

The Accreditation Council for Continuing Medical Education (ACCME) Accreditation Criteria & Policies Adopted by the Massachusetts Medical Society

Updated November 2018

NOTE FOR THE NOVEMER 2018 EDITION

The Massachusetts Medical Society has adopted the ACCME's New Menu of Criteria for Accreditation with Commendation. All reaccreditation materials distributed as of November 2018 will reflect the new commendation criteria menu (C23-C38) as these reaccreditation decisions will be made after November 2019.

NOTE FOR THE JANUARY 2017 EDITION

The Massachusetts Medical Society is recognized by the Accreditation Council for Continuing Medical Education (ACCME) as an accreditor of intra-state organizations in Massachusetts. As such, the Massachusetts Medical Society adopts the Menu of New Criteria for Accreditation with Commendation. This updated document reflects the option of accredited providers to demonstrate compliance with all of the current commendation criteria (C16-22) *or* the new commendation criteria menu (C23-C38). This phase will apply to providers that will receive accreditation decisions through November 2019.

NOTE FROM THE FEBRUARY AND APRIL 2014 EDITION

Massachusetts Medical Society adopted the simplification changes and other modifications adopted by the ACCME in February and April 2014. This updated document reflects the simplification changes which include the simplification and elimination of some of the requirements and modifications to Standards for Commercial Support [™]: Standards to Ensure Independence in CME Activities (SCS) 4.3, SCS 6.4, and the Commercial Support Acknowledgment Policy

The changes include:

- Simplifying and removing some of the Accreditation Criteria and policy requirements
- Changing terminology from "joint sponsorship" to "joint providership"
- Offering providers an abstract as an MMS/ACCME-approved tool to use when verifying performance-in-practice
- Simplifying the process for organizations applying for initial accreditation

In addition to the accreditation requirements, this document includes several operational policies for your convenience. There are **no new requirements**.

Changes to the Accreditation Criteria

Criterion 1 has been simplified. Criteria 4, 14, and 15 have been **eliminated**. The criteria that have been eliminated are noted in red. To avoid confusion, **the numbering of the criteria has not changed. (2014)**

Standards for Commercial Support (2014)

Standard 4.2 incorporates the requirements related to Internet CME and journal-based CME that previously were included in the policies.

Terminology

The term "joint sponsorship" has been replaced with "joint providership" throughout the requirements, including in the Standards for Commercial Support and in the Accreditation Statement Policy. The term "Essentials" in the accreditation statement has been replaced with the term "accreditation requirements."

CME Activity Types (2014)

The CME Activity Types section in the policies has been **eliminated**. Some of the special requirements for Internet CME, enduring materials, regularly scheduled series, and journal-based CME, were **eliminated** as part of the simplification process. The remaining requirements related to the Standards for Commercial Support and therefore have been incorporated into the Standards, as described above. Previously, these policies also included descriptions of these activity types. These are not requirements-but rather, descriptions, used by accredited providers for annual reporting and have been moved to the Glossary of Terms document.

Menu of New Criteria for Accreditation with Commendation (2017)

The ACCME adopted a menu approach achieving Accreditation with Commendation to create flexibility, reflect the diversity of the CME community, and offer a pathway for all CME provider types to achieve Accreditation with Commendation.

There are 16 commendation criteria, divided into five categories:

- Promotes Team-based Education
- Addresses Public Health Priorities
- Enhances Skills
- Demonstrates Educational Leadership
- Achieves Outcomes

To be eligible for Accreditation with Commendation, providers will need to demonstrate compliance with any seven criteria of their choice, from any category—plus one criterion from the Achieves Outcomes category—for a total of eight criteria.

This will apply to providers that will receive accreditation decisions after November 2019.

The Accreditation Criteria

The Accreditation Criteria are divided into three levels as follows:

- **Provisional Accreditation:** a **two- year** term that requires providers to comply with Criteria 1, 2, 3, and 7–12.

- **Accreditation or reaccreditation:** a **four-year** term that requires provides to comply with Criteria 1–13.

- **Accreditation with Commendation:** a **six-year** term that requires providers to demonstrate compliance with Criteria (1–13) **and** a total of eight criteria (including one from the Achieves Outcomes category) using the ACCME's Menu of Criteria for Accreditation with Commendation.

