



**UTAH MEDICAL ASSOCIATION'S  
SYSTEM FOR  
ACCREDITATION OF  
INTRASTATE PROVIDERS  
OF CONTINUING  
MEDICAL EDUCATION**

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Dear Colleague:

Congratulations on your interest in becoming an accredited provider of continuing medical education. The Utah Medical Association believes that the professional responsibility of physicians includes continuous learning throughout their careers and that this learning should result in improvements in physician performance and patient outcomes.

The Utah Medical Association is recognized by the Accreditation Council for Continuing Medical Education (ACCME) as the accrediting body for hospitals, specialty societies, and other medical organizations in the state of Utah that offer programs of continuing medical education. This accrediting function is carried out by the Utah Medical Association's Accreditation Committee.

Accreditation speaks to the quality of an institution's overall CME program, based on its adherence to the UMA's *Essential Areas and Their Elements, Decision-Making Criteria, Standards for Commercial Support, and Accreditation Policies*, referred to as the Accreditation Requirements. The UMA has adopted these Accreditation Requirements as the practices that a provider must implement for accreditation. The Accreditation Committee utilizes referenced based criteria for making its accreditation decisions. These criteria are outlined in the *Updated Decision-Making Criteria* document that follows the *Essential Areas and Their Elements* and thus provide the criteria that the UMA uses in evaluating a program of continuing medical education. A copy of the *Essential Areas and Their Elements* and *Standards of Commercial Support*, along with the *Updated Accreditation Criteria*, are included in Part II of this manual.

The process of seeking and maintaining accreditation may seem complex at first glance. Our intent in developing this manual is to simplify this process by explaining the basic requirements of becoming an accredited provider and by describing how the UMA conducts its program of accreditation. It is our goal that this information will assist CME providers in establishing and maintaining a strong, effective continuing medical education program which meets the requirements set forth in the Accreditation Requirements.

Our Committee encourages inquiries about continuing medical education and the accreditation process. We welcome the opportunity to help you build and maintain a strong CME program, and we commend you for your interest in accreditation.

ACCREDITATION COMMITTEE  
Utah Medical Association

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## PART I

### INTRODUCTION

The Accreditation Council for Continuing Medical Education (ACCME) was formed to assume responsibility for developing and promoting the quality of continuing medical education (CME) in the United States. Its purpose is to identify, develop, and promote standards for quality continuing medical education; to relate continuing medical education to medical care and the continuum of medical education; and to apply these principles, policies, and standards in the accreditation of institutions and organizations offering continuing medical education.

The ACCME includes seven member organizations - American Board of Medical Specialties, American Hospital Association, American Medical Association, Association for Hospital Medical Education, Association of American Medical Colleges, Council of Medical Specialty Societies, and Federation of State Medical Boards.

The ACCME has identified its primary functions as

- Serving as the body accrediting institutions and organizations offering continuing medical education;
- Serving as the body recognizing institutions and organizations offering continuing medical education accreditation;
- Developing criteria for evaluation of both educational programs and their activities by which ACCME and state accrediting bodies will accredit institutions and organizations and be responsible for assuring compliance with these standards;
- Developing or fostering the development of, methods for measuring the effectiveness of continuing medical education and its accreditation;
- Recommending and initiating studies for improving the organization and processes of continuing medical education and its accreditation;
- Reviewing and assessing developments in continuing medical education's support of quality health;
- Reviewing its role in continuing medical education to ensure it remains responsive to public and professional needs.

The ACCME recognizes the Utah Medical Association (UMA) as the accreditor of intrastate providers of continuing medical education in Utah. In this role, the UMA actively supports the development and accreditation of quality CME programs in the state. As the recognized accrediting body for the state of Utah, the Utah Medical Association has developed a process, based on that of the ACCME, by which Utah organizations may become accredited providers. This accreditation affords CME providers the ability to designate activities for *AMA-PRA Category 1 Credit™*.

## **A. UMA MISSION AS AN INTRASTATE ACCREDITOR**

As an ACCME recognized state accrediting organization, the Utah Medical Association has charged the Accreditation Committee with administering the accreditation program for intrastate providers of continuing medical education. Its mission is to identify and accredit Utah organizations whose overall CME program meets the accreditation standards of the Utah Medical Association; assist organizations in developing high quality CME programs; and increase physician access to quality practice-based CME in local communities. Accreditation is official recognition by the ACCME or a recognized state accrediting body that an organization's overall program of continuing medical education for physicians substantially complies with accepted standards for planning, implementing, and evaluating CME activities.

The Utah Medical Association recognizes that physicians' professional responsibilities entail a commitment to lifelong learning. By supporting the development and accreditation of quality CME programs in the state, the UMA assures physicians that CME presented by an accredited provider meets accepted standards of education. This uniformity in accreditation enables physicians to use the credit earned by participating in a CME activity sponsored by an accredited provider for relicensure as well as for membership in local, state and/or national medical societies. Finally, uniformity in accreditation enhances credibility with state legislatures, CME providers, and the public.

## **B. WHY BECOME ACCREDITED?**

The purpose of the accreditation process is to enhance the quality of physician CME by establishing and maintaining educational standards for the development and implementation of formally structured CME programs. This process measures the ability of an organization to plan effective CME activities and to maintain an overall CME program in accordance with these standards. Accreditation of an organization is an indication that its CME program meets generally accepted standards of quality. It provides assurance to physicians and the public that the organization has satisfactorily met defined national standards of quality in planning and presenting CME.

The American Medical Association (AMA) extends the privilege of designating AMA PRA *Category 1 Credit*<sup>™</sup> to accredited providers of CME. Category 1 credit may be used to satisfy requirements for the AMA Physician's Recognition Award and state licensure, hospital or specialty society requirements for CME.

## **C. WHO SHOULD CONSIDER ACCREDITATION?**

Institutions and organizations located in the state of Utah who offer a program of CME for physicians on a regular and recurring basis, developed in accordance with all UMA Accreditation Requirements will be considered eligible to apply for accreditation. An organization is not eligible to apply for accreditation if, in the judgment of the UMA, its program is devoted to the advocacy of unscientific modalities of diagnosis or therapy. The UMA reserves the right to make decisions on eligibility for accreditation.

## Eligibility Criteria

An organization must

- Offer a program of continuing medical education primarily targeted to physicians licensed and practicing medicine in Utah and its immediately bordering states;
- Be located within the state of Utah;
- Not be a commercial interest
- Present activities that have valid content
- Demonstrate an overall organizational commitment to the continuing medical education program, including physician support, budget support, staffing, and record-keeping resources;
- Demonstrate the capacity to substantially comply with all UMA Accreditation Requirements;
- Offer a program of CME for physicians on a regular and recurring basis.

## Track Record

It is impossible for an organization to demonstrate compliance with the Accreditation Requirements if it has not produced CME activities prior to preparing the application for accreditation. While it is not mandatory that these activities be granted credit, they must demonstrate compliance with the *Essential Areas and Elements* as well as the *Standards for Commercial Support* and be planned and implemented in accordance with procedures that will be followed by the organization as an accredited provider.

There is no minimum annual number of CME activities required for accreditation. However, an organization that presents only one or two CME activities on an occasional basis may wish to seek joint sponsorship with an accredited provider.

## Eligible Organizations

The UMA, through its Committee on CME Accreditation, will consider accreditation for a number of different organizations, including the following:

- hospitals and hospital systems
- county medical societies
- state or local medical specialty societies
- voluntary health agencies
- health care delivery systems
- insurance companies/managed care organizations
- government or military
- other eligible institutions and organizations whose programs of CME serve physician learners.

The Accreditation Committee will not consider applications for accreditation submitted by persons or organizations outside the state of Utah. Medical schools, national physician membership organizations, national medical specialty societies, and organizations whose programs of CME are directed to a national audience should apply to the ACCME for accreditation. See UMA's Accreditation Policies for more information.

## **D. AUTHORITY AND RESPONSIBILITY IN DESIGNATING CREDIT**

Only organizations accredited as CME providers by the ACCME or a recognized state medical society such as the Utah Medical Association may designate a CME activity for AMA PRA credit. Accredited entities are responsible for understanding AMA PRA credit requirements and have the authority to determine which of their activities meet these requirements.

## **E. THE AMA PHYSICIAN'S RECOGNITION AWARD**

In 1968, the AMA House of Delegates established the Physician's Recognition Award (PRA) to encourage physicians' participation in continuing medical education and to recognize physicians who have voluntarily completed individual programs for CME. As of January 1993, physicians now have two choices for PRA certification: a standard certificate (provided largely according to the requirement in effect prior to 1990) and a new PRA certificate "with Special Commendation for Self Directed Learning."

The AMA PRA is a voluntary recognition program, although many licensing or certifying boards and specialty societies accept receipt of the PRA as fulfillment of their CME requirements.

PRA requirements and materials are revised periodically. For complete guidelines for the AMA PRA, please contact the American Medical Association, 515 North State Street, Chicago, IL 60610, (312) 464-4664. You may download a copy of the *The Physician's Recognition Award Information Booklet* by going to <http://www.ama-assn.org>.

## **F. DEFINITION OF CONTINUING MEDICAL EDUCATION**

The following definition of continuing medical education was adopted by the American Medical Association House of Delegates in July 1982:

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 to 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.

This broad definition of CME recognizes that all continuing educational activities that 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 for practitioners interested in providing better service to patients.

Not all continuing educational activities that physicians may engage in, however, are CME. Physicians may participate in worthwhile continuing educational activities not related directly to their professional work, and these activities are not CME. Continuing educational activities in response to

a physician's non-professional educational need or interest, such as personal financial planning and appreciation of literature or music, are not CME.

#### **G. ASSIGNING CME CREDIT**

Credit for the AMA PRA is determined by the actual contact time involved in the educational activity. Time allotted for registration, breaks, lunch, etc., is not applied toward the number of hours. Time spent in the educational activity should be rounded to the nearest quarter hour and credit hours should be awarded accordingly. Physicians should be instructed to claim only the actual time spent in the activity. One exception to this general rule is physician participation in a performance improvement activity (PI CME). Please refer to the AMA PRA booklet for information on PI CME.

## PART II

### THE ESSENTIAL AREAS AND THEIR ELEMENTS: AN OVERVIEW

The major purposes of accreditation are to ensure the quality and integrity of accredited providers by

- Establishing criteria for evaluation of educational programs and their activities;
- Assessing whether accredited organizations meet and maintain standards;
- Promoting organizational self-assessment and improvement; and
- Recognizing excellence.

The ACCME has defined its mission as the identification, development, and promotion of standards for quality continuing medical education (CME), utilized by physicians in their maintenance of competence and incorporation of new knowledge to improve quality medical care for patients and their communities. To serve as criteria for determining whether a CME sponsor merits accreditation, ACCME developed the *Essentials for Accreditation of Sponsors of Continuing Medical Education* that became effective in January 1984. A new system of accreditation was ratified by the ACCME in January 1999. In 2006, the ACCME adopted the Updated Accreditation Criteria (UAC); the UAC subsequently were adopted by the UMA. This updated criterion-based decision making system is now incorporated in UMA's Accreditation Requirements. The ACCME *Essential Areas and Their Elements* represent national guidelines for the accreditation of continuing medical education programs that accredited providers must comply with whether accredited by the ACCME or as an intrastate provider by a state accrediting body. Intrastate sponsors should remember that they are accredited by the UMA, not the ACCME, and should seek guidance from the UMA should CME questions arise. The Utah Medical Association has officially approved and adopted the *Essential Areas and Their Elements* as its own. The following summarizes the UMA *Essential Areas*.

