

# Hawaii Consortium for Continuing Medical Education

*A joint venture between  
the Hawai'i Medical Association  
and  
the John A. Burns School of Medicine  
University of Hawai'i*

## **Handbook of Policies and Procedures for Sponsorship of Continuing Medical Education Activities**

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This document includes a compilation of material developed by the Accreditation Council for Medical Education, the American Medical Association and many ACCME accredited providers. Sources are referenced with the Handbook.

The handbook is designed to serve as a working guide. Please note that the information and procedures are subject to change.

References: ACCME at [www.accme.org](http://www.accme.org)  
AMA PRA, 2006 revisions at [www.ama-assn.org/go/cme](http://www.ama-assn.org/go/cme)

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## **The Hawaii Consortium for Continuing Medical Education Program of Continuing Medical Education**

The Hawaii Consortium for Continuing Medical Education (HCCME), a joint venture between the Hawaii Medical Association and the John A. Burns School of Medicine, University of Hawai'i, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. As an accredited provider, the HCCME has adopted and conducts a program of CME in compliance with the ACCME Essential Areas & Elements, Standards for Commercial Support and ACCME Policies (available on the ACCME website: [www.accme.org](http://www.accme.org)).

Additionally, as an accredited provider, the HCCME may designate an activity for *AMA PRA Category 1 Credit*<sup>™</sup> provided the activity meets all accreditation standards and conforms to the AMA ethical opinions on Gifts to Physicians from Industry and on Ethical Issues in CME.

The three types of activities that may be certified or designated for *AMA PRA Category 1 Credit*<sup>™</sup> by the HCCME are directly sponsored, jointly sponsored, and co-sponsored.

1. Directly sponsored activities are planned, developed, presented and evaluated by a committee of the Hawaii Medical Association or a department, division, or office of the John A. Burns School of Medicine.

2. Jointly sponsored activities are planned, developed, presented, and evaluated with non-ACCME accredited providers.

3. Co-sponsored activities are planned, developed, presented and evaluated by two or more accredited providers working together. One of the accredited providers must ensure compliance with the ACCME Essentials, Policies and Standards and takes responsibility for the activity as indicated in the accreditation statement.

**MISSION STATEMENT**  
**of the**  
**Hawaii Consortium for Continuing Medical Education**

The mission of the Hawaii Consortium for Continuing Medical Education (HCCME) of the Hawaii Medical Association (HMA) and the John A. Burns School of Medicine (JABSOM) is to support the highest quality of patient care through appropriate and timely education and information about current and vital issues of medicine and medical practice for doctors of medicine and osteopathy in the State of Hawaii and Pacific Rim.

The scope of the CME program will focus on patient care, teaching, and research. The program will make an effort to continue communication with and assess the needs of the target audience. The educational programming will be based on sound educational principles. Additionally, the physician education mission of appropriate collaborators will be supported through joint sponsorship.

To accomplish this mission, the format of activities presented may use new and innovative technology and may include but is not limited to: lecture/discussion, small group presentations, annual symposia, panel discussions, workshops, departmental and interdepartmental scientific meetings, grand rounds, conferences, tutorials, and neighbor island outreach activities. The educational activities will provide opportunities for participants to: review the basic medical sciences and their application to clinical medicine; learn new knowledge and technology; master specific skills and techniques; and improve professional performance. The effectiveness of the program will be evaluated in terms of changes in competence, performance, or patient outcomes.

Revised September 19, 2001, HCCME

Approved October 19, 2001, John A. Burns School of Medicine Executive Committee

Adopted November 16, 2001, Hawaii Medical Association House of Delegates

Reaffirmed January 15, 2003, HCCME

Reaffirmed January 19, 2005, HCCME

Reaffirmed January 18, 2006, HCCME

\*Revised May 16, 2007, HCCME

Adopted September 14, 2007, Hawaii Medical Association House of Delegates

Approved January 18, 2008, John A. Burns School of Medicine Executive Committee

*\*Revised to include ACCME Updated Accreditation Criteria related to the mission statement: The effectiveness of the program will be evaluated in terms of changes in competence, performance, or patient outcomes*

## Introduction to Continuing Medical Education

### **The American Medical Association definition of 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. [AMA House of Delegates policy #300.988].

**The Accreditation Council for Continuing Medical Education** describes what content is acceptable for activities that are certified for credit. 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 need or interest such as personal financial planning or appreciation of literature or music, are not CME.

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

### **Content Validation, ACCME policy 2002-B-09**

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

### **The Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support - Standards to Ensure Independence in CME Activities**

The ACCME Standards were designed to ensure independence in CME activities. The standards describe appropriate behavior of accredited providers in planning, designing, implementing, and evaluation certified CME activities for which commercial support is received. As an accredited provider, the Hawaii Consortium for Continuing Medical Education has agreed to follow all policy and procedures as specified by the ACCME. A copy of the Standards is provided in the HCCME Policy and Procedure Handbook.

## Overview of the Application Process for Credit Designation

The application for credit designation of a specific CME activity and appropriate fees should be submitted for committee review and action at least **90 days in advance** of the scheduled start date of the activity to allow adequate time for processing and review. Committee meetings are generally held once monthly. The complexity of the proposed activity, scope of the audience, and deadlines for brochure production, mailing, and print ads often determine when the application is submitted and presented to the committee. Retroactive credit designation is not provided.

**Unauthorized announcements:** While the application is in process, print announcements and electronic postings may **not** be disseminated without prior approval of the HCCME. The ACCME has specific policy regarding the content of program announcements. To ensure compliance with the requirements, the HCCME must review and approve drafts of **all** announcements, brochures, flyers, electronic postings, “save the date notices”, etc. prior to final production. Advance program announcements may not include phrases such as “CME applied for”, “CME pending” or “CME approved”. The CME accreditation and designation statements may not be displayed until the activity has been approved for credit designation. Unauthorized print or electronic publications will invalidate any possibility of credit designation.

HCCME staff is available to review preliminary drafts of the application. The formal presentation will take place at a regularly scheduled monthly meeting of the HCCME. At that time, the physician activity chairperson is to be present to discuss the planning process and answer questions.



## Program Planning, Implementation & Evaluation Checklist

### HCCME Mission

- The activity supports the mission of the HCCME.

### Definition of CME

- The content of the activity conforms with the AMA definition of CME.