Commendation Criteria (C16-C22) will be eliminated effective November 2019.

Criterion 1 The provider has a CME mission statement that includes expected results articulated in terms of changes in competence, performance, or patient outcomes that will be the result of the program.

Criterion 2 The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.

Criterion 3 The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.

Criterion 4 This criterion has been eliminated effective February 2014.

Criterion 5 The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives, and desired results of the activity.

Criterion 6 The provider develops activities/educational interventions in the context of desirable physician attributes [e.g., Institute of Medicine (IOM) competencies, Accreditation Council for Graduate Medical Education (ACGME) Competencies].

Criterion 7 The provider develops activities/educational interventions independent of commercial interests (SCS 1, 2, and 6).

Criterion 8 The provider appropriately manages commercial support (if applicable, SCS 3 of the ACCME Standards for Commercial SupportSM).

Criterion 9 The provider maintains a separation of promotion from education (SCS 4).

Criterion 10 The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).

Criterion 11 The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions.

Criterion 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.

Criterion 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.

Criterion 14 This criterion has been eliminated effective February 2014.

Criterion 15 This criterion has been eliminated effective February 2014.

MENU OF NEW CRITERIA FOR COMMENDATION (Select 8 from Criteria 23-38)

Criterion 23 Members of interprofessional teams are engaged in the planning and delivery of interprofessional continuing education (IPCE).

Criterion 24 Patient/public representatives are engaged in the planning and delivery of CME.

Criterion 25 Students of the health professions are engaged in the planning and delivery of CME.

Criterion 26 The provider advances the use of health and practice data for healthcare improvement.

Criterion 27 The provider addresses factors beyond clinical care that affect the health of populations.

Criterion 28 The provider collaborates with other organizations to more effectively address population health issues.

Criterion 29 The provider designs CME to optimize communication skills of learners.

Criterion 30 The provider designs CME to optimize technical and procedural skills of learners.

Criterion 31 The provider creates individualized learning plans for learners.

Criterion 32 The provider utilizes support strategies to enhance change as an adjunct to its CME.

Criterion 33 The provider engages in CME research and scholarship.

Criterion 34 The provider supports the continuous professional development of its CME team.

Criterion 35 The provider demonstrates creativity and innovation in the evolution of its CME program.

Criterion 36 The provider demonstrates improvement in the performance of learners.

Criterion 37 The provider demonstrates healthcare quality improvement.

Criterion 38 The provider demonstrates the impact of the CME program on patients or their communities.

Standards for Commercial Support:

Standards to Ensure Independence in CME Activities

Standard 1: Independence

<u>Standard 1.1</u>: A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See the Policies Supplementing the Standards for Commercial Sup- port for a definition of a "commercial interest" and some exemptions.) (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.

<u>Standard 1.2</u>: A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.

Standard 2: Resolution of Personal Conflicts of Interest

<u>Standard 2.1</u>: 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 ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

<u>Standard 2.2</u>: 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.

<u>Standard 2.3</u>: 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

<u>Standard 3.1</u>: The provider must make all decisions regarding the disposition and disbursement of commercial support.

<u>Standard3.2</u>: 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.

<u>Standard 3.3</u>: All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

<u>Standard 3.4</u>: 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 provider.

<u>Standard 3.5</u>: The written agreement must specify the commercial interest that is the source of commercial support.

<u>Standard 3.6</u>: Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

<u>Standard3.7</u>: The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

<u>Standard 3.8</u>: The provider, the joint provider, 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.

<u>Standard 3.9</u>: No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint provider, or any others involved with the supported activity.

<u>Standard 3.10</u>: 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.

<u>Standard 3.11</u>: Social events or meals at CME activities cannot compete with or take precedence over the educational events.

<u>Standard 3.12</u>: 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 provider or educational partner.

Standard 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

<u>Standard 4.1</u>: 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.

<u>Standard 4.2</u>: 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 interleafed 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 CME activities, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content. Also, MMS-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational Web site, links from the Web site of an MMS-accredited provider to pharmaceutical and device manufacturers' product Web sites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.

For 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.

For Journal-based CME, none of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

<u>Standard 4.3</u>: Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest*.

<u>Standard4.4</u>: 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.

<u>Standard 4.5</u>: 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

<u>Standard 5.1</u>: 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.