#### The UMA'S Essential Areas and Their Elements

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The UMA recognizes that the professional responsibility of physicians requires continuous learning throughout their careers, appropriate to the individual physician's needs. The UMA 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 Their Elements, Standards for Commercial Support*, and related Accreditation Policies, 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*, the *Standards for Commercial Support*, and Accreditation Policies, the UMA 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. They provide a valuable resource for physicians planning their own CME and for providers designing CME activities and programs.



## THE 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 UMA's policies for disclosure and commercial support.

[NOTE: The UMA's policies for disclosure and commercial support are articulated in: (1) *The Standards For Commercial Support: Standards to Ensure Independence in CME Activities*; and (2) UMA policies applicable to commercial support and disclosure.

### 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.

**Compliance with the following will be determined at Pre-application and, as required, during the provider's term of accreditation**

### Administration

The provider must,

- Element 3.1 Have an organizational framework for the CME unit that provides the necessary resources to support its mission including support by the parent organization, if a parent organization exists
- Element 3.2 The provider must operate the business and management policies and procedures of its CME program (as they relate to human resources, financial affairs and legal obligations), so that its obligations and commitments are met.

**2006 Updated Decision-Making Criteria  
Relevant to the Essential Areas and Elements**

Measurement criteria have been established for the Elements of the Essential Areas. If a provider meets the criteria for the Elements within the Essential Area, the provider will be deemed to be 'In Compliance.'

<b>Essential Area and Element(s)</b>	<b>Criteria for Compliance</b>
<p><b>Essential Area 1: Purpose And Mission</b></p> <p>The provider must, <b>E 1</b> 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.</p>	<p>C 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.</p>
<p><b>Essential Area 2: Educational Planning</b></p> <p>The provider must, <b>E 2.1</b> Use a planning process(es) that links identified educational needs with a desired result in its provision of all CME activities. <b>E 2.2</b> Use needs assessment data to plan CME activities. <b>E 2.3</b> Communicate the purpose or objectives of the activity so the learner is informed before participating in the activity. <b>E 3.3</b> Present CME activities in compliance with the ACCME's policies for disclosure and commercial support.</p>	<p>C 2 The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners. C 3 The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement. C 4 The provider generates activities/educational interventions around content that matches the learners' current or potential scope of professional activities. C 5 The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives and desired results of the activity. C 6 The provider develops activities/educational interventions in the context of desirable physician attributes (e.g., IOM competencies, ACGME Competencies). C 7 The provider develops activities/educational interventions independent of commercial interests (SCS 1, 2 and 6). C 8 The provider appropriately manages commercial support (if applicable, SCS 3). C 9 The provider maintains a separation of promotion from education (SCS 4). C 10 The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).</p>

<b>Essential Area and Element(s)</b>		<b>Criteria for Compliance</b>
<b>Essential Area 3: Evaluation and Improvement</b>	<p>The provider must,</p> <p><b>E 2.4</b> Evaluate the effectiveness of its CME activities in meeting identified educational needs.</p> <p><b>E 2.5</b> Evaluate the effectiveness of its overall CME program and make improvements to the program.</p>	<p>C 11. The provider analyzes changes in learners (competence, performance, or patient outcomes) achieved as a result of the overall program's activities/educational interventions</p> <p>C 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.</p> <p>C 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.</p> <p>C 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.</p> <p>C 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.</p>
<b>Accreditation with Commendation</b>	<p>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.</p>	<p><b>C 16. The provider operates in a manner that integrates CME into the process for improving professional practice.</b></p> <p><b>C 17. The provider utilizes non-education strategies to enhance change as an adjunct to its activities/educational interventions (e.g., reminders, patient feedback).</b></p> <p><b>C 18. The provider identifies factors outside the provider's control that impact on patient outcomes.</b></p> <p><b>C 19. The provider implements educational strategies to remove, overcome or address barriers to physician change.</b></p> <p><b>C 20. The provider builds bridges with other stakeholders through collaboration and cooperation.</b></p> <p><b>C 21. The provider participates within an institutional or system framework for quality improvement.</b></p> <p><b>C 22. The provider is positioned to influence the scope and content of activities/educational interventions.</b></p>

## PART III

### ***THE STANDARDS FOR COMMERCIAL SUPPORT: AN OVERVIEW***

When commercial interests, defined as any proprietary entity producing health care goods or services, consumed by, or used on, patients, contribute funds and services for the development of CME activities, it is considered commercial support. Although commercial support can enhance the ability of the CME enterprise to fulfill its purpose, commercial support also has the potential to introduce bias that threatens the integrity of CME. When individuals have financial relationships with commercial interests and are in a position to control the content of CME, there is also the potential for commercial bias. The ACCME believes that all CME must be free of the control of commercial interests and that this independence will help ensure that CME is free of commercial bias.

Elements of the federal government have, over the years, indicated the value and importance of this independence. In 1997, the United States Food and Drug Administration wrote:

“The FDA has not regulated and does not intend to regulate, under the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act, Industry Supported Scientific and Educational Activities that are independent of the influence of the supporting company. Companies and providers who wish to insure that their activities will not be subjected to regulation should design and carry out their activities free from the supporting companies’ influence and bias....” (Federal Register, Vol 62, No 232, December 3, 1997)

In 2003, the Office of Inspector General of the US Department of Health and Human Services wrote:

“Absent unusual circumstances, grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty... Codes of conduct promulgated by the CME industry may provide a useful starting point for manufacturers when reviewing their CME arrangements. (Federal Register, Vol 68, No 86, May 5, 2003)

The purpose of the *Standards for Commercial Support* (SCS) is to promote independence from commercial interests and to separate promotion from education. In 1987 the ACCME first adopted “Guidelines for Commercial Support” which were updated and expanded into the 1992 “Standards for Commercial Support.” In 2004, after an extensive review, the Standards were updated.

The updated *Standards for Commercial Support* describe practices that the ACCME considers appropriate for accredited providers to ensure that their CME activities are independent, free of commercial bias, and beyond the control of persons or organizations with an economic interest in influencing the content of CME. The updated SCS describe six Standards: (1) independence; (2) resolution of personal conflicts of interest; (3) appropriate use of commercial support; (4) appropriate management of associated commercial promotion; (5) content and format without commercial bias; and (6) disclosures relevant to potential commercial bias. These updated Standards underscore continued voluntary self-regulation by CME providers, ensuring that physicians have opportunities to engage in commercially unbiased life-long learning facilitated by accredited providers.

*The Standards for Commercial Support*  
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 ACCME 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 ACCME 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.

## **PART IV**

### **UMA ACCREDITATION POLICIES**

UMA policies supplement the Essential Areas and Elements and result from actions taken by UMA's Accreditation Committee. These policies were developed by the ACCME's Board of Directors and then adopted by the UMA Accreditation Committee.

These policies are organized according to topic, and presented in a format that is intended to assist providers in understanding the policies themselves, as well as UMA's expectations for their implementation. If you have questions regarding these accreditation policies, please contact us at [cmeaccreditation@utahmed.org](mailto:cmeaccreditation@utahmed.org).

UMA Accreditation Policies are listed separately on the CME Accreditation section of the UMA website as policies are routinely updated. See "Accreditation Policies."

## PART V

### The Accreditation Process

#### A. Getting Started

For first-time, or “initial” applicants, the accreditation process can take twelve to eighteen months. Almost all of those completing the initial application process are successful in achieving UMA accreditation. If your organization is considering applying for UMA initial accreditation, there are several factors you should consider in determining whether accreditation is right for you. For those applying for reaccreditation, the process can take from nine to twelve months. The process begins when the provider receives the notification letter along with the reaccreditation materials.

#### B. Purpose of Accreditation

UMA accreditation is a mark of quality signifying that a provider’s continuing medical education activities are planned, implemented and evaluated in accordance with the UMA’s *Essential Areas and Elements* along with the *Standards for Commercial Support* and Accreditation Policies (Accreditation Requirements). UMA accreditation (1) assures the medical community and the public that such activities provide physicians with information that can assist them in maintaining or improving their practice of medicine and (2) that these activities are free of commercial bias and based on valid content.

#### C. Role of the UMA

The UMA has adopted the educational standards for CME activities established by the Accreditation Council for Continuing Medical Education (ACCME). The UMA also monitors its accredited providers’ adherence to these standards. Please note that the *UMA Accreditation Committee accredits organizations and does not accredit individual activities*. Non-accredited organizations that would like to partner with an either a UMA or ACCME accredited provider in the provision of quality CME can enter into a joint sponsorship with an accredited organization.

It is important to note that UMA does not reward the continuing educational accomplishments of individual physicians. Rather, those accomplishments are rewarded by other organizations that, for example, require physicians to complete a certain amount and/or type of CME for membership or re-licensure. As such, CME providers are not UMA accredited for the purpose of granting licensure or certification. The requirements for granting these privileges are maintained by the other organizations themselves. Since different credentialing bodies have varying requirements, CME providers should be aware of the requirements of the particular credentialing body for which credit is being granted.

#### D. Expectations of the UMA

The UMA has several expectations of those who apply for intrastate accreditation:

- Eligible organizations that decide to apply for UMA accreditation should be prepared to

both describe and furnish evidence that demonstrates compliance with the Accreditation Requirements. For this reason, organizations considering applying for UMA accreditation must plan, implement and evaluate at least one CME activity prior to beginning the accreditation process.

- Accredited providers are expected to monitor their overall CME program for compliance with the Accreditation Requirements and to fulfill annual reporting requirements. For a description of the ongoing responsibilities of UMA accredited providers, see “Maintaining Accreditation – Ongoing Responsibilities of Accredited Providers.”
- Payment of certain fees is required to obtain and maintain UMA accreditation. For a schedule of current UMA fees, please refer to “Accreditation Fee Schedule.”

### **E. UMA’s Policy Regarding Confidentiality of Information**

Through the accreditation process, the UMA collects data related to a provider’s compliance with Accreditation Requirements. The UMA will maintain the following as confidential, except as required for UMA accreditation or recognition purposes or as may be required by legal process or as otherwise authorized by the CME provider to which it relates:

- Information acquired by the UMA from a provider during the accreditation process for that CME provider except for accumulated data that does not specifically identify individual CME providers;
- Correspondence and memoranda within the UMA relating to the accreditation process for a CME provider;
- UMA proceedings relating to a CME provider.

In order to maintain confidential information as such, UMA and UMA volunteers are required not to make copies of, disclose, discuss, describe, distribute, or disseminate in any manner whatsoever, including oral, written, or electronic form, any confidential information that they receive or generate, or any part of it, except directly for UMA accreditation purposes. UMA and UMA volunteers are also required not to use such confidential information for personal or professional benefit, or for any other reason, except directly for UMA accreditation or recognition purposes.