### Needs Assessment & Identification

- The need for the activity is documented.
- The practice gaps have been identified.
- A diversity of sources is expected to be used to produce an effective needs assessment.

Sources include:

- continuous quality improvement issues
- evaluations from previous activities
- committee notes
- surveys
- research
- health policy issues
- incident reports
- journal articles
- patient records & databases
- consensus of experts
- requests from the target audience
- government reports on health statistics
- technology developments

### Target Audience

- The physician target audience has been identified.

### Planning Group & Process

- The planning group resembles the make-up of the target audience.
- A planning process is in place and evidence of physician involvement is present.
- The planning process includes information from previous program evaluations.

### Purpose or Program Objectives

- The purpose or objectives of the activity supports the educational design of the program.
- A plan to communicate the purpose or objectives of the program to the learner prior to participating in the activity is in place.

### Learning Objectives (see 'Objectives' for details)

- Objectives address the identified needs/practice gaps.
- Objectives are learner focused and describe what the attendee will have the opportunity to acquire as a result of attending the program.
- Objectives are measurable.

### Evaluation

- A plan to evaluate the effectiveness of the activity in terms of changes in competence, performance, or patient outcomes is in place.
- The results are summarized in writing, passed on to the faculty for their information and presented to future planning committees that involve similar topic areas.

### **Program Content and Schedule**

- The topics reflect the activity purpose or objective.
- The topics are appropriate for the target audience.
- The schedule is appropriate for the content and learning objectives.
- The schedule includes opportunities for interaction between attendees and faculty.
- The schedule includes opportunities for interaction between attendees.
- The topics and schedule include opportunities for the attainment of objectives.

### **Social Events at the CME Activity**

- Time devoted to the social event is less than the time devoted to the educational activity.
- The cost is less than \$100.00 per attendee.
- The event is open to all attendees.
- The event is not made a major highlight of the promotional brochure.
- The event is planned to increase interaction and communication among the attendees or between the faculty and the attendees.

### **Pre-requisites**

- Pre-requisites have been identified and made known to the prospective learner.

### **Faculty**

- Faculties are recognized as experts and are good speakers.
- School of Medicine clinical and basic science faculties are included.

### **Legal Obligations**

- The activity is in compliance with the Americans with Disabilities Act (ADA).
- The activity is in compliance with the copyright act.

### **Commercial Support & Disclosure**

- The activity is in compliance with the ACCME Standards for Commercial Support of CME.
- All individuals in the position to influence content of the activity have disclosed relevant financial relationships with commercial interests that have occurred within the past 12 months. ACCME considers relationships of a person involved in the CME activity to include financial relationships of a spouse or partner.
- Conflicts of interests have been identified.
- Conflicts of interested have been resolved.
- Letters of Agreement Regarding the Terms and Conditions of an Educational Grant are executed.
- The activity is in compliance with the AMA opinions on Gifts to Physicians from Industry.
- A mechanism to acknowledge commercial support to the learners, prior to the start of the activity, is in place.

### **Promotional Materials**

- All promotional materials (including save the date announcements, registration brochures, advertisements and web copy) must be submitted to the HCCME for approval prior to distribution. (see 'Brochures' for details).
- The HCCME must confirm that the required elements are appropriately listed in these materials.

### **Course Materials (Syllabus/Handouts):**

- All course materials must be submitted to the HCCME for approval prior to distribution.

The following should appear early in the course materials:

- Statement of need
- Intended Audience
- Learning Objectives
- Accreditation Statement
- Credit Designation Statement (with italics)
- Written disclosure of planning group and faculty relationships with commercial interests (place before the faculty's materials appear in the syllabus)
- Written disclosure of speakers intent to discuss unlabeled or unapproved uses of drugs and devices (place before the faculty's materials appear in the syllabus)
- Course content/Agenda
- Listing of planning group
- List of faculty with qualifications
- Acknowledgement of commercial support and other support
- Copyright permission statements are appropriate listed with the materials.
- Instructions on how to claim credit.

### **Budget**

- The proposed budget reflects a sound financial basis for the program.
- The proposed budget includes a line item for ADA accommodations.
- At the completion of the activity an accounting of income and expenses must be submitted to the HCCME.

### **Post-Activity Report**

- The post-activity report is filed within 45 days of the conduct of the activity.

Post –Activity Checklist  
Due to HCCME within 45 days of the date of the CME activity

Name of Activity:

Type of Activity: ( ) Live ( ) Live Internet ( ) Enduring

Date(s):

- ( ) Copies of correspondence informing faculty of the learning objectives, disclosure requirements, and copyright rules.
- ( ) Executed faculty & planning committee disclosure statement(s).
- ( ) Executed letter(s) of agreement (commercial support)
- ( ) Copies of checks from commercial supporters
- ( ) Copies of checks representing speaker honoraria and reimbursement of expenses
- ( ) Attendance records. When an activity is held over the course of two or more days, the following are to be submitted: 1) original daily sign-in sheets and 2) compiled list sorted by total number of credits claimed.
- ( ) Learner Credit Claim Forms
- ( ) Teacher Credit Claim Forms
- ( ) Summary of program and speaker evaluations completed by CME eligible participants (MD's and DO's)
- ( ) Copies of correspondence to faculty documenting that feedback was provided
- ( ) 1 set - course syllabus or handouts
- ( ) Documentation of compliance with copyright rules.
- ( ) 3 - original program announcements, brochures, save the date cards, posters, and flyers
- ( ) 1 - printout of electronic postings of brochures, announcements, flyers, etc.
- ( ) Template for Credit Certificates (if issued)
- ( ) Template for Certificate of Attendance (if issued)
- ( ) Final financial statement

\*\*\*\*\*

For Internet/Enduring Materials Only:

\_\_\_\_\_ 2 copies of the Internet/Enduring Material documenting that the following required information was communicated to the learner:

- Principal faculty and their credentials.
- Medium or combination of media used.
- Method of physician participation in the learning process.
- Estimated time to complete the educational activity (the credit designation statement with number of credits designated fulfills this requirement).
- Date of original release.
- Date of the most recent review and update, or approval.
- Termination date (date after which enduring material is no longer certified)
- Commercial support is acknowledged at the beginning of the enduring material.
- Absence of product specific advertising of any type in the enduring material.