<u>Standard 5.2</u>: 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

<u>Standard 6.1</u>: 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.

<u>Standard 6.2</u>: For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

<u>Standard 6.3</u>: 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.

<u>Standard 6.4</u>: Disclosure must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

<u>Standard 6.5</u>: A provider must disclose the above information to learners prior to the beginning of the educational activity.

* An ACCME-defined **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

Procedural Guidelines

The MMS issues procedural guidelines that supplement the ACCME's Criteria and Standards for Commercial Support. Accredited providers must adhere to the MMS procedural guidelines that are relevant to their organizations, as well as to the Accreditation Criteria and the ACCME Standards for Commercial Support.

ACCREDITATION STATEMENT

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 such as the date, location, and title. If more specific information is included, such as faculty and objectives, the accreditation statement must be included.

The MMS accreditation statement is as follows:

For Directly Provided Activities: "The (name of accredited provider) is accredited by the Massachusetts Medical Society to provide continuing medical education for physicians."

For Jointly Provided Activities: "This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Massachusetts Medical Society through the joint providership of (name of accredited provider) and (name of non-accredited provider). The (name of accredited provider) is accredited by the Massachusetts Medical Society to provide continuing medical education for physicians."

There is no "co-providership" 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-provided CME activities should use the directly provided activity statement, naming the one accredited provider that is responsible for the activity. The MMS has no policy regarding specific ways in which providers may acknowledge the involvement of other accredited providers in their CME activities.

CME CONTENT: DEFINITION AND EXAMPLES

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.

CME Clinical Content Validation

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

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 MMS 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 MMS accreditation.

Content Validity of Enduring Materials

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 offered as an accredited activity 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.

CME CONTENT AND THE AMERICAN MEDICAL ASSOCIATION PHYSICIANS' RECOGNITION AWARD

All CME educational activities developed and presented by a provider accredited by the MMS system and associated with *AMA PRA Category 1 Credit*[™] must be developed and presented in compliance with all MMS accreditation requirements - in addition to all the requirements of the AMA PRA program. All activities so designated for, or awarded, credit will be subject to review by the MMS accreditation process as verification of fulfillment of the MMS accreditation requirements. The following statements must be included on all promotional materials advertising *AMA PRA Category 1 Credit*[™] CME activities:

REQUIRED - Accreditation Statement for Directly Provided Activities:

The [name of accredited CME provider] is accredited by the Massachusetts Medical Society to provide continuing medical education for physicians.

OR

REQUIRED - Accreditation Statement for Jointly Provided Activities:

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Massachusetts Medical Society through the joint providership of (name of accredited provider) and (name of non-accredited provider). The (name of accredited provider) is accredited by the Massachusetts Medical Society to provide continuing medical education for physicians."

AND

REQUIRED – AMA Credit Designation Statement:

The [name of accredited CME provider] designates this [learning format]* for a maximum of [number of credits] *AMA PRA Category 1 Credit (s)* \mathbb{M} . Physicians should claim only credit commensurate with the extent of their participation in the activity.

AND, WHEN APPROPRIATE - For Risk Management Study:

This activity meets the criteria of the Massachusetts Board of Registration in Medicine for risk

management study. OR (number of credits) credit(s) meet the criteria of the Massachusetts Board of Registration in Medicine for risk management study.

The **learning format** listed in the **Credit Designation Statement** must be one of the following AMA approved learning formats:

- 1. Live activity
- 2. Enduring material
- 3. Journal-based CME activity
- 4. Test-item writing activity
- 5. Manuscript review activity
- 6. PI CME activity
- 7. Internet point-of-care activity
- 8. Other

Use of phrase "AMA PRA Category 1 Credit™"

"AMA PRA Category 1 CreditTM" is a trademark of the American Medical Association. Accredited CME providers are required to use "AMA PRA Category 1 Credit TM" whenever the complete phrase is first used in any publication, and periodically through the publication. The AMA PRA reference must be in italics and must include the trademark symbol.

This standard language benefits both providers and physicians by clearly communicating the provider's privilege to award *AMA PRA Category 1 Credit*^M on behalf of the AMA.

Providers may never publish or announce that "AMA PRA credit has been applied for."

RECORDS RETENTION

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

Physician Participation: An accredited provider must have mechanisms in place to record and, when authorized by the participating physician, verify participation for <u>six years</u> 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 MMS does not require sign-in sheets.