The following information is considered public information and may be released the UMA:

- Names and contact information for accredited providers;
- Accreditation status of providers;
- Annual report data, including number of activities, number of credits, number of physician participants, number of non-physician participants, acceptance of commercial support, acceptance of advertising or exhibit revenue; joint sponsorship participation, and types of activities produced;
- Aggregated accreditation finding and decision data by provider type;
- Complaint and inquiry decision information;
- Other information the UMA believes might qualify as public information.

Note: The UMA will not release any dollar amounts reported by individual providers for income, expenses, commercial support, or advertising/exhibit.

## **F. Eligibility to Apply for UMA Accreditation**

UMA has specific criteria for determining an organization's eligibility to receive UMA accreditation as outlined in Part 1 of this guide. In summary, the organization must

- Offer a program of continuing medical education primarily targeted to physicians licensed and practicing medicine in Utah and its immediately bordering states;
- Be located within the state of Utah;
- Not be a commercial interest;
- Present activities that have valid content;
- Demonstrate an overall organizational commitment to the continuing medical education program, including physician support, budget support, staffing, and record-keeping resources;
- Demonstrate the capacity to substantially comply with all UMA Accreditation Requirements;
- Offer a program of CME for physicians on a regular and recurring basis.

## **G. The Pre-Application Process**

The first step in becoming accredited is completion of a "Pre-application for UMA Accreditation" ("Pre-application"). The purpose of the Pre-application is to provide you with an opportunity to explain your eligibility for UMA accreditation as well as to demonstrate that your organization has mechanisms in place to fulfill UMA's Accreditation Requirements in the CME activities that you will produce.

Once your organization has completed and submitted the Pre-application to the UMA and the Pre-application fee, UMA staff will notify your organization whether it is eligible to continue with the initial accreditation process. This notification is in writing and is usually sent within two weeks of receipt of your Pre-application. UMA staff review Pre-applications as quickly as possible and will notify you immediately once a decision has been made regarding your eligibility to continue with the initial accreditation process.

## **H. The Initial Self Study Process**

If your organization is deemed eligible to continue with the initial accreditation process, you will complete and submit an Initial Self Study Report for UMA accreditation, including payment of the Initial Accreditation Fee. Once all required information and payment has been received, the UMA will schedule your survey. A first-time applicant must fulfill two requirements with respect to the survey. First, the applicant must have a survey at its administrative offices and, secondly, have a CME activity reviewed. There is no prescribed order for the two requirements, but the first survey must take place prior to Provisional Accreditation and both requirements must be completed prior to Accreditation.

The survey provides an opportunity for your organization to meet with two UMA surveyors to discuss the objectives of your CME program and your approach to compliance with UMA

Accreditation Requirements. The surveyors will clarify any questions they may have about your application and will also expect to discuss your organization's ongoing plans for improvement as they relate to your practice of CME. You can expect your surveyors to ask thoughtful questions and to listen carefully to what your organization has to say about its CME program.

Following the survey, the surveyors will document the results of their conversations with your organization and send the findings to Accreditation Committee. Once the findings are received, UMA's decision making process begins.

### **I. The Reaccreditation Process**

The UMA will initiate the process of reaccreditation by notifying your organization in writing of its need to re-apply. The UMA's primary contact for your organization will receive this notification approximately nine months before your current term of accreditation ends. Each provider seeking reaccreditation must participate in a UMA survey. The survey provides an opportunity for your organization to meet with two UMA surveyors to discuss the objectives of your CME program, and your approach to compliance with UMA's Accreditation Requirements. The survey will also include a review of documentation to determine whether your practice of CME conforms to what is described in your self study.

### **J. Goals of the Survey**

The goals of the survey are to gather data about the organizational structure, resources and responsibilities; review documents as indicators of compliance with all UMA Essential Areas and Their Elements and Accreditation Policies; discuss monitoring data; and identify excellence and improvement whenever present. The survey data will be combined with other data to provide a final overall accreditation recommendation prior to the decision making process.

During the survey, the provider will have an opportunity to

- Introduce their CME unit to the survey team;
- Clarify the information supplied in the application or self study report;
- Provide information about the CME Program that goes beyond the scope of the self study but is in support of compliance with the UMA's Accreditation Requirements;
- Identify areas of planned improvement for the CME Program; and
- Demonstrate the adequacy of the CME Program's administrative structure and the resources that support the CME unit.

At the same time, the survey will give the UMA the opportunity to

- Observe whether activities have been implemented in compliance with the UMA's Accreditation Requirements;
- Discuss the Annual Report, Monitoring Data, and other information when conducting a reaccreditation survey; and
- Ensure that the survey team has sufficient information about the provider's organization to formulate a report to the UMA.

## **K. Types of Surveys**

The UMA uses only face-to-face surveys.

***On-site Survey*** - This survey is a face-to-face meeting of the leadership of the CME Program and the survey team of the UMA at the administrative offices or activity of the CME Program. This type of survey is required for initial accreditation surveys and for reaccreditation surveys when the provider is on probation, has not had an on-site in the previous 10 years, or there is a significant change in the provider's ownership, mission, or volume of CME activities.

On-site surveys may be conducted at other times in accordance with UMA policy. Specific activity files will be identified in advance for review by the survey team during a survey. In addition, all records and activities for the current accreditation period must be made available for review. UMA reserves the right to review additional activity files as is necessary for it to arrive at an accreditation decision.

***Other Face to Face Site Survey***– This survey is an in-person meeting of the leadership of the CME Program and the survey team at a location determined by the UMA and the provider. This may be at the UMA's offices or other location, such as a medical office.

For either type of survey, the provider sends appropriate individuals to meet with the UMA survey team. Activity files are requested and may be submitted to the UMA in advance of the site survey or may be reviewed at the provider's administrative offices. UMA reserves the right to review additional activity files as is necessary for it to arrive at an accreditation decision.

The UMA reserves the right to determine the type of survey used for the provider.

## **L. Format of the Survey**

The format for all surveys involves interviews between the representatives of the accredited provider and the UMA survey team. The survey also includes time for the surveyors to complete their activity files review and surveyor report form.

The survey should be scheduled to allow ample time for the survey team to get a complete and accurate understanding of the organization and its compliance with UMA's Accreditation Requirements. Standard components of the survey generally include the following:

## **M. Site Survey Components**

### **Pre-survey Meeting of Survey Team**

Objective: To discuss the provider's self study report and develop a strategy for the conduct of the survey.

Format: A phone or face-to face meeting of the survey team prior to the survey. The pre-survey meeting includes discussion and review of past UMA accreditation decisions related to the provider, the provider's actions to correct any past partial or non-compliance findings noted in a progress report, annual report issues (if applicable), complaint/inquiry materials (if applicable), and the self study report. The team will also develop a strategy for the conduct of the survey, including an agenda and how to address specific issues identified by the team.

### **Activity Review**

Objective: To observe the performance in practice of the CME program and to provide additional data about compliance or exceptional performance.

Format: The UMA will coordinate with the provider to identify a CME activity to evaluate. If the applicant is applying for initial accreditation, the activity need not be designated for category 1 credit but must be planned according to UMA Accreditation Requirements. An Activity Review can occur during an on-site survey or through the review of an enduring material, internet CME, or Journal CME activities. An Activity Review is necessary for all providers prior to receiving full accreditation. The Activity Review may take place prior to the initial site survey or between the period of provisional accreditation and full accreditation.

### **Documentation Review for a CME Activity**

Objectives: (1) To review files from all types of CME activities to assure documented compliance with UMA's Accreditation Requirements and (2) To validate the evidence or documentation to support the information supplied in the self study report.

Format: UMA will send providers via email a template to submit electronically a complete list of CME activities that occurred during their current period of accreditation. For an initial applicant, UMA will request any activities that have been jointly sponsored with an accredited provider and any activities developed as part of the track record. UMA staff will select a list of activities from those listed by the provider and the provider will be asked to have the files available prior to the visit. The UMA may request that the files be sent to the UMA or that the files be available on-site for review prior to the survey. The provider may be requested to have other files available during the visit should there be a question about the level of compliance because of missing data from the self study report. The surveyors will review the documents for demonstration of compliance with the UMA's Accreditation Requirements.

### **Introductory Session with the Provider's Representatives**

Objective: To review with the CME Program leadership the goals, schedule and format of the survey.

Format: The survey commences with a group meeting with the CME Program leadership.

### **Organizational Review with the Provider's Representatives**

Objective: To allow both the provider and the surveyors to clarify the information supplied in the self study report or collect additional data to ensure adequate information is available to formulate a survey report.

Format: A face-to-face conversation with the CME Program leadership and UMA surveyors.

### **Closing Comments**

Objective: To provide an opportunity for the provider to offer any additional information about its CME Program, to summarize information obtained about the CME program, and to notify the provider of the final steps in the accreditation. The surveyors and provider also will develop a list of planned improvements to be documented in the survey report.

Format: Face-to-face conversation with the CME Program leadership and UMA surveyors.

### **Surveyor Report Completion**

Objective: Complete the survey report which will be distributed to the Accreditation Committee.

Format: The surveyors may complete the report at the provider's offices or at a later time. The surveyors will notify the provider if a room is needed to complete the team's work.

### **Decision-Making**

Objective: To assess the provider's level of compliance with the Accreditation Requirements based on information furnished in the Self Study, Activity file reviews, and verbal information during the survey, as well as additional information collected by the surveyors or the UMA.

Format: Decision-making takes place at regularly scheduled Accreditation Committee meetings.

### **Provider Feedback**

Objective: To notify the provider of the accreditation decision and specific findings for each Essential Area.

Format: The provider will receive a letter that includes the accreditation decision and a summary of findings, the survey report, and an accreditation certificate.

## **N. Accreditation Decisions**

As stated above, the decision making process assesses the provider's level of compliance with UMA's Accreditation Requirements. Under the 22 Updated Accreditation Criteria (UAC), compliance options are either "yes" or "no".

Based on the survey teams' report and discussion, the Accreditation Committee will choose from the following options:

**Provisional Accreditation:** Provisional Accreditation is the standard status for initial, or first-time, applicants, and is associated with a two year term. To achieve Provisional Accreditation, the applicant must meet Level 1 compliance with the Updated Accreditation Criteria. Provisional Accreditation may also be granted when an accredited organization's CME program is so altered that it is essentially a new program.

**Accreditation:** Accreditation is the standard status for those providers applying for reaccreditation and is associated with a four year term. For accreditation, providers must meet Level 2 compliance with the Updated Accreditation Criteria. For accredited providers seeking Accreditation, Non-Compliance with any Criterion will necessitate a Progress Report and/or focused or full survey. Failure to demonstrate compliance in the Progress Report and/or focused or full survey may result in Probation.

**Accreditation with Commendation:** Accreditation with Commendation is associated with a six year term and is available only to reaccreditation applicants. An applicant is eligible for Accreditation with Commendation if the applicant meets Level 3 compliance with the Updated Accreditation Criteria.

**Probation:** 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.

Providers who receive Probation at reaccreditation receive the standard four-year term of accreditation for two years, maximum. Once the provider submits a Progress Report that is validated and accepted by the UMA, the provider's accreditation status and the ability for a provider to complete its four-year term will resume.