## **Activity Planning & Credit Designation Approval Process Directly Sponsored Activities**

All CME activities of the HCCME Program of CME must be developed in support of the HCCME mission and must meet the requirements of the ACCME *Essential Areas and their Elements and Standards for Commercial Support of CME*. Examples of CME activities include: scientific program of the Annual Meeting of the Hawaii Medical Association; regularly scheduled conferences such as department grand rounds; and topical conferences, such as "Medical Issues in HIV Care".

Departments, Divisions and Programs of the School of Medicine and committees of the Hawaii Medical Association are eligible to submit applications for HCCME direct sponsorship and credit designation. The following outlines the general planning, application, and approval process:

- JABSOM faculty or HMA member notifies the HCCME of the **intent** to plan and conduct a CME activity. It's never **too early** to make the initial telephone call. The planning, review, and approval process can be complex.
- A prescreening telephone interview is conducted to determine if the conditions for HCCME sponsorship are in order. If conditions are met, the planning process proceeds.

**Dissemination of unapproved print or electronically transmitted program announcements may invalidate any possibility of HCCME sponsorship and credit designation.**

- HCCME staff consults with physician chair or designee to review the requirements and timeline for HCCME sponsorship and credit designation. A representative of the HCCME may be appointed to serve as an active member of the program planning committee.
- The applicant notifies the HCCME when the application is ready for presentation to the HCCME CME sponsorship committee and requests that the matter be placed on the agenda of a regularly scheduled meeting of the HCCME (currently scheduled for the 3rd Wednesday of the month). The physician chairman and/or course director must be in attendance.
- The applicant sends the original and required number of copies of application, attachments, and application fee to the HCCME **at least 10 working days** in advance of the meeting date.

**Deadlines for application submission:** Since program announcements may not display any verbiage related to CME until the application has been reviewed and certified for credit, applicants may wish submit an application before the deadlines listed below to meet internal program announcement production and mailing deadlines.

- a) **9 - 12 months** prior to the date of the proposed activity for programs that are planned for a national audience;
- b) **no later than 90 days** prior to the date of the proposed activity for programs planned for a local audience;
- c) **at least 90 days** prior to the start of a regularly scheduled conferences series.

### **Application Review & Presentation scenario:**

- Hard copies of the applications are mailed to committee members in advance of the meeting.
- In the absence of the applicant, the committee holds a brief discussion about the application.
- The physician activity chair or course director is introduced and given an opportunity to make brief introductory remarks (1-3 minutes) prior to the Q/A session.
- Following the Q/A session, the applicant is excused from the room.
- The committee discusses the merits and/or deficiencies of the proposed activity and planning process.

### **Activity Approval**

The application for credit designation will be approved if the committee determines that the activity is consistent with the HCCME mission, has been developed in accordance with accreditation essentials and standards, conforms to AMA ethical opinions on Gifts to Physicians from Industry and on Ethical Issues in CME.

- the Chair of the HCCME calls for the vote.
- the committee appoints an observer to monitor the activity.
- the applicant is asked to return to the room and is informed of the action.
- the HCCME observer is appointed

### **Activity Non-Approval**

Applications for credit designation may be denied for the following reasons:

- unauthorized announcements or electronic postings are distributed prior to approval.
- insufficient time before program presentation.
- topics not within the AMA definition of CME.
- activity does not support the HCCME mission.
- activity does not address a physician audience in both the depth and scope of its content.
- insufficient physician representation on the planning committee
- insufficient planning involvement by physicians.
- needs assessment insufficient.
- insufficient plans for evaluating the effectiveness of the activity in terms of changes in competence, performance OR patient outcomes.

### **Action Deferred**

If the committee is unable to make a determination that the activity has been developed in accordance with accreditation guidelines due to an incomplete application, action may be deferred. The applicant will be given an opportunity to resubmit the application for reconsideration at the next regularly scheduled meeting.

**Post Activity Requirements:** A post activity report is due to the HCCME within 45 days of the activity. The checklist is provided in the appendix.

- HCCME CME sponsorship committee reviews the observer's report and summary of evaluations. Concerns (if any) are noted and forwarded to the activity chairperson.
- HCCME sends observer's report and final invoice for CME fees to the activity chairperson.

## Learning Objectives

Learning objectives communicate what a participant is expected to do in a practice setting with the information being taught. This is more than just a list of what the participant is expected to learn. Planners will want the participant to be able to **USE** the information they have learned. In other words, to show that learning has occurred, participants should **be able to demonstrate** that they have learned the subject material at hand.

Learning objectives must be included in all activity announcements so the prospective participant can evaluate the relevancy of the educational activity to his or her own CME needs.

**Note:** Because many CME planners have also taught at CME activities, they often think in terms of what the teacher of the activity will need to do during the CME activity. For example, the faculty member may have the teaching objective *"to review the symptoms of Type I diabetes in a school-age child."* In order to show that learning has occurred, the student of the teacher should be able to *"list or to describe the symptoms of Type I diabetes in a school-aged child"*. The focus here is on what the **learner can DO to demonstrate that learning has occurred**. Teachers should be able to **see** the learner **doing** something that relates to the learning that has occurred.

One way to write learner-centered, behavioral objectives is to picture what one of the participants will be able to do after attending the CME activity.

1. Begin writing:

At the conclusion of this CME activity, the learner will be able to:

1. **Do** this.
2. **Do** that.
3. **Do** a third thing.

2. Substitute "**Do**" with an action verb and object.

Example: for the activity described above, the learning objectives could be:

1. List four physician symptoms of a school-age child with undiagnosed Type I diabetes.
2. Describe the physical attributes of a school-age child with undiagnosed diabetes.
3. Cite or state ways in which a parent might explain behavior patterns of a school-age child with undiagnosed diabetes.

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Some verbs to **USE** in learning objectives:

apply	describe	identify	perform
analyze	develop	illustrate	prepare
arrange	diagnose	implement	recall
articulate	diagram	integrate	recognize
assess	discriminate	interpret	relate
categorize	discuss	list	report
classify	distinguish	manage	solve
compare	employ	name	summarize
construct	evaluate	outline	translate
create	explain	plan	update
demonstrate	formulate	predict	use

**AVOID** the following terms when writing learning objectives:

appreciate	become	increase	learn
approach	believe	internalize	understand
approach	improve	know	

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Example of adequate learning objectives:

The participant will be able to:

- **describe** current nutritional and pharmacologic techniques in the management of short bowel syndrome
- **implement** current guidelines in the use of PSA

Example of inadequate learning objectives:

The participant will be able to:

- **understand** new 80-hour work week rules
- **know** treatment plans related to cancer

3. Consider adding performance standards to the learning objective.

Wording that describes acceptable standards might include:  
in a fifteen-minute time period

- with no mistakes
- with 98% accuracy
- getting 22 out of 25 correct

4. Consider defining the criteria or conditions under which learning is to be demonstrated.

Wording that describes learning conditions might include:

- Given a problem of the follow type ...
- Without the use of any reference materials ...
- Using a specific instrument.

References:

Boonshoft School of Medicine, Wright State University, CME  
Southern Illinois University School of Medicine, CME  
Mount Carmel Health System, Ohio



## Evaluation

The ACCME's requirement for compliance with Element 2.4 calls for the HCCME to measure the effectiveness of the CME activity in meeting the identified educational need in terms of satisfaction, knowledge, or skills.

Evaluations can be simple or complex but should measure the process (method and quality of presentation) and the outcomes (how well the objectives were achieved). Ideally, evaluations should assess changes in the participants' *knowledge* of a topic, their *attitude* or willingness to employ a new technique, or their *skills* or ability to perform a technique.

Evaluation methods are to be appropriate and consistent in scope with the educational activity. Program planners are encouraged to make use of a variety of tools. The evaluation form is the most common tool. The form is completed by participants at the conclusion of the educational activity and can provide useful data for activity improvement and future programs.

Program planners may design their own evaluation form but the questions asked must address the following:

- The extent to which the educational objectives are met  
The educational objectives must be stated on the evaluation form
- The quality of the instructional process
- The quality of the content
- The value to the participant's medical practice
- Suggestions for future activities/Comments
- Any commercial bias conveyed by the presentation(s)  
Was the information presented without commercial bias?  
yes    no  
If no, describe
- Disclosure of presence or absence of relevant financial relationships with commercial interests  
Were you informed of planning committee and faculty/speaker financial relationships with commercial interests relative to this activity?  
yes    no  
If no, describe

For directly and jointly sponsored conferences:

A summary of the evaluations is passed on to faculty for their information, presented to future planning committee that involve similar topics, and submitted to the HCCME as part of the post-activity report. For repeat conferences, program planners are expected to use evaluations from previous activities for planning and program improvement purposes.

For regularly scheduled conference series:

The evaluation for each session is submitted to CME for data entry. A copy of the summary is returned to the department and the original filed with CME. The evaluation summaries are shared with the respective speakers and used to plan and improve future sessions. The overall activity is evaluated as part of annual report to the HCCME. Each department will determine the need for more frequent evaluation each regularly scheduled conference series.

HAWAII CONSORTIUM FOR CONTINUING MEDICAL EDUCATION  
APPLICATION FOR *AMA PRA CATEGORY 1 CREDIT*<sup>TM</sup> DESIGNATION  
PLEASE TYPE

**INSTRUCTIONS:**

- > Complete the planning form (if in Microsoft Excel, do not change any formats to ensure proper alignment of the form)
- > Request that the CME activity be placed on the agenda of a regularly scheduled meeting of the HCCME CME sponsorship committee.
- > **At least ten (10) working days prior to the meeting, submit:**
  - \* **Original and 21 copies (photocopied 2-sided, attachments numbered sequentially, stapled left corner)**
  - \* **Activity review fee of \$50.00 payable to "Hawaii Medical Foundation"**

**GENERAL INFORMATION:**

1) Check one:

HMA

JABSOM Department (list):

2) Activity Chair or Course Director:

Title/Academic Appointment:

Address:

City/State/Zip Code:

Telephone:

Fax:

E-mail:

3) Proposed CME Activity Basic Data

Proposed Title:

Dates of Activity:

Location/Site:

Number of *AMA PRA Category 1 Credits*<sup>TM</sup> Requested:

**\*Attach a program outline with a) start/end times of sessions; b) proposed faculty/speakers and c) brief bio for each faculty/speaker\* Page(s)**

Target Audience:

Anticipated Total Audience:

# MD's

# DO's

# Allied Health  
Professionals

Geographic Scope of Audience:

Single Island (specify):

( ) Statewide

( ) National

( ) International

( ) Other \_\_\_\_\_

Describe characteristics of the target audience that may be important to planning this CME activity (e.g. unique aspects of their patient population, unique types of care provided, geographic region of their practice).

**PURPOSE AND MISSION-ESSENTIAL AREA 1**

1) Describe how the proposed activity supports the CME mission of the HCCME (revised 5/16/07):

2) Describe how the content conforms to the AMA & ACCME definitions of CME.

**EDUCATIONAL PLANNING AND EVALUATION-ESSENTIAL AREA 2**

**Element 2.1- A planning process that links identified educational needs with a desired result in the provision of the CME activity must be used.**

1) List planning committee members (attach additional sheets if necessary):

	<u>Name</u>	<u>Title</u>	<u>Degree</u>	<u>JABSOM Affiliation</u>
1				
2				
3				
4				
5				
6				

2) Is the activity planned for physicians by physicians? Yes  No

3) Have representatives from the target audience been actively involved in the planning?  
Yes  No

4) Describe the planning process used for this activity linking review of past participant evaluations, selection of topics, identification of educational needs, development of objectives and desired results.

**\* Attach documentation of the planning process, including physician involvement (meeting minutes, E-mails, or handwritten notes are acceptable)\* Page \_\_\_\_\_**

5) What educational methods will be used? (Check all that apply)

<input type="checkbox"/> Lecture w/discussion	<input type="checkbox"/> Workshop
<input type="checkbox"/> Teleconference lecture alone	<input type="checkbox"/> Discussion groups
<input type="checkbox"/> Teleconference lecture w/facilitator	<input type="checkbox"/> Open question/answer
<input type="checkbox"/> Case analysis/discussion	<input type="checkbox"/> Panel discussion(s)
<input type="checkbox"/> Role play	<input type="checkbox"/> Patient management problem(s)
<input type="checkbox"/> "Hands on" experience	<input type="checkbox"/> Patient demonstrations
<input type="checkbox"/> Demonstration/observation	<input type="checkbox"/> Other: <input type="text"/>

6) In view of the learning objectives, why were these methods selected?

**Element 2.2-Needs assessment data must be used to plan CME activities.**

1) What are the learning needs (practice gaps) for this activity?

2) Check, describe, and attach documentation for the source(s) or method(s) used to identify your learners' education needs.

**\*Documentation is required for each source/method. Attach 1 set to the original application.**

<input type="checkbox"/> Prior evaluations	<input type="checkbox"/> Physician perception
<input type="checkbox"/> Survey of target audiences	<input type="checkbox"/> Perception of faculty
<input type="checkbox"/> Patient care audit	<input type="checkbox"/> Part of larger educational program
<input type="checkbox"/> Quality assurance reports	<input type="checkbox"/> Direct observation of problem
<input type="checkbox"/> New knowledge/skills	<input type="checkbox"/> Request from MD's or community
<input type="checkbox"/> Current literature	<input type="checkbox"/> Other: <input type="text"/>
<input type="checkbox"/> Morbidity/mortality statistic	

**Element 2.3- The purpose or objectives of the activity must be communicated so the learner is informed before participating in the activity.**

1) Describe how the learning objectives were derived from the needs assessments for the CME activity.

2) Who wrote the objectives?

3) Describe how the purposes or objectives will be communicated to the faculty:

4) Describe how the purposes or objectives will be communicated to the learner before he/she participates in the activity:

5) A clearly stated objective helps prospective participants understand the purpose of the CME activity. The objective describes the intended outcome or results of the instruction. The following is an approach to developing learning objectives:

- a) Begin the sentence with, "Upon completion of this (session, course, workshop, clinical conference, etc.) participants will be able to..."
- b) Continue the statement with an action verb that describes the performance by the learner: "explain, compare, analyze, distinguish, list, translate, differentiate, demonstrate, identify, interpret, evaluate, assess, diagnose, integrate, formulate, summarize..." The following verbs are open to many interpretations and should be avoided: "appreciate, have faith in, know, learn, understand, believe"
- c) Complete the sentence with a statement of what the learner will be doing to demonstrate achievement of the objective. (Ex: At the conclusion of the presentation, the participant will be able to..."Discuss the potential roles of hormones in mood disorders," "Explain current treatment modalities for women-specific disorders," "Differentiate gender specific mood disorders.")
- d) List the objective(s) of the activity in terms of physician knowledge, skill, performance, or practice desired, or health outcome:

1)

2)

3)

4)

5)

6)

**Element 2.4- The effectiveness of the CME activity in meeting identified educational needs must be evaluated.**

- 1) **\*Attach a copy of the evaluation tool(s) you will use\* Page \_\_\_\_\_**  
2) How will you determine if your CME activity is effective in meeting the needs for which the activity was designed?

- 3) Who will receive results of the evaluation data?

- 4) How will feedback be provided to faculty?

- 5) What criteria did you use when selecting evaluation methods for your activity?

- 6) How will evaluation data be collected? (Check all that apply.)

Written evaluation

Follow-up surveys

Pre and post tests

Other:

Individual interviews

- 7) Which of the following parameters do you plan to assess? (Check all that apply.)

Extent to which educational objectives were met

Design & structure of the program

Speaker effectiveness

Course syllabus

Program content

Knowledge gain

Instructional methods

Behavior change

Facility

Other:

Audiovisual

- 8) How do you seek feedback from faculty for program improvement?

- 9) New: List changes in competence (knowledge), performance, OR patient outcomes that could be achieved as a result of the educational program.

- 10 New: Describe the plan to measure changes in competence, performance OR patient outcomes as a result of the educational program.

**Element 2.5-The effectiveness of the overall CME program must be evaluated and improvements made.**

Proceed to Essential Area 3 if this is a new course.

- 1) If this is a repeated course, list key improvements suggested by participants, faculty and/or planning committee. For each improvement, describe the changes that were made to improve the present program.

**\*Attach evaluation summary\* Page \_\_\_\_\_**

**ADMINISTRATION-ESSENTIAL AREA 3**

**Element 3.1-An organizational framework that provides the necessary resources to support the CME mission must be in place.**

- 1) List all program funding sources.

**\*Attach a pre-program budget, including CME fees {(\$50.00 activity review fee) + (\$25.00 x number of credit hours requested) + (\$5.00 x number of projected CME eligible participants, MDs and DOs)}. A final budget will be required at the conclusion of the program.\* Page \_\_\_\_\_**

2) What support staff does the course director have at his/her disposal? Indicate percentage of time devoted to CME.

**Element 3.2-Business and management policies and procedures (as they relate to human resources, financial affairs and legal obligations) are in place so its obligations and commitments may be met.**

1) Describe how the requirements of the Americans With Disabilities Act will be met. How will participants be informed?

**Element 3.3-CME activities must be presented in compliance with ACCME's policies for disclosure and commercial support.**

1) How is the faculty selected?

2) What is the role of the activity chairperson or planning committee in selecting faculty?

3) Describe your practice regarding acceptance of educational grants from commercial supporters. How do you ensure that the ACCME Standards for Commercial Support are met? \*new ACCME definition of commercial interest 8/07

4) New: Describe your practice in managing & disclosing relevant financial relationships with commercial interests of all individuals who may influence content, such as planners, speakers or others to the participants prior to the activity.

New: \*Attach disclosure/attestation statements for all individuals who have influence on the content of the proposed activity\* PAGE \_\_\_\_\_

5) Describe your practice in disclosing the presentation of investigational products or products not labeled for use.



6) Describe the practices you use to ensure the quality and scientific integrity of the content.

7) How will promotion and education be kept separate?

8) If a social event is planned, how will you ensure that the event does not compete with, nor take precedence over the educational event?

9) How will funds from commercial interests be managed?

10) Do you anticipate support from commercial interests?

( ) Yes ( ) No

If yes, please list name of company and representative or \*Attach List PAGE \_\_\_\_\_

11) Has the individual representative whose signature appears below received a copy of the ACCME Standards for Commercial Support, the HCCME's Policy and Procedures for Sponsorship of Continuing Medical Education, including Enduring Materials & Internet CME?

Yes

No

12) Signatures

Signature, Program Chair/Coordinator

Date

Signature, Clinical Department Chair  
(for School of Medicine sponsored activity)

Date

**ACTION TAKEN BY HCCME CME COMMITTEE:**

1) Request presented to CME Committee on:  (mo/day/yr)

Approved for category 1

Request returned to applicant for additional information on:   
(mo/day/yr)

Request not approved for category 1 due to:

Announcement printed and distributed prior to program approval

Insufficient time before program presentation

Insufficient physician representation on planning committee

Insufficient planning involvement by physicians.

Learning objectives lacking, insufficient, or inappropriate

Topics not within the definition of CME

Needs assessment insufficient

Insufficient plans for evaluating the effectiveness of the activity in terms of changes in competence, performance OR patient outcomes.

## Regularly Scheduled Conference Series (RSC)

A Regularly Scheduled Conference (RSC) is defined as an activity that is planned to have 1) a series with multiple sessions that 2) occur on an ongoing basis (offered weekly, monthly, or quarterly) and 3) are primarily planned by and presented to the accredited organization's professional staff. Examples of activities that are planned and presented as a regularly scheduled conference are Grand Rounds, M&M Conferences, and Tumor Boards.

1. All RSC's are expected to be planned, implemented, and evaluated in compliance with:
  - a) the ACCME Essential Areas and Policies
  - b) the ACCME Standards for Commercial Support, Standards to Ensure Independence in CME Activities
  - c) HCCME established policies and procedures
2. All RSC's sessions are expected to meet the AMA **definition of continuing medical education**.
3. Each regularly scheduled conference series certified for credit by the HCCME is organized as one activity. Credit will be approved for a maximum number of credit hours based on duration of one session. For example, a Medicine Grand Rounds session that meets for one hour per week would be approved for a maximum of 1.0 *AMA PRA Category 1 Credit*<sup>™</sup> per session.
4. **Applications** for new RSCs may be submitted at any time and at least 3 month's prior to start of the activity.
5. **Educational needs/practice gaps** of the target audience must be identified by the activity chair. Needs may evolve over the course of the RSC implementation, but the sources for identifying needs (e.g. current cases, journal articles, current events, etc.) must be identified at the outset. Planners are encouraged to use more than one source of 'needs' to plan RSCs and should include information gathered from past evaluations.
6. **Learning objectives, goals, and/or purpose** of an RSC series must be developed and communicated to learners in advance of the individual session. This can be done on the flyer/brochure/calendar/e-mail.
7. RSC activity chairs or support staff must **inform invited speakers** in writing of:
  - a) the overall objectives
  - b) description of the target audience
  - c) obligations to deliver content that is fair and balanced
  - d) obligations to identify and resolve actual/potential conflicts of interest
  - e) obligations to inform the audience of relevant financial relationships
8. RSC planners must obtain signed **Letters of Agreements for Commercial Support (LOA)**. The RSC activity chair or support staff must work proactively with HCCME to ensure complete compliance with the ACCME Standards for Commercial Support. All grant agreements must be signed by the designated representative of the HCCME, the RSC activity chair and the representative of the commercial interests. The activity chair, HCCME and the representative of

the commercial interest. The HCCME has developed a standard LOA; however, it is acceptable to use LOAs from external organizations so long as all the key components of the HCCME LOA are present. The HCCME will not retroactively accept a grant from a commercial interest. Commercial support sent in the absence of a fully executed LOA will be returned to the commercial interest.

9. Fully executed LOAs will be forwarded to the HCCME for the file.

10. Upon receipt of grant funds and instructions from the activity chair, HCCME will issue honoraria and travel reimbursements for appropriate presenters at CME certified RSCs. At no time may grant providers, third parties, or other CME entities initiate the honoraria and reimbursement process.

11. The **effectiveness** of RSCs must be **evaluated** in terms of changes in **competence, performance, or patient outcomes**. This may be done in a number of ways, including survey of learners, observations of the activity chair, and changes in practice over time. Changes or improvements will be reported to the HCCME via the annual report.

12. Credit designation for RSC's in good standing will be effect for the period of HCCME accreditation.

13. **Monitoring** for compliance with the requirements of the HCCME and ACCME will be accomplished through:

- a) RSC annual report
- b) direct observation by the department representative to the HCCME
- c) periodic review of the evaluation forms by HCCME staff
- d) unannounced direct observation by HCCME staff

14. Electronic Peopleware **records of participation** will be created and maintained for each learner who signed in for the session. One complimentary transcript per year is provided by HCCME upon request. The transcript will be mailed, faxed or E-mailed within 3-5 days of the request.

## **Implementation**

*Before each session:*

1. Communicate with the speaker to confirm date/time/location, learning objectives, characteristics of the target audience, honorarium and expense reimbursement process (if applicable), collection of disclosure information, timeline for submission of handouts, and other arrangements.
2. Activity chair reviews the disclosure information of the speaker to identify and resolve COI (if applicable). Documentation of how COI was resolved will be maintained in the file.
3. Execute educational grant letter of request and Letter of Agreement for Commercial Support (if applicable).
4. Create the announcement with the required elements. Include an acknowledgement of commercial support (if applicable). Include speaker disclosure information.

5. Create evaluation/attendance form; include speaker disclosure information.

*After each session:*

6. Forward the evaluation/attendance forms to HCCME for data entry. HCCME will return evaluation summary to the departments. HCCME will create an electronic record for each participant who has turned in an evaluation/attendance form and will provide a transcript to that individual upon request.

7. Send thank you letter to speaker with feedback information.

8. Close session file.

### **Documentation Required for RSCs**

*Note: Documentation must be kept in the presenting department files for a minimum of 4 years or during the period of current HCCME accreditation.*

Initial application and annual reports; per series

Planning Meeting Minutes: overall

Handouts: for each session (if applicable)

Session evaluation summary

Budget for the series

Letter of Agreement for each educational grant

Evidence of provision of disclosure information to the learners

Flyers or other promotional materials must contain:

name of presenting department

title of RSC

title of presentation

speaker name/affiliation

learning objectives for the session or purpose/overall goal of the series

CME accreditation statement

CME designation statement (with italics)

date/time/location

acknowledgement of commercial support (if applicable)

speaker disclosure information

speaker intent to discuss unlabeled uses of products

### **Annual Report**

The annual report will cover the academic year from July 1 to June 30. The PDF file and CME fees are due to HCCME no later than September 1.

The HCCME CME committee will review the annual reports and make determinations regarding the status of continued credit certification.

Annual Report  
 John A. Burns School of Medicine, University of Hawai'i  
 Regularly Scheduled Conference Series  
 July 1, 200x - June 30, 200x

Instructions:

1. Type using 11 point type.
1. Consecutively number each page, including the attachments.
2. Submit one electronic copy in PDF format to jwoo@hawaii.edu
3. Due Date:

General Information		
Series Director	JABSOM Appointment	
Address		
Phone	Fax	Email
Series Coordinator		Title
Phone	Fax	Email

Type of Activity				
<input type="checkbox"/> Grand Rounds	<input type="checkbox"/> Clinical/Case Conference	<input type="checkbox"/> M&M	<input type="checkbox"/> Journal Club	<input type="checkbox"/> other, specify
Activity Details				
Series Title:				
Series Location:				
<input type="checkbox"/> weekly	<input type="checkbox"/> monthly	<input type="checkbox"/> bi-weekly	<input type="checkbox"/> quarterly	<input type="checkbox"/> other, specify
Day & Time:				
Will commercial support be sought? <input type="checkbox"/> yes <input type="checkbox"/> no				

CME Program Summary
<p>Please provide a summary of the Department's CME program, devoting at least one paragraph to each of the following:</p> <ul style="list-style-type: none"> <li>a) development and present organization (include roster of CME committee)</li> <li>b) leadership and structure of your CME program</li> <li>c) financing</li> <li>d) strengths, including highlights of your program</li> <li>e) areas for improvement and specific plans for addressing improvements</li> <li>f) CME program's future direction</li> </ul> <p>Please do not exceed three single-spaced typewritten pages, number additional pages 1.1, 1.2, 1.3</p>

## Essential Area 1: Purpose and Mission

- A. What is the purpose for developing this activity? What are the content areas? Target audience? Expected results? *Note: beginning November 2008, the effectiveness of the program will be evaluated in terms of changes in competence, performance, or patient outcomes.*
- B. Describe how the CME mission of the department supports the CME mission of the Hawaii Consortium for Continuing Medical Education.

## Essential Area 2: Educational Planning and Evaluation

### 2.1 **Planning Process(es)**

- A. Describe your planning process(es), specifically addressing the link between identified educational needs and desired results.

### 2.2 **Needs Assessment**

- A. Describe how needs assessment data are used in planning the series.
- B. What sources/data did you use to identify your learners' educational needs?
- C. How did you collect your needs assessment data?
- D. What educational need(s) of your target audience will be met by participating in the series?
- E. What are the gaps in practice you wish to address?
- F. Are there quality improvement initiatives that your department is trying to achieve through the series?  
( ) yes ( ) no  
If yes, how did the series help you achieve them? Describe the strategy used to measure them.

### 2.3 **Purpose and Objectives**

- A. Describe how the purpose and/or objectives of the CME activity are made known to participants before participating in the activity.
- B. What are the overall (global) learning objectives you hope to achieve through this series?
- C. Describe how the purpose/or objectives for the individual sessions of the series are developed?
- D. How do these objectives relate to the needs described above?

### 2.4 **Activity Evaluation**

- A. Describe how the department evaluates the effectiveness of the **individual sessions** of the series in meeting the session objectives. Who receives the evaluation data? How is evaluation data collected, analyzed and utilized to make improvements in the overall CME effort.

### 2.5 **Series Evaluation**

- A. Describe how the department evaluates the effectiveness of the regularly scheduled conference series.
- B. What improvements were made as a result of this process?

Essential Area 3: Administration

3.3 **Standards for Commercial Support (Standards to Ensure Independence in CME Activities)**

- A. Describe the mechanism your department uses to ensure that everyone in the position to control educational content has disclosed relevant financial relationships with commercial interests, including your department's mechanism for managing individuals who refuse to disclose.
- B. Describe the mechanism(s) you use to **identify** conflicts of interest prior to an activity.
- C. Describe the mechanism(s) you use to **resolve** conflicts of interest prior to the activity.
- D. Describe the mechanism(s) you use to **disclose** the presence or absence of relevant financial relationships for all persons in a position to control educational content to the learners prior to the activity.
- E. Describe and explain the mechanism(s) you use to ensure that the content of CME activities promotes improvements or quality in healthcare.
- F. Describe and explain the mechanism(s) you use to ensure that the content of CME activities gives a balanced view of therapeutic options.

CME Financing and Budget:

Using the line items below, please provide the budget for this series.

INCOME

- Funds allocated by the department
- Grants, gifts, endowments from non-commercial interests
- Fees/registrations
- Educational Grant from commercial interests
- Display/Exhibit Fees from commercial interest
- Other (specify)

EXPENSES

- Administrative
- Supplies, printing, postage
- Faculty/Speaker/Instructor
  - Honoraria
  - Travel/lodging
- Food/beverage
- Equipment rental/services
- Meeting space rental
- CME fees
- Other (specify)

TOTAL EXPENSES:



Documentation:

Attachment 1: minutes of planning committee meetings as evidence that the planning process was in place for sessions held during the reporting period.

Attachment 2: sources used to identify your learners' overall educational needs.

Attachment 3: evaluation tool(s).

Attachment 4: Activity File Review

For each session held during the month of [month] 200x, attach the following:

Announcements (print & electronic)

Correspondence with speaker/faculty verifying communication of learning objectives and post-session

feedback

Summaries of evaluations

Letters of Agreement with commercial interests, if applicable

###

## **Joint Sponsorship Policy & Process**

The Accreditation Council for Continuing Medication (ACCME) accredits the Hawaii Consortium for Continuing Medical Education (HCCME) as a provider of continuing medical education. In this role, the HCCME is responsible for fulfilling requirements as set forth by the ACCME. Non-accredited sponsors of CME activities or a group of physicians may seek out an accredited provider to facilitate the planning and delivery of educational activities. By doing this, and providing *AMA PRA Category 1 Credits*™, HCCME is participating in the process of **joint sponsorship**.

**Definition:** Joint sponsorship is activity planning and presentation with non-ACCME accredited providers. Joint sponsorship allows non-accredited organizations an opportunity to offer their constituencies CME activities designed for credit by the accredited joint sponsor. Joint sponsorship expands the HCCME's ability to provide CME to a greater number of physicians.

Accredited providers must ensure that their entire program of CME is in compliance with the Essentials and Standards established by the ACCME as well as the AMA requirements for designation of category 1 credit. This means the HCCME accepts the responsibility that the ACCME's Accreditation Policies and Procedures and AMA PRA credit designation requirements are met when educational activities are planned and presented in joint sponsorship with non-accredited providers.

If planning for the activity or program for which you are seeking joint sponsorship has already begun or if print materials or electronic postings have already been distributed, the HCCME may not be able to jointly sponsor the activity.

**Policy:** The HCCME recognizes the diverse needs, strengths and capabilities of non-accredited entities locally and nationwide. The HCCME may enter into joint sponsorship with non-accredited organizations provided the organization's physician education mission is consistent with that of the HCCME's, the organization demonstrates sound educational policies and practices, and demonstrates adequate resources to plan, conduct, and evaluate CME activities.

**Process:** Seeking and obtaining HCCME joint sponsorship is a 2-step process. Step 1 is the non-accredited organization's request for joint sponsorship and Step 2 is the application for credit designation for specific CME activities. For new applicants, requests for HCCME joint sponsorship (step 1) must be submitted before the initial development of the activity.

In Step 1, the applicant completes a general information questionnaire designed to provide information about the organization's physician education mission, understanding of the CME process and ability to meet the requirements for planning, conducting and evaluating category 1 credit activities.

In Step 2, the applicant completes the application for credit designation for a specific CME activity.

**Deadlines:** The complete joint sponsorship request process may take approximately 6 months from the HCCME's receipt of the completed General Information Questionnaire. This time estimate holds only if the requesting organization responds to requests for additional information in a timely manner. While the HCCME does not set the deadlines for the internal decisions of individual organizations, planners should be aware of internal deadlines for distribution of program announcements and plan accordingly. All announcements (print and electronic) must be approved by the HCCME prior to dissemination and must display the appropriate jointly sponsored and designation statements. With HCCME approval, save-the-date type announcements may be disseminated while the application for credit designation is in process.

Applications for *AMA PRA Category 1 Credit™* designation must be reviewed by the HCCME sponsorship committee **no later than 90 days prior** to the start of the activity.

**Fees:** Every activity certified by the HCCME will be assessed a fee (based on a fee schedule developed by the HCCME CME committee) for the processing of applications, for the number of credits designated and for recording the participation in the participant's individual record.

**Documentation:** The HCCME must be able to provide to the ACCME written documentation that demonstrates how each jointly sponsored CME activity was planned, conducted and evaluated in compliance with the ACCME's Accreditation Policies and Procedures. Material submitted can be from files of either the HCCME or the non-accredited provider.

Documentation of compliance with the ACCME Essentials and Standards for Commercial Support begins with the "Application for *AMA PRA Category 1 CME Credit™* Designation". The activity file is to include (but is not limited to):

- ❖ evidence that a planning process is in place;
- ❖ development, completion and documentation of an adequate needs assessment;
- ❖ identification of practice gaps;
- ❖ delineation of specific learning objectives for presentation;
- ❖ copies of correspondence to faculty containing required elements;
- ❖ documentation of planning group and faculty disclosure of relevant financial relationships with commercial interests;
- ❖ evidence of review of the disclosure information; identification of COIs, resolution of COIs.
- ❖ evidence that disclosure information was provided to the learners prior to the start of the activity;
- ❖ full involvement in the receipt and distribution of faculty honoraria and travel expenses when commercial support is solicited;
- ❖ execution of letters of agreement regarding educational grants from commercial supporters;
- ❖ evidence of that acknowledgement of commercial support was made prior to the start of the activity;
- ❖ evidence that the effectiveness of the activity was evaluated in terms on changes in competence, performance OR patient outcomes;
- ❖ completion and full review of an evaluation instrument by all attendees seeking credit;
- ❖ a final review of the activity by the HCCME CME sponsorship committee.

## Summary of the 2-Step Joint Sponsorship Process

### *Step 1 – Request for Joint Sponsorship*

- ❖ HCCME receives the telephone inquiry.
- ❖ HCCME conducts a pre-screening telephone interview.
- ❖ HCCME sends the General Information Questionnaire for Joint Sponsorship
- ❖ Non-accredited organization returns completed General Information Questionnaire with processing fee.
- ❖ Request is placed on the agenda of the next regularly scheduled meeting.
- ❖ HCCME reviews the information form with representative present and takes action.
- ❖ HCCME agrees to joint sponsor with the non-accredited organization.
- ❖ Non-accredited joint sponsor and HCCME execute the Agreement for Joint Sponsorship of CME.

### *Step 2 – Approval of Credit Designation for a specific jointly sponsored CME Activity*

HCCME informed of intent to conduct a CME activity.

- ❖ Program planning proceeds as per HCCME Policies & Procedures and in consultation with HCCME representative.
- ❖ Application for credit designation submitted to HCCME for review.
- ❖ Credit designation approved.
- ❖ Activity observer appointed.
- ❖ Implementation continues in consultation with HCCME.

### *Post-Activity*

- ❖ Post-activity requirements completed.
- ❖ HCCME reviews observer's report and summary of evaluations.
- ❖ Payment of final CME fees paid to HCCME.

**Hawaii Consortium for Continuing Medical Education**  
 General Information Questionnaire for Joint Sponsorship (step 1)

**All Information Received is Confidential**

<b>Name of Organization</b>		
<b>Name of Executive Officer</b>		
<b>Telephone:</b>	<b>Fax:</b>	<b>E-mail:</b>
<b>Address</b>		
<b>City</b>	<b>State</b>	<b>Zip</b>
<b>Name &amp; Title of Person Completing Questionnaire:</b>		
<b>Activity Chairperson (if applicable)</b>		
<b>Names &amp; Titles of Individuals Responsible for planning and conducting CME activities (attach separate sheet if more space is needed)</b>		
<b>Name &amp; Title of Staff assigned to support the CME effort of the organization or professional education committee:</b>		

**Please attach your responses to the questions to this page. Send the original and 21 copies (photocopied 2-sided), accompanied with the nonrefundable processing fee of \$100.00 payable to Hawaii Medical Foundation, to the CME office at the School of Medicine, 651 Ilalo Street MEB/CME, Honolulu, HI 96822.**

Hawaii Consortium for Continuing Medical Education  
**General Information Questionnaire**

1. Provide a history and description of your organization, including the leadership.
2. Describe your organization's CME mission. How does your CME mission support the mission of the HCCME?
3. Describe the process(es) used to determine the educational needs (knowledge, competence, or performance) that underlie the professional practice gap(s) of the prospective learners?
4. Describe the process used to match the content of the activities/educational interventions to the learners' current or potential scope of professional activities.
5. Describe how educational formats for activities/educational interventions will be selected.
6. Describe how activities/educational interventions will be designed to change competence, performance or patient outcomes.
7. Describe