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 reaccreditation; show MMS how the activities it provided during its current term of accreditation were compliant with all MMS accreditation requirements including the ACCME Standards for Commercial Support SM.

ANNUAL YEAR-END REPORTING

MMS accredited providers are required to provide the ACCME with data about their CME activities and overall CME program using ACCME's Program and Activity Reporting System (PARS) in order to maintain their accreditation status. The purpose of the Annual Report is to confirm contact information for the accredited provider, and to compile an aggregate of the size and scope of the CME enterprise in the United States, e.g., the number and type of activities planned and executed, the number of hours offered, the number of physician learners taught, the amount of commercial support received, and the total income and expense of the enterprise. Accumulated data received from all ACCME and state medical society accredited providers is published annually at www.accme.org as a service to accredited providers, other members of the CME community, and the public.

Providers who fail to complete the report by the published due date are subject to a change of their accreditation status to probation and a reporting late fee. Notification that the Annual Report has not been submitted by the published due date may be sent to the accredited provider's President and/or Chief Executive Officer. Providers that do not complete the report by the deadline may be subject to a decision of non- accreditation.

PAYMENT OF FEES

MMS accredited providers are accountable for timely submission of fees that are required either to attain or maintain accreditation. MMS' Accreditation Fee Schedule lists current fees, and is posted at http://www.massmed.org/Continuing-Education-and-Events/CME-Accreditation-for-Institutions/Accreditation-Fees-for-MMS-State-Accredited-Providers/

JOINT PROVIDERSHIP

The MMS defines joint providership as the providership of a CME activity by one accredited and one non-accredited organization. <u>Therefore, MMS accredited providers that plan and present one or more activities with non- accredited providers are engaging in "joint providership."</u>

The accredited provider must take responsibility for a CME activity when it is presented in cooperation with a non-accredited organization and must use the appropriate accreditation statement.

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

Informing the Learner

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

"This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Massachusetts Medical Society through the joint providership of (name of accredited provider) and (name of non-accredited provider). The (name of accredited provider) is accredited by the Massachusetts Medical Society to provide continuing medical education for physicians."

COMPLIANCE AND NONCOMPLIANCE ISSUES

The MMS expects <u>all</u> CME activities to be in compliance with the accreditation requirements. In cases of joint providership, it is the MMS- accredited provider's responsibility to be able to demonstrate through written documentation this compliance to the MMS. Materials submitted that demonstrate compliance may be from either the MMS- accredited provider's files or those of the non-accredited provider.

Providers on Probation

If a provider is placed on Probation, it may not jointly provide 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 MMS of all existing joint providership relationships and must notify its current contracted joint providers of its probationary status.

Policies Supplementing the Standards for Commercial Support

The MMS adopted the ACCME Standards for Commercial Support [™] in May 2005.

Definition of a Commercial Interest as Per the ACCME

A **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

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

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

- 501c non-profit organizations (Note: ACCME screens 501c organizations for eligibility. Those that advocate for 'commercial interests' as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint provider, but they can be a commercial supporter.)
- 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
- o Blood banks
- Diagnostic laboratories

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

FINANCIAL RELATIONSHIPS AND CONFLICTS OF INTEREST

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers' bureau, 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. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

The ACCME has not set a minimum dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

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

Disclosure of the Financial Relationships to the Accredited Provider

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

Commercial Support: Definition and Guidance Regarding Written Agreements

Commercial Support is financial, or in-kind, contributions given by a commercial interest (see Policies relevant to SCS1), which is used to pay all or part of the costs of a CME activity.

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

A provider will be found in Noncompliance with SCS 1.1 and SCS 3.2 if the provider enters into a commercial support agreement where the commercial supporter specifies the manner in which the provider will fulfill the requirements of the ACCME's Accreditation Criteria and Standards for Commercial Support.

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

Verbal Disclosure to Learners

Disclosure of information about relevant financial 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 the MMS 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 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.

Commercial Support: Acknowledgements

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 an ACCME-defined commercial interest but may not include corporate logos and slogans.

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.

