs; (c) are responsibly conducted by qualified faculty; (d) conform to Opinion 8.061, "Gifts to Physicians from Industry." (2) The educational value of the CME conference or activity must be the primary consideration in the physician's decision to attend or participate. Though amenities unrelated to the educational purpose of the activity may play a role in the physician's decision to participate, this role should be secondary to the educational content of the conference. (3) Physicians should claim credit commensurate with only the actual time spent attending a CME activity or in studying a CME enduring material. (4) Attending promotional activities put on by industry or their designees is not unethical as long as the conference conforms to Opinion 8.061, "Gifts to Physicians from Industry," and is clearly identified as promotional to all participants.

Faculty. Guidelines for physicians serving as presenters, moderators, or other faculty at a CME conference are as follows: (1) Physicians serving as presenters, moderators, or other faculty at a CME conference should ensure that (a) research findings and therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a balanced, objective manner; (b) the content of their presentation is not modified or influenced by representatives of industry or other financial contributors, and they do not employ materials whose content is shaped by industry. Faculty may, however, use scientific data generated from industry-sponsored research, and they may also accept technical assistance from industry in preparing slides or other presentation materials, as long as this assistance is of only nominal monetary value and the company has no input in the actual content of the material. (2) When invited to present at non-CME activities that are primarily promotional, faculty should avoid participation unless the activity is clearly identified as promotional in its program announcements and other advertising. (3) All conflicts of interest or biases, such as a financial connection to a particular commercial firm or product, should be disclosed by faculty members to the activity's sponsor and to the audience. Faculty may accept reasonable honoraria and reimbursement for expenses in accordance with Opinion 8.061, "Gifts to Physicians from Industry."

Sponsors. Guidelines for physicians involved in the sponsorship of CME activities are as follows: (1) Physicians involved in the sponsorship of CME activities should ensure that (a) the program is balanced, with faculty members presenting a broad range of scientifically supportable viewpoints related to the topic at hand; (b) representatives of industry or other financial contributors do not exert control over the choice of moderators, presenters, or other faculty, or modify the content of faculty presentations. Funding from industry or others may be accepted in accordance with Opinion 8.061, "Gifts to Physicians from Industry." (2) Sponsors should not promote CME activities in a way that encourages attendees to violate the guidelines of the Council on Ethical and Judicial Affairs, including Opinion 8.061, "Gifts to Physicians from Industry," or the principles established for the AMA's Physician Recognition Award. CME activities should be developed and

promoted consistent with guideline 2 for Attendees. (3) Any non-CME activity that is primarily promotional must be identified as such to faculty and participants, both in its advertising and at the conference itself. (4) The entity presenting the program should not profit unfairly or charge a fee which is excessive for the content and length of the program. (5) The program, content, duration, and ancillary activities should be consistent with the ideals of the AMA CME program. (I, V) Issued December 1993; Updated June 1996.