Probation may not be extended. Therefore, providers on Probation that fail to demonstrate Compliance with all UMA requirements within two years will receive Non-Accreditation. Note that provisionally accredited providers cannot be put on Probation. Rather, provisionally accredited providers that seriously deviate from Compliance will receive Non-Accreditation.

**Non-Accreditation:** Although decisions of Non-Accreditation are rare, UMA reserves the right to deliver such decisions under any of the following circumstances:

- After the initial survey. To achieve Provisional Accreditation, first-time applicants must be found in compliance with Level 1 criteria. Initial applicants who receive Non-Accreditation may not be reviewed again by the UMA until one year from the date of the UMA meeting at which the decision was made.
- After Provisional Accreditation. Provisionally accredited providers that seriously deviate from Compliance will receive Non-Accreditation. These providers are not eligible for Probation.
- After a Progress Report. For accredited providers on Probation, an inability to bring all Non-Compliance findings into compliance by the end of the probation period will be cause for Non-Accreditation.

The effective date for Non-Accreditation is usually one year from the UMA decision. A provider who receives Non-Accreditation is responsible for payment of all fees and submission of all required reports until the effective date of Non-Accreditation. Failure to do so will result in immediate Non-Accreditation. The UMA waives the requirement of a Pre-application for the provider that chooses to submit an Initial Self Study Report during the one-year time period prior to the effective date of Non-Accreditation. The process and

standards for review of newly Non-Accredited applicants are the same as for all other applicants.

The UMA Accreditation Committee three times each year – March, July, and November. Accreditation decisions are made at these meetings as well as reviews of Progress Reports. All providers are given accreditation dates that expire in one of these three months; the provider will be notified of the decision within a month following the meeting date.

The UMA considers the names of providers whose accreditation has been withdrawn to be public information and may provide lists of these names upon request.

### **O. Progress Reports**

A provider may be required to submit a Progress Report to the UMA if the provider has received a non-compliant finding. A provider will be required to submit a Progress Report Improvement Plan at the next regularly scheduled Accreditation Committee meeting. At that time, the Accreditation Committee will provide feedback on the provider's plan to bring non-compliance findings into compliance. A decision regarding a provider's Progress Report could be one of three options.

1. *Accept:* UMA accepts a Progress Report when the provider has furnished evidence of Compliance with the Requirements that were in Non-Compliance. A provider's demonstration of Compliance in all Elements will result in its ability to complete its four-year term with a status of Accreditation.
2. *Clarification Required:* If the Progress Report requires clarification, the provider has corrected most of the Elements that were in Non-Compliance but some additional information is required to be certain the provider is in Compliance. An additional Progress Report may be required.
3. *Reject:* The UMA rejects a Progress Report if it does not provide evidence that the areas of Non-Compliance have been corrected. Either a second Progress Report or a focused accreditation survey may be required. The UMA can place a provider on Probation or Non-Accreditation as the result of findings on a Progress Report.

### **P. Reconsiderations and Appeals**

A provider that receives a decision of either Non-Accreditation or Probation may request Reconsideration when it feels that the evidence it presented to the UMA justifies a different decision. Only material which was considered at the time of the site survey may be reviewed upon Reconsideration.

If, following the Reconsideration, the UMA sustains its original decision, the organization may request a hearing before a UMA Appeal Board. Appeals may be based only on the grounds that the UMA's decision was: (1) arbitrary, capricious, or otherwise not in accordance with the accreditation standards and procedures of the UMA, or (2) not supported by substantial evidence. Attorneys may participate in the Reconsideration and Appeals processes.

Note that Non-Accreditation or Probation decisions delivered as a result of administrative issues such as failure to submit fees are not eligible for the Reconsideration and Appeals processes. Please refer to the UMA's *Reconsideration and Appeal Policy* in Appendix A.

## Q. Resources for Accreditation

The UMA will provide the following resources on its website to assist providers in completing the accreditation process:

- UMA’s *System for the Accreditation of Intrastate Providers of Continuing Medical Education* (Accreditation Manual)
- UMA’s *Essential Areas, Their Elements, and Decision-Making Criteria*
- *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*
- UMA Accreditation Policies
- Pre-Application
- Initial Self Study Instructions and Outline
- Reaccreditation Self Study Instructions and Outline
- Surveyor Report Form
- Documentation Review Form
- Activity Review Form

The UMA is available to answer questions about accreditation and the Self Study. UMA staff may be reached by email at [cmeaccreditation@utahmed.org](mailto:cmeaccreditation@utahmed.org).

## R. Initial Accreditation Timeline

Calendar (You add months)	Maximum Time to Completion (Months*	Function
		Pre-application downloaded from UMA website by potential applicant and completed
	1	Pre-application submitted by applying organization to UMA. UMA decision on pre-application forwarded to applicant along with an <i>Initial Self Study Package for UMA Accreditation</i> , if eligible
	6-8	Initial <i>Self Study</i> Report returned to UMA along with payment and preferences for survey dates
	4-6	<i>Self Study</i> Report reviewed by staff and an On-Site Survey is scheduled. On-Site Survey conducted and applicant scheduled for appropriate UMA Accreditation Committee meeting
	1	UMA Accreditation Committee makes the final accreditation decision. Provider notified of accreditation status

\* This timeline is the maximum time for the completion and review of an Initial Self Study Report for UMA Accreditation. The actual time is dependent on the applying organization and the timing of UMA Accreditation Committee meetings.

## Reaccreditation Timeline

Calendar (You add months)	Maximum Time to Completion (Months*	Function
		Notification of reaccreditation date and reaccreditation materials mailed to the provider
	6-8	Self Study submitted by applying organization to UMA along with payment and preferences for survey dates.
	2-4	<i>Self Study</i> Report reviewed by staff and an On-Site Survey is scheduled. On-Site Survey conducted and applicant scheduled for appropriate UMA Accreditation Committee meeting
	1	UMA Accreditation Committee makes the final accreditation decision. Provider notified of accreditation status

\* This timeline is the maximum time for the completion and review of an Initial Self Study Report for UMA Accreditation. The actual time is dependent on the applying organization and the timing of UMA Accreditation Committee meetings.

## Part VI

### Maintaining Accreditation

#### **A. Annual Reporting Requirements**

UMA accredited providers are required to submit a UMA Annual Report and Annual Fee in order to maintain their accreditation status. The purpose of the Annual Report is two-fold: first, to confirm contact information for the accredited provider, and second, to compile a description of the size and scope of the provider's CME enterprise, 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. The UMA accumulates data from its accredited providers and then submits it to the ACCME which compiles a report of the size and scope of the CME enterprise in the United States. This report is a service to accredited providers, other members of the CME community, and the public. The accumulated data do not specifically identify individual providers. Information of this nature that is specific to an individual provider is kept confidential. Current and historical summary data is available. The UMA will notify providers of the need to complete the report early each year. Providers that do not complete the report by the stated due date are subject to late fee a possibly to a change in accreditation status.

#### **B. Informing the UMA of a Provider's Personnel or Organizational Changes**

**Contact Information:** In order to keep providers aware of important policy updates as well as information specific to their individual accreditation, UMA requires providers to inform the UMA of any personnel or organizational changes that could impact our ability to contact them. These types of changes include changes of address or phone number and changes to the individual to whom providers would like UMA to send correspondence.

The UMA considers the names and contact information for providers it accredits to be public information and provides lists of these names to the public, accordingly.

**Corporate Change:** If a UMA accredited provider undergoes a corporate change resulting, for instance, from a merger or acquisition, the UMA expects first, to be made aware of the merger or acquisition and second, to be informed by the provider of the impact of the merger or acquisition on the CME program. Please refer to UMA policies on mergers in the Appendix.

Keep in mind that UMA accreditation was awarded to the organization that sought the accreditation and was able to demonstrate compliance with Accreditation Requirements. For this reason, in the event of corporate change, the UMA will work with the accredited provider to explore the changes to the CME program and/or organizational structure that have resulted. The provider will either maintain its current accreditation status or be asked to undergo a more thorough survey to determine the compliance of the "new" entity. If a provider is determined to be so changed as to be new, then its accreditation status might be reverted to provisional.

### **C. Maintaining Continuous Compliance through Self-Monitoring**

Most UMA providers are evaluated for reaccreditation every three to four years. Once a provider has achieved accreditation, the UMA expects that during its accreditation term, the organization will take an active role in ensuring that it is continuously meeting the expectations of UMA in its purview of CME.

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

- Read all mail and electronic mail from the UMA regarding accreditation and changes or clarifications about accreditation policies.
- Email [accreditation@utahmed.org](mailto:accreditation@utahmed.org) or call the UMA if you have questions about your organization's compliance with the Accreditation Requirements.
- Register on ACCME's website ([www.accme.org](http://www.accme.org)) to receive e-mail alerts that will inform you of developing policies at the national level and changes to or clarification of existing policy. The UMA adopts most ACCME policies. Receiving ACCME alerts will give you a head start in implementing of any new policies or guidelines.
- Take advantage of UMA and ACCME educational opportunities that you believe would be helpful to increasing your organization's understanding of the accreditation system and its Requirements.

The UMA makes every effort to be supportive to its accredited providers throughout their terms of accreditation. We hope that you will not hesitate to take full advantage of the assistance that we offer to you as an accredited provider.

### **D. Measuring Continuous Compliance through UMA Monitoring**

Because of UMA's responsibility to the CME community and to the public for ensuring that providers meet UMA standards for quality continuing medical education, the UMA may on occasion ask you to provide evidence of your continuous compliance with the Accreditation Requirements prior to your normally scheduled review for reaccreditation. In most cases, UMA would request such evidence if information were brought to UMA's attention, either through a complaint or inquiry, or via other means, that questioned your organization's ongoing compliance with the Accreditation Requirements. Please refer to the UMA's Procedure for Handling Complaints and Inquiries Regarding Accredited Providers in the Appendix.

## E. UMA Accreditation Fee Schedule

The following outlines the fees charged to UMA Accredited Providers. These fees are subject to change. Please contact the UMA if you have specific questions about UMA Accreditation fees.

Accreditation Fee	Amount
Pre-application Fee (for the consideration of a Pre-application for UMA Accreditation)	\$ 50.00
Initial Accreditation Fee (for the consideration of a Self-Study for Initial Accreditation)	\$750.00
Reaccreditation Fee (for the consideration of a Self-Study for Reaccreditation)	\$750.00
Extension Fee (for the extension of the deadline for submission of a Self-Study for Reaccreditation)	\$200.00
Annual Accreditation Fee (payable in every full year of accreditation)	\$250.00
Progress Report Fee (for the consideration of a Progress Report)	\$100.00

## F. UMA Fee Policies

**Submission of Fees:** Providers are required to submit payment of all required accreditation fees prior to the UMA's consideration of an Accreditation Committee recommendation. Failure to do so will result in a one-cycle deferral of the committee's recommendation. Failure to do so within that one-cycle deferral will result in a non-accreditation decision at the next regularly scheduled UMA Accreditation Committee meeting.

**Late Fees:** If the UMA receives a Self Study for Reaccreditation after the specified deadline, it will assess a late fee in the amount of 10% of the Reaccreditation Fee. If the UMA receives an accreditation Progress Report after the specified deadline, it will assess a \$50 late fee. A provider will be assessed \$50 each month for receipt of the annual accreditation fee after the deadline. These fees must be paid in order for a provider to receive UMA consideration of an accreditation recommendation.

If payment of the original fee, the late fee and submission of the required documentation are not received by the first UMA meeting after the deadline, the UMA will take action to change the accredited provider's accreditation status to probation. If, at the second UMA meeting after the deadline, payment of the original fee, the late fee, and the required documentation have not been received, the UMA will take action to change the accredited provider's accreditation status to non-accreditation. The effective date of non-accreditation will be the same as the date of the UMA action. Reversal of this action can only be accomplished by submission of a new Self Study for Accreditation.

**Annual Accreditation Fee:** Similarly, if the UMA receives an Annual Accreditation Fee or Annual Report after the specified deadline, it will assess a late fee in the amount of 10% of the Annual Accreditation Fee. A monthly late fee equal to 10% of the amount owed will be charged on the first of each month following the due date until the Annual Accreditation Fee balance is paid in full and/or the Annual Report is submitted.

If the UMA does not receive the Annual Accreditation Fee and/or a completed Annual Report by the first UMA Accreditation Committee meeting following the due date, the UMA will take an action to change the accredited provider's accreditation status to probation. However, if payment and/or a completed Annual Report plus the late fee are received before the second meeting, then the provider's accreditation status will revert back to its original status prior to the probation. If the UMA does not receive the Annual Accreditation Fee and/or a completed Annual Report plus the late fee by the second UMA Accreditation Committee meeting following the due date, the UMA will take action to change the accredited provider's accreditation status to non-accreditation. The effective date of non-accreditation will be the same as the date of the non-accreditation action. Reversal of this action can only be accomplished by submission of a Self Study for Reaccreditation.

#### **G. Expenses for Survey Team**

Currently, the UMA Accreditation Committee pays for surveyor expenses of the initial accreditation or reaccreditation. This includes mileage, airfare, hotel, food, and incidental expenses. All providers applying for initial accreditation or reaccreditation are expected to pick up any expenses for their own participants in the survey.

#### **H. Non-Accreditation or Voluntary Withdrawal of Accreditation**

The usual effective date for non-accreditation decisions is one year from the date of the UMA Accreditation Committee's non-accreditation action. In certain cases, a shorter time frame may be assigned. Providers that receive non-accreditation decisions are responsible for payment of all fees, including the Annual Accreditation Fee, and submission of all required documents until the effective date of non-accreditation. Failure to do so will result in immediate non-accreditation.

If an applicant for reaccreditation cannot meet the UMA's accreditation process deadlines, their accreditation term may be extended once, by four months, with written request from the applicant. The accreditation status of a provider will automatically revert to non-accreditation at the end of their accreditation term unless the UMA has taken action to extend their term of accreditation or has rendered a new accreditation decision.

Providers must notify the UMA in writing of their intent to voluntarily withdraw from the UMA accreditation system. No rebates will be given for Annual Accreditation Fees collected from providers requesting voluntary withdrawal.

**PART VII**  
**APPENDICES**

**These appendices include several accreditation policies and procedures as well as additional resources to support the planning and development of continuing medical education activities.**

## **APPENDIX A**

### **Procedures for Reconsideration and Appeal of Adverse CME Accreditation Decisions**

#### **Executive Summary**

A provider who is placed on probation or denied accreditation (an “adverse decision”) may request reconsideration by the UMA Accreditation Committee by submitting a written request within 30 days of being notified of the adverse decision. The request for reconsideration should be filed only if the provider believes the adverse decision was arbitrary; the surveyors ignored or did not give the provider adequate opportunity to provide documentation of compliance; or the adverse decision was not supported by the evidence.

The Accreditation Committee must complete the reconsideration no more than 90 days after receiving the request. The Accreditation Committee may sustain the initial decision or reverse it. During the reconsideration, the accreditation status of the provider will remain as it was prior to the adverse decision.

If the Accreditation Committee sustains its initial adverse decision, the provider may request a hearing before an Appeal Board by submitting a written request to the Accreditation Committee within 30 days of receiving notice that the adverse decision was sustained.

The President of the Utah Medical Association will obtain a list of seven individuals qualified and willing to serve on the Appeal Board within 20 days of receiving the notification of appeal. The provider may eliminate two individuals from the list and must notify the UMA of its selection within ten days of receiving the list. The President shall then appoint three of the remaining five individuals to the Appeal Board. The Appeal Board will receive copies of all materials relevant to the appeal.

The hearing shall take place no more than 60 days following the appointment of the Appeal Board. The provider shall be notified of the time and place at least 30 days prior to the hearing date. The provider may offer testimony and present other information to support its appeal at the hearing. Within 20 days of the hearing, the Appeal Board shall make a decision on the accreditation status of the provider. The Appeal Board may sustain the initial adverse decision; grant provisional accreditation for two years if the adverse decision was non-accreditation for an initial applicant; grant full accreditation for three or four years if the adverse decision was probation for a reapplicant; or extend probationary accreditation if the adverse decision was non-accreditation for a reapplicant already on probation. The decision of the Appeal Board becomes effective on the date it was made and is final.

## **PROCEDURES FOR RECONSIDERATION AND APPEAL OF ADVERSE CME ACCREDITATION DECISIONS**

### **I. RECONSIDERATION**

- a. The decision by the Utah Medical Association (UMA) Committee on CME Accreditation (Accreditation Committee) to deny or withdraw accreditation or to place a provider on probation, hereinafter referred to as an "adverse accreditation decision," shall be transmitted promptly by letter to the provider. This letter shall include the basis for the decision and inform the provider of the right to request reconsideration. A written request for reconsideration, timely filed, shall automatically stay the adverse accreditation decision until the reconsideration is completed. The accreditation status of the provider, during the process of reconsideration, shall remain as it was prior to the adverse accreditation decision.
- b. To initiate a request for reconsideration, the provider must submit a written request, specifying the reasons for the reconsideration, to the Chair of the Accreditation Committee within thirty (30) calendar days of receipt of the letter of notification of the adverse decision. Otherwise, the decision made by the Accreditation Committee becomes final. A request for reconsideration should be submitted only under one or more of the following conditions:
  1. The Accreditation Committee's decision was based on the evaluation of arbitrary or capricious factors not addressed in written requirements of the Essential Areas and their Elements or Accreditation Policies as published and distributed to all accredited providers.
  2. During the site survey, the provider was not given sufficient opportunity to provide documentation of its compliance with the Essential Areas and their Elements or Accreditation Policies or that the surveyors did not take into account information provided during the site survey.
  3. The adverse decision was not supported by sufficient evidence that the provider was significantly out of compliance with the written requirements of the Essential Areas and their Elements or Accreditation Policies.
- c. The Accreditation Committee will base reconsideration upon the entire continuing medical education program as it existed at the time of the survey and the initial consideration of the application by the Accreditation Committee. Only material made available to the reviewers at the time of the review will be considered as part of the reconsideration. New information, based on data subsequent to the survey and initial review, and information representing changes in the program following an adverse decision, will not be considered by the Accreditation Committee.

If substantial changes have occurred subsequent to the initial survey and review, the provider should submit these changes as part of a new application for accreditation rather than as part of a request for reconsideration.
- d. The Accreditation Committee shall complete the reconsideration no later than 90 calendar days after it receives the request for reconsideration. The Accreditation Committee may sustain its initial decision or reverse its initial decision and grant the provider accreditation. The type and length of accreditation will be governed by accreditation actions as outlined in the UMA's *System for the Accreditation of Intrastate Providers of Continuing Medical Education*. Following the Accreditation Committee meeting at which the reconsideration occurs, the provider will be promptly notified of the decision and of its right to appeal.

## II. APPEAL HEARING

- a. If, following the reconsideration, the Accreditation Committee sustains its initial action, the provider may request a hearing before an Appeal Board. The provider must submit a written request to Chair of the Accreditation Committee for an appeal within thirty (30) calendar days following the date of receipt of the letter notifying the institution that the adverse decision was sustained. If such a request is not received, the decision of the Accreditation Committee will be final. The request for a hearing shall include a statement of reasons for appealing the decision. An appeal may be based only on those conditions outlined in I.b. The accreditation status of the provider, during the process of appeal, shall remain as it was prior to the adverse accreditation decision.
- b. The Appeal Board shall be composed of three members to be appointed by the President of the Utah Medical Association according to the following procedure:  
The President of the UMA, or his/her designee, will generate a list of seven (7) individuals, excluding current members of the Accreditation Committee and anyone with ties (financial or administrative) to the provider requesting the appeal, qualified and willing to serve as members of the Appeal Board. Within twenty (20) days of receiving the notification of appeal, the list shall be sent by certified mail to the appellant. The appellant may eliminate two of the individuals from the list and shall notify the President of the Utah Medical Association of its selection within ten (10) days of its receipt of the list. The President shall then appoint three of the remaining five individuals to the Appeal Board. If no notification is received within the ten (10) days, the President of the Utah Medical Association shall then select any three individuals from the list who shall constitute the Appeal Board and notify the appellant of the individuals selected.
- c. The hearing shall take place no later than sixty (60) calendar days following the appointment of an Appeal Board. Prior to the hearing, Accreditation Committee staff will send each member of the Appeal Board all materials relevant to the appeal including, but not limited to, the following:
  - Copy of the UMA's *Essential Areas, Their Elements, Decision-Making Criteria, and Accreditation Policies*
  - Copy of Applicant's Self Study for Initial Accreditation or Reaccreditation
  - Procedures for Reconsideration and Appeal of Adverse CME Accreditation Decisions
  - UMA's *System for Accreditation of Intrastate Providers of Continuing Medical Education*
  - Survey Report Form with attachments
  - Relevant Accreditation Committee minutes
  - Correspondence related to the initial decision
  - Appellant's letter requesting Reconsideration
  - Correspondence related to the Reconsideration
  - Appellant's letter requesting Appeal, including all information supplied by appellant

At least thirty (30) calendar days prior to the hearing, the appellant shall be notified of the time and place of the hearing as determined by the UMA. The appellant has the right to request and obtain the information in the appellant's application file on which the Accreditation Committee actions were taken. Any additional information supplied by the

appellant must be **for purposes of clarification only and cannot describe new components of the institution or changes made subsequent to the initial action (as described under Section I.c.).**

Written statements may be submitted to the Appeal Board prior to the hearing, at the hearing, or up to ten (10) calendar days following the hearing, provided that a formal request to submit such statements is made to the Appeal Board.

- d. At any hearing before the Appeal Board, the representatives of the appellant may be accompanied by counsel, make oral presentations, offer testimony, and present such information as the appellant deems proper to support its appeal. The appellant may request that a representative of the Accreditation Committee or of the site survey team appear as witness to be examined with respect to the subject of the appeal. The appellant, at least fifteen (15) calendar days prior to any such hearing, shall request in writing the presence of a representative.
- e. The Accreditation Committee may appoint representatives to attend the hearing and may examine the appellant's representatives. The hearing need not be conducted according to the rules of law relating to the examination of witnesses or the presentation of evidence. The purpose of the hearing is to assemble as much information as practical regarding all material aspects of the appeal and the Appeal Board shall be entitled to take into account any such information of the type normally relied upon by individuals of reasonable prudence in the conduct of important personal matters. The members of the Appeal Board shall make all determinations on procedural matters and all determinations on the admissibility of information sought to be presented.
- f. The record of survey and review, together with formal presentations at the hearing, the transcript of proceedings of the hearing, and statements submitted under the provisions outlined above, shall be the basis for the findings of the Appeal Board.
- g. Within twenty (20) calendar days of the hearing, or the receipt of written statements, whichever is later, the Appeals Board shall make a decision on the accreditation status of the appellant. Its recommendations are limited to the following as outlined in the UMA's *System for Accreditation of Intrastate Providers of Continuing Medical Education*:
  - Initial Accreditation or Reaccreditation Appeal: Confirm decision of the Accreditation Committee
  - Initial Accreditation Appeal: Grant provisional accreditation for two years if initial adverse decision was non-accreditation
  - Reaccreditation Appeal: Grant full accreditation for three or four years if initial adverse decision was probation
  - Reaccreditation Appeal: Grant probationary or full accreditation for two to four years if initial adverse decision was non-accreditation and reapplicant not previously on probation
  - Reaccreditation Appeal: Grant extended probationary accreditation or full accreditation for two to four years if initial adverse decision was non-accreditation and reapplicant previously on probation

The Appeal Board's decision becomes effective on the date it is made and is final.

- h. The appellant shall be notified in writing of the Appeal Board's decision within five (5) days of its decision. The written confirmation shall include (a) the date of the decision; (b) the Appeal Board's final decision; and (c) whether the decision confirms or amends the reconsideration decision of the Accreditation Committee and the reasons for the Appeal Board's action. Copies of the notification shall be sent to the President of the Utah Medical Association and the Chair of the Accreditation Committee.

- i. Expenses of the Appeal Board shall be shared equally by the appellant and the Accreditation Committee. The expenses of witnesses requested by the appellant shall be the responsibility of the appellant. The expenses of the representatives of the Accreditation Committee, who appear at its request, shall be borne by the UMA. Expenses of any representatives of the Accreditation Committee, who appear at the request of the appellant, shall be the responsibility of the appellant.

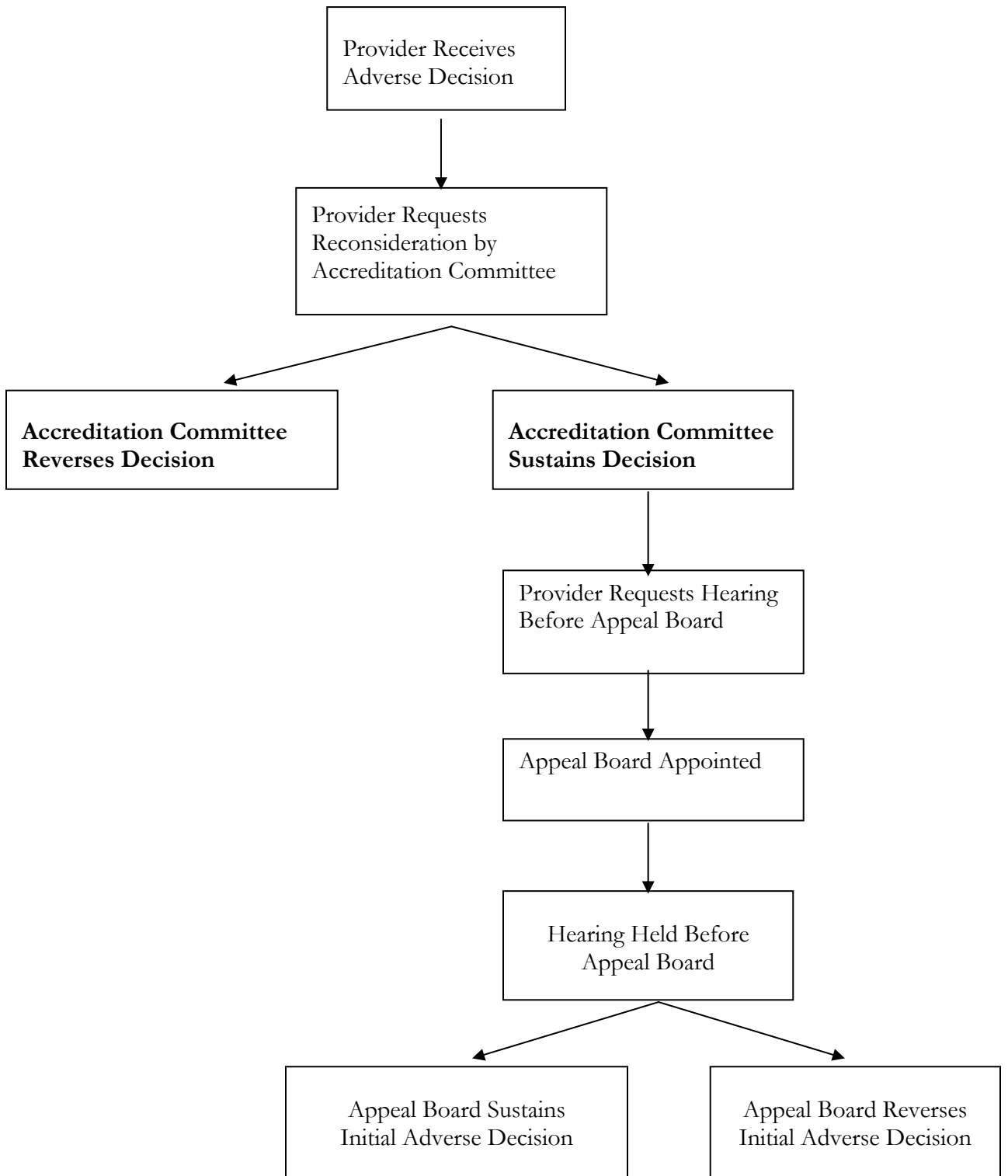
Adopted October 10, 2001, UMA Accreditation Committee

Approved February 6, 2002, UMA Board of Trustees

Modified June 8, 2005, UMA Accreditation Committee

Approved June 15, 2005, UMA Executive Committee

**UMA Procedures Algorithm for Reconsideration and Appeal of Adverse CME Accreditation Decisions**



## APPENDIX B

### PROCEDURE FOR COMPLAINTS AGAINST ACCREDITED PROVIDERS

The Utah Medical Association Accreditation Committee (Accreditation Committee) expects all accredited providers to comply with its requirements throughout their terms of accreditation. When the Accreditation Committee receives information (complaint/inquiry/data) that suggests that one of its providers may not be in compliance with the Essential Areas, their Elements, or Accreditation Policies, it will make every effort to investigate the complaint. The following is a guide for handling complaints/inquiries received by the Accreditation Committee that suggest an accredited provider may not be in compliance with UMA Essential Areas, their Elements, or Accreditation Policies with regard to one or more of its activities.

- I. To receive formal consideration, all complaints must be submitted in writing and signed. The statute of limitation of the length of time during which an accredited provider must be accountable for any complaints/inquiries received by the Accreditation Committee is twelve months from the date of the activity, or in the case of a series, twelve months from the date of the activity that is in question. The length of time for a provider to be accountable for an Enduring Material will be one year past the third year of current review.
- II. Accreditation staff, in consultation with the Accreditation Committee chairperson, will review the complaint/inquiry to determine whether it relates to the manner in which the provider complies with Essential Areas, their Elements, or Accreditation Policies.
  - A. The confidentiality of the complaining/inquiring party shall be protected.
  - B. If the complaint/inquiry is judged not to be related to compliance with Essential Areas, their Elements, or Accreditation Policies, the person initiating the complaint will be notified as such by accreditation staff.
  - C. If the complaint inquiry is judged to be related to compliance with Essential Areas, their Elements, or Accreditation Policies, accreditation staff will notify the person initiating the complaint of the planned course of action.
- III. If the complaint/inquiry is judged to be related to compliance with Essential Areas, their Elements, or Accreditation Policies, accreditation staff will send a Letter of Inquiry to the provider via certified mail describing the nature of the complaint/inquiry. The Letter of Inquiry will request a response in which the provider can offer its interpretation of how it complies with the Essential Areas, their Elements, or Accreditation Policies. The provider's response must be received by the Accreditation Committee within thirty days after the provider receives the Letter of Inquiry. The provider's response must be accompanied, where possible, by supporting documentation.
  - A. If a provider fails to respond to a request for information, the Accreditation Committee, upon recommendation from the Accreditation Committee chairperson, may require an immediate full or focused on-site survey and/or change the provider's accreditation status to probation.

B. Upon receipt of the provider's response, the accreditation staff, in consultation with the Accreditation Committee chairperson, shall determine whether additional information is necessary and may request such information from the provider. When staff determines that the information submitted is adequate, one of two courses of action may be taken:

1. The inquiry will be processed by accreditation staff if, in the opinion of staff, it is of a clear and uncomplicated nature. Staff will refer to a list generated by the ACCME's Accreditation Review Committee (ARC) that identifies issues that tend to be clear and uncomplicated. Staff will review the materials and make a recommendation for action. The recommendation will be placed on a consent agenda to be presented to the Accreditation Committee for ratification.
2. The inquiry will be sent to two members of the Accreditation Committee if it is not a clear and uncomplicated issue. Those members will review the materials and communicate one single recommendation in writing to the accreditation staff. The recommendation will be placed on the agenda to be presented to the Accreditation Committee for discussion.
  - a. If the two reviewers do not agree on a recommendation, a conference will be held among the reviewers, the Accreditation Committee chairperson, and accreditation staff. If consensus is achieved, the recommendation will be presented to the full Accreditation Committee for discussion. If no consensus can be achieved, the full committee shall discuss the issue. Staff will provide a summary report to the committee for this discussion.
  - b. The members of the review team, the chairperson of the Accreditation Committee, or the full committee may request additional materials from the provider if they determine that the materials they have are insufficient to allow them to render a recommendation.

IV. The Accreditation Committee, based on its review, will make the final determination. The following are the possible determinations:

A. Notice of Compliance

1. From the documentation submitted, the Accreditation Committee has determined that the provider appears to be in compliance with Essential Areas, their Elements, or Accreditation Policies regarding the issues presented.
2. The information will be filed and the Letter of Inquiry and decision letter to the provider will be included in the next review.

B. Notice of Non-Compliance

1. From the documentation submitted, the Accreditation Committee has determined that the provider is not in compliance with the Essential Areas, their Elements, or Accreditation Policies regarding the issues presented.

2. Areas of non-compliance will be enumerated in the decision letter to the provider which, along with the Letter of Inquiry and the provider's response, will be placed in the provider's file and will be made available to the survey team at the next review.
  3. The provider will be asked to provide documentation of corrective action to the Accreditation Committee within thirty days of receipt of the Notice of Non-Compliance, and will be notified that failure to correct the deficiencies may result in an immediate resurvey which may affect the provider's accreditation status.
    - a. Accreditation staff will review the notice of corrective action for adequacy and will summarize and present the notice to the Accreditation Committee. If the response is adequate, it will be kept in the provider file to be included in its next review. If the response is inadequate, the Accreditation Committee may request additional information or may request an immediate resurvey and/or change in accreditation status to probation.
    - b. If a provider fails to respond to a request for a notice of corrective action, the Accreditation Committee may request an immediate on-site survey and/or change in accreditation status to probation.
  4. In addition, the provider may, at the recommendation of the Accreditation Committee, be required to submit a Monitoring Report at a time determined by the Accreditation Committee, and will be notified that failure to respond or to correct the deficiencies may result in an immediate resurvey which may affect the provider's accreditation status.
    - a. Accreditation staff, in consultation with the Accreditation Committee chairperson, will review the provider's Monitoring Report and determine its adequacy.
      - i. If the Report is adequate, staff will recommend its acceptance. The recommendation will be presented to the Accreditation Committee for discussion and concurrence. The Report will be kept in the provider file to be included in its next review.
      - ii. If the Report is inadequate, the Accreditation Committee may request additional information or may request an immediate resurvey and/or change in accreditation status to probation.
    - b. If a provider fails to respond to a request for a Monitoring Report, the Accreditation Committee may request an immediate on-site survey and/or change in accreditation status to probation.
- V. The Accreditation Committee may request at any time to review notices of corrective action (see paragraph IV.B.3) and Monitoring Reports from the provider in addition to reports from staff.
- VI. The Accreditation Committee will intervene by affecting the accreditation status of a provider only when it identifies practices and conditions that indicate that a provider is not in compliance with the Essential Areas, their Elements, or Accreditation Policies.

VII..Complaints/inquiries from the ACCME regarding UMA-accredited providers will be handled as if the ACCME were any other individual or party. Full identification of the party making the complaint/inquiry to the ACCME will be required in all cases.

Approved June 2005 UMA Accreditation Committee

## APPENDIX C

### GUIDELINES AND CRITERIA FOR CME CONSORTIA

The Utah Medical Association's Committee on CME Accreditation has adopted the following guidelines and criteria for consortia as a supplement to the Essential Areas and Policies. A CME mission with common goals to be accomplished by the consortium's overall CME program must be established. The CME mission should be developed jointly by representatives of all member organizations and approved by each member organization. In addition to a common CME mission, a formal written contract or letter of agreement must be signed by each member organization. The contract must clearly define the following:

- Consortium membership criteria
- Responsibilities of member organizations
- The consortium structure and operational policies
- Financial obligations of member organizations
- Agreement to abide by the UMA Essential Areas and Policies

Accreditation will be granted based on the specific member organizations and structure as defined at the time of the accreditation review. Additions or changes in consortium member organizations or structure constitute a major change to the overall program and must be reported to UMA. Decisions to resurvey the consortium as a new program will be based on the nature and scope of the reported changes.

Centralized procedures and established methods to identify, prioritize and share needs assessment data among member organizations should be established. To the extent possible, patient care and quality improvement data from component facilities should feed into the central CME committee for use in overall program planning as well as for development of activities within member facilities.

In a consortium accreditation, the overall program is defined as the composite of individual activities and services which are provided by member organizations whether they be initiated centrally or from member facilities. Annual review of the overall program, and its accomplishment of the consortium's CME mission, must be conducted within the context of the consortium-wide overall CME program. Ideally, the central office, with direction from the CME committee, should establish standard methods and formats for the evaluation of individual activities to aid in eventual evaluation of the overall program. The overall program must be directed and administered through a centralized committee and staff who have clearly defined responsibility and authority for operation of the overall program.

A consortium must clearly demonstrate that its CME committee identifies the needs of potential participants, determines the target audience, develops objectives, selects faculty, evaluates, and fully manages the overall program. The committee may not merely function as a clearinghouse for approval of activities generated by its member organizations. A well structured and well functioning central CME committee will have:

- Appropriate representation from each member of the consortium
- Clearly defined authority for control of the program's operation at both the central and member organization levels
- Procedures and policies which allow the committee to establish priorities and evaluate and approve the development of activities within the context of available resources and the consortium's CME mission.

An application or other procedures which merely provide for approval of activities after they have been planned within a respective facility does not constitute appropriate control of the program. While member organizations may require CME subcommittees within the respective facility, these committees should be integral components of the central committee and the chairman should actively serve on the central committee as the facility's representative. This structure will allow input from each member to assure that needs identified within the organizations are adequately met and will assure that all activities are developed within the context of the consortium's goals and mission as a whole.

Centralized staffing and resources must be adequate to provide appropriate oversight and control of program planning and implementation within the consortium. A well structured and well functioning central CME office will have:

- Sufficient personnel to meet with component planning committees within the consortium facilities, provide ongoing oversight of compliance with the Essential Areas, and maintain the documentation required for program files
- Established procedures for central control and approval of all commercial support for CME activities within the system
- Appropriate procedures for training and supervision of staff to whom CME duties are delegated within component facilities and defined back-up procedures for continuity during staffing changes
- A well organized system of communication between component facilities
- Procedures and policies to maintain financial accountability for the overall CME program, including budgets and financial statements for component facilities
- Procedures and policies to maintain centralized attendance records for all activities held by the consortium

## APPENDIX D

### GUIDELINES AND CRITERIA FOR SYSTEM/MULTI-FACILITY ACCREDITATION

In today's changing environment, health care entities may find it more practical and cost effective to establish CME programs on a system-wide rather than an individual facility basis. System accreditation may make it more practical to provide CME activities to physicians practicing in rural or small hospital settings as well as facilitate more effective utilization of educational resources.

To assist organizations in meeting the Essential Areas and Policies in the development and operation of a system-wide or multi-facility CME program, Utah Medical Association's Accreditation Committee has adopted the following criteria as a supplement to the Essential Areas and Policies.

*Essential Area 1:* A common CME mission with system-wide goals to be accomplished through implementation of a centrally coordinated overall CME program must be established. The CME mission should be approved by each facility with final approval by a governing body to which all facilities in the system are accountable.

*Essential Area 2:* Centralized procedures and established methods to identify, prioritize and share needs assessment data throughout the system must be established. Patient care and quality improvement data from component facilities should feed into the central system for use in overall program planning as well as for use in developing activities within individual facilities. In a system accreditation, the overall program is defined by the individual activities and services which are provided throughout the system, whether they are initiated centrally or from facilities within the system. Therefore, annual review of the overall program, and its accomplishment of the system's CME mission, must be conducted within the context of the system-wide program. Ideally, the central office, with direction from the CME committee, should establish standard methods and formats for the evaluation of individual activities to aid in eventual evaluation of the overall program.

*Essential Area 3:* The overall program must be directed and administered through a centralized committee and staff who have clearly defined responsibility and authority for operation of the overall program. The CME committee must be actively involved in development of the overall program. The committee may not merely function as a clearinghouse for indiscriminate approval of activities generated by component facilities in the system. A well-structured and well functioning central CME committee will have:

- Appropriate representation from facilities in the system
- Clearly defined authority for control of the program's operation at both the system and local facility levels
- Procedures and policies which allow the committee to establish priorities and evaluate and approve the development of activities within the context of available resources and the system's CME mission.

An application or other procedures which merely provide for approval of activities after they have been planned within a respective facility does not constitute appropriate control of the program. While component facilities may require CME subcommittees within the respective facility, these committees should be integral components of the central committee and the chairman should actively serve on the central committee as the facility's representative. This structure will allow input from each component to assure that needs identified within the facilities are adequately met and will assure that all activities are developed within context of the system's goals and mission as a whole. Centralized staffing and resources must be adequate to provide hands-on daily oversight of program planning and implementation within the system. A well structured and well functioning central CME office will have:

- Sufficient personnel to meet with component planning committees within the system facilities, provide ongoing oversight of compliance with the Essential Areas and Their Elements and Accreditation Policies, and maintain the documentation required for program files
- Established procedures for central control and approval of all commercial support for CME activities within the system
- Appropriate procedures for training and supervision of staff to whom CME duties are delegated within component facilities and defined back-up procedures for continuity during staffing changes
- A well organized system of communication between component facilities
- Procedures and policies to maintain financial accountability for the overall CME program, including budgets and financial statements for component facilities
- Procedures and policies to maintain centralized attendance records for all activities held within the system.

## APPENDIX E

### ACCREDITATION GLOSSARY

**Accredit:** To recognize or certify an organization or institution as having met certain CME accreditation standards. Only accreditors, such as the ACCME or recognized state medical societies, are authorized to accredit. Accreditors accredit only organizations or institutions, never CME activities.

**Accreditor:** An organization with the authority to accredit. The Utah Medical Association is “recognized” by the ACCME as the accrediting body for intrastate providers in Utah.

**Accreditation:** The decision by the ACCME or a recognized state medical society that an organization has met the requirements for a CME provider as outlined by the ACCME or the recognized state medical society. The standard term of accreditation is four years.

**Accreditation Council for Continuing Medical Education (ACCME):** The ACCME sets the standards for the accreditation of all providers of CME activities. The ACCME has two major functions: the accreditation of providers whose CME activities attract a national audience and the recognition of state or territorial medical societies to accredit providers whose audiences for its CME activities are primarily from that state/territory and contiguous states/territories. The ACCME’s seven member organizations are the American Board of Medical Specialties (ABMS), the American Hospital Association (AHA), the American Medical Association (AMA), the Association of American Medical Colleges (AAMC), the Association for Hospital Medical Education (AHME), the Council of Medical Specialty Societies (CMSS), and the Federation of State Medical Boards of the U.S., Inc. (FSMB).

**Accreditation Decisions:** The types of accreditation offered and made by the ACCME, or a state medical society, to accredited providers. They include accreditation with commendation, accreditation, probationary accreditation, provisional accreditation and non-accreditation.

**Accreditation Requirements:** A short-hand reference to the *Essential Areas and Their Elements*, *Decision-Making Criteria*; the *Standards for Commercial Support*; and all Accreditation Policies related to the accreditation process and maintenance of accreditation.

**Accreditation Review Committee (ARC):** The Accreditation Review Committee, a working committee of the ACCME, collects, reviews, and analyzes data from multiple sources about compliance with ACCME Essential Areas Elements and Policies; notes program improvements; and makes a recommendation to the ACCME for their final decision about accreditation of an applicant/provider.

**Accreditation Statement:** The standard statement that must be used by all accredited institutions and organizations. There are three different statements that might be used depending on the number and relationships of the organizations involved in planning and implementing the activity:

Directly sponsored activity -- An activity planned and implemented by an ACCME or state medical society accredited provider of CME.

*The (name of the accredited provider) is accredited by Utah Medical Association to provide continuing medical education for physicians.*

Jointly sponsored activity -- An activity planned and implemented by one ACCME or state medical society accredited provider working in partnership with a non-accredited entity. The accredited provider must ensure compliance with the Accreditation Requirements and therefore take responsibility for the activity as indicated in the accreditation statement.

*This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of (name of accredited provider) and (name of non-accredited provider). The (name of accredited provider) is accredited by the UMA to provide continuing medical education for physicians.*

CME activities that are co-sponsored should use the directly sponsored activity statement, naming the one accredited provider that is responsible for the activity.

**Accreditation Survey:** A form of data collection by the ACCME or recognized state medical society that includes a review of the organization (structure, administration, mission, relationships), documentation, and activities. The survey can be conducted in one of three ways: *on site*, which is in-person at the site of the accredited institution/organization, or its activity; *face-to-face*, which is in-person, usually at the offices of the accrediting body; or through a *televideo* conference. Its purpose is to gather data about who is responsible for the CME program and activities, how documentation is accomplished, and how well the Accreditation Requirements are applied.

**Accreditation with Commendation:** The decision by the ACCME or a recognized state medical society that an organization has met all the Criteria for Compliance with the Accreditation Requirements. The standard term of accreditation with commendation is six years.

**Activity:** An educational event for physicians, which is based upon identified needs, has a purpose or objectives, and is evaluated to assure the needs are met.

**Activity Review:** The form of data collection that allows the accreditor to observe an activity and document compliance with the requirements for accreditation.

**American Board of Medical Specialties (ABMS):** The ABMS is a member organization of the Accreditation Council for Continuing Medical Education. The ABMS nominates two individuals for election to the Board of the ACCME.

**American Hospital Association (AHA):** The AHA is a member organization of the Accreditation Council for Continuing Medical Education. The AHA nominates two individuals for election to the Board of the ACCME.

**American Medical Association (AMA):** The AMA is a member organization of the Accreditation Council for Continuing Medical Education. The AMA nominates two individuals for election to the Board of the ACCME.

**Annual Report:** Data collection by the ACCME that requires an annual submission of data from each accredited provider and allows the ACCME to monitor changes in an individual accredited provider's program and within the population of accredited providers.

**Association for Hospital Medical Education (AHME):** The AHME is a member organization of the Accreditation Council for Continuing Medical Education. The AHME nominates two individuals for election to the Board of the ACCME.

**Association of American Medical Colleges (AAMC):** The AAMC is a member organization of the Accreditation Council for Continuing Medical Education. The AAMC nominates two individuals for election to the Board of the ACCME.

**Commercial Bias:** A personal judgment in favor of a specific proprietary business interest of a commercial interest.

**Commercial Interest:** 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 services directly to patients to be commercial interests. A commercial interest is not eligible for accreditation.

**Commercial Support:** Financial or in-kind contributions given by a commercial interest which is used to pay all or part of the costs of a CME activity. The definition of roles and requirements when commercial support is received are outlined in the Standards of Commercial Support (Element 3.3)

**Committee for Review and Recognition (CRR):** The Committee for Review and Recognition, a working committee of the ACCME, recognizes state, or territorial, medical societies to accredit providers whose target audience is restricted to that state, or territory, or contiguous state, or territories. The CRR makes the determination of compliance about recognition on behalf of the ACCME. To be recognized by the ACCME, a state, or territorial, medical society (SMS) must meet the requirements for recognition as determined by the ACCME.

**Compliance:** The provider is meeting the standard of practice for the judged accreditation requirement.

**Conflict of Interest:** When an individual's interests are aligned with those of a commercial interest, the interests of the individual are in "conflict" with the interests of the public. 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 potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias.

**Continuing Medical Education (CME):** 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, appreciation of literature or music, or parent effectiveness, are not CME.

**Cosponsored Activity:** A CME activity that is presented by two or more accredited providers. One accredited provider must take responsibility for the activity

**Council of Medical Specialty Societies (CMSS):** A member organization of the Accreditation Council for Continuing Medical Education. The CMSS nominates two individuals for election to the Board of the ACCME.

**Credit:** The “currency” assigned to hours of CME activities. Requirements for the designation of credit are determined by the organization responsible for the credit system, e.g., AMA-PRA (Category 1 and 2 Credit); AAFP (Prescribed and Elective Credit); ACOG (Cognates); AOA (Category 1-A, 1-B, 2-A, and 2-B Credit). Please refer to those organizations for details about the specific requirements for assigning credit.

**Criteria:** The set of performance expectations, corresponding to the Essential Areas and Elements, required of an accredited provider.

**Designation of CME Credit:** The declaration that an activity meets the criteria for a specific type of credit. In addition, designation relates to the requirements of credentialing agencies, certificate programs or membership qualifications of various societies. The accredited provider is responsible to these agencies, programs and societies in the matter of designation of credits and verifications of physician attendance. NOTE: The designation of credit for specific CME activities is not within the purview of the ACCME or the state medical associations as accrediting bodies.

**Documentation Review:** The form of data collection that allows the ACCME or recognized state medical society to verify that compliance with the accreditation requirements has been met within a specific activity. This review occurs during an accreditation survey.

**Enduring Materials:** Enduring materials are printed, recorded or computer assisted instructional materials which may be used over time at various locations and which in themselves constitute a planned CME activity. Examples of such materials for independent physician learning include programmed texts, audio-tapes, videotapes and computer assisted instructional materials which are used alone or in combination with written materials.

**Essential Areas and Elements:** ACCME's accreditation requirements are outlined in the Essential Areas and Elements. Compliance with the Essential Areas and Elements is determined by the extent to which a provider meets the Criteria.

**Faculty:** The speakers or education leaders responsible for communicating the educational content of an activity to a learner.

**Federation of State Medical Boards of the U.S., Inc. (FSMB):** A member organization of the Accreditation Council for Continuing Medical Education. The FSMB nominates two individuals for election to the Board of the ACCME.

**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. ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.

**Focused Accreditation Survey:** A specially arranged survey of a provider to collect data about a specific problem that has been reported or has not been corrected as a result of a progress report.

**Joint Sponsorship:** Sponsorship of a CME activity by two institutions or organizations when only one of the institutions or organizations is accredited. The accredited provider must take responsibility for a CME activity when it is presented in cooperation with a non-accredited institution or organization and must use the appropriate accreditation statement. A commercial interest cannot take the role of non-accredited entity in a joint sponsorship relationship.

**Monitoring:** Data collection which allows the ACCME or recognized state medical society to note changes in the program of CME between formal accreditation reviews. These data are collected in the annual reports required of each provider and/or in the pursuit of a compliant/inquiry about a specific CME activity.

**Needs Assessment/Data:** A process of identifying and analyzing data that reflects the need for a particular CME activity. Needs assessment data provide the basis for developing learner objectives for the CME activity.

**Non-accreditation:** The accreditation decision by the ACCME or recognized SMS that an organization has not demonstrated compliance with the standards for a CME provider as outlined in the Accreditation Requirements.

**Noncompliance:** The provider is not meeting the standard of practice for the judged for the judged accreditation requirement.

**Objectives:** Statements that clearly describe what the learner will be able know or do after participating in the CME activity. The statements should result from the needs assessment data.

**Organizational Framework:** The structure (organizational chart), process, support and relationships of the CME unit that are used to conduct the business of the unit and meet its mission.

**Parent Organization:** An outside entity, separate from the accredited provider, that has control over the funds, staff, facilities, and/or CME activities of the accredited provider.

**Participant:** An attendee, primarily physicians, at a CME activity.

**Planning Process(es):** The method(s) used to identify needs and assure that the designed educational intervention meets the need(s) and produces the desired result.

**Probation:** The accreditation decision by the ACCME or recognized SMS that an accredited provider has not met all the standards for a CME provider as outlined by the Accreditation Requirements. The accredited provider must correct the deficiencies to receive a decision of accreditation. While on probation, a provider may not jointly sponsor new activities.

**Program of CME:** The CME activities and functions of the provider taken as a whole.

**Progress Report:** A report prepared for the ACCME or recognized SMS by the accredited provider communicating changes in the provider's program to demonstrate compliance with the Elements that were found in partial compliance or non-compliance during the most recent accreditation review.

**Provider:** The institution or organization that is accredited to present CME activities.

**Provisional Accreditation:** The accreditation decision by the ACCME or recognized SMS that an initial applicant for accreditation has met the standards for a CME provider as outlined by the Accreditation Requirements.

**Recognition:** The process used by the ACCME to approve state medical societies as accreditors of intrastate providers.

**Regularly Scheduled Conferences:** See Regularly Scheduled Series.

**Regularly Scheduled Series (RSSs):** A daily, weekly, monthly or quarterly CME activity that is primarily planned by and presented to the accredited provider's professional staff. RSSs also are referred to as Regularly Scheduled Conferences (RSCs).

**Relevant Financial Relationships:** The ACCME and recognized SMSs focus on financial relationships with commercial interests in the twelve-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines "relevant financial relationships" as financial relationships in any amount occurring within the past twelve months that create a conflict of interest.

**Self Study Report:** A report of data and observations collected the accredited provider to document its accomplishments, assess areas where improvements may be necessary, and outline a plan for making those improvements.

**Standards for Commercial Support<sup>(SM)</sup>:** Standards to ensure independence in planning and implementing CME activities.

**Supporter:** See Commercial Interest

## APPENDIX F

### RESOURCES AND INFORMATION

#### **Accreditation Council for Continuing Medical Education (ACCME)**

515 North State Street, Suite 1801  
Chicago, IL 60654  
Phone: (312) 527-9200  
Website: [www.accme.org](http://www.accme.org)

The Accreditation Council for Continuing Medical Education (ACCME) was organized to promote and develop principles, policies, and standards for continuing medical education and to apply them to the accreditation of institutions and organizations offering continuing medical education. The ACCME accredits institutions and organizations offering continuing medical education on a national basis and develops standards by which state medical societies accredit local institutions and organizations.

#### **Alliance for Continuing Medical Education (ACME)**

Southcrest Building, Suite 105  
1025 Montgomery Highway  
Birmingham, AL 35216  
Phone: (205) 824-1355  
Fax: (205) 824-1357  
Website: [www.acme-assn.org](http://www.acme-assn.org)

The Alliance for Continuing Medical Education (ACME) is an international professional association with over 1000 members concerned exclusively with CME. It was founded in 1975 to serve as a forum in which both experienced and novice practitioners of CME could continue their own education about the art and science of adult learning and learn to incorporate emerging technology in the programs for which they are responsible.

#### **American Medical Association (AMA)**

Division of Continuing Physician Professional Development  
515 North State Street  
Chicago, IL 60610  
Phone: (312) 464-4664  
Website: <http://www.ama-assn.org/ama/pub/education-careers/continuing-medical-education.shtml>

Improving the quality of medical education has been a major goal of the American Medical Association (AMA) since its founding in 1847. The PRA Division responds to the lifelong learning needs of physicians by facilitating the AMA's CME policy activities and conducting national CME conferences. The Division also maintains a comprehensive data base on continuing medical education opportunities for physicians sponsored by accredited institutions.

## APPENDIX G

### American Medical Association Ethical Opinion 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)

### **Clarification of 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, i.e., 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, pre-selection 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 (e.g., 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.

Report: 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.

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## APPENDIX H

### American Medical Association Ethical Opinion 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)

Report: Issued December 1993; Updated June 1996

## APPENDIX I

### PhRMA's Code on Interactions with Healthcare Professionals

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. PhRMA recently revised its voluntary code of conduct on relationships with healthcare professionals.

To download a copy of PhRMA's *Code on Interactions with Healthcare Professionals*, go to <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>. Section 4 deals specifically with pharmaceutical support for continuing medical education.