MONITORING CONTINUOUS COMPLIANCE

MMS Monitoring

Because of MMS' responsibility to the CME community and to the public for ensuring that providers meet MMS standards for quality continuing medical education, MMS may on occasion require providers to submit evidence of continuous compliance with the Accreditation Requirements prior to the normally scheduled review for reaccreditation. MMS would most likely request such evidence if information were brought to MMS' attention, either through a complaint or inquiry, or via other means, that questioned the accredited provider's ongoing compliance with the Accreditation Requirements.

If, through either the complaint/inquiry process or the re-accreditation process, MMS finds a provider's jointly-provided activities to be non-compliant with content validation requirements or the requirements for disclosure and commercial support, MMS may begin a formal process to

continuously monitor the provider's ongoing compliance with the relevant accreditation requirements. This process could include verification of compliance through one or more Monitoring Progress Reports.

Additionally, when a non-accredited organization is associated with more than one MMS monitoring decision of Non-Compliance related to either content validity or disclosure and commercial support, MMS will notify its accredited providers of the name of the non-accredited organization. Accredited providers that enter into a joint providership relationship or have jointly-provided activities with the non-accredited organization will be required to demonstrate compliance of those activities via a Monitoring Progress Report.

Self-Monitoring

Most MMS accredited providers are evaluated for re-accreditation every four or six years. Once you have achieved accreditation, MMS expects that during your accreditation term, your organization will take an active role in ensuring that it is continuously meeting the expectations of MMS in its purview of CME.

Following are specific actions that you can do to assist your organization in keeping informed about the Accreditation Requirements:

- Ensure your email address is current with MMS to receive notifications on changes in continuing medical education (CME) or important accreditation requirements.
- Access the MMS accreditation webpage for most recent accreditation information: <u>http://www.massmed.org/Continuing-Education-and-Events/CME-Accreditation-for-Institutions/CME-Accreditation-for-Institutions/</u>
- Periodically review MMS' educational opportunities to help increase your organization's understanding of the MMS accreditation process and its Requirements.
- Contact the MMS with any questions you may have about your organization's compliance with the Accreditation Requirements.

ORGANIZATIONAL OR PERSONNEL CHANGES

Contact Information

To keep providers aware of important policy updates as well as information specific to their individual accreditation, MMS requires accredited providers to promptly inform MMS of any personnel or organizational changes. These types of changes include changes of address or phone number or email address, and changes to the individual to whom providers would like MMS to send correspondence ("primary contact").

Changes may be submitted to Nancy Marotta via email at <u>nmarotta@mms.org</u>.

Corporate Change

If an MMS accredited provider undergoes a corporate change, (i.e., from a merger or acquisition), the MMS must be notified of the change as soon as possible.

Note: MMS accreditation is awarded to organizations that demonstrate compliance with Accreditation Requirements. For this reason, an organization cannot become an accredited provider by purchasing or merging with an organization that is already accredited. Transference of accreditation is not permitted without prior MMS approval.

Similarly, if an accredited provider undergoes **significant** organizational change, for example, becoming partially owned by a commercial interest or losing its 501(c) IRS tax status, the MMS considers the provider to be significantly different than the organization which was accredited. Therefore, the MMS will expect the provider to cease offering *AMA PRA Category 1 Credit*^M as an MMS accredited provider. The MMS will set a date of non-accreditation for these providers.

The MMS will withdraw a provider's accreditation if the provider is dissolved, or ceases to exist, as a result of a merger, acquisition or dissolution.

When two or more MMS accredited providers merge, the MMS will consider that all but one of the accredited providers will cease to exist as an entity. The name of the remaining provider may be changed to reflect or include the name(s) of the former provider(s). The remaining provider must assume responsibility for unfinished CME activities and/or unexpired enduring materials of the provider(s) with which it merged and must maintain activity registration records for six years for the provider(s) with which it merged.

New providers created through corporate change must submit a Pre-application and/or Self-Study Report, per the direction of MMS as a first step towards initial MMS accreditation.

Additionally, if MMS receives a complaint about an accredited provider, and the complaint relates to the provider's implementation of one or more Accreditation Requirements, MMS may ask the provider to respond to the complaint according to MMS' Procedure for Handling Complaints/Inquiries. The length of time during which an accredited provider must be accountable for any complaints/inquiries received by the MMS is limited to twelve months from the date of the activity, or in the case of a Regularly Scheduled Series (RSS), twelve months from the date of the activity which is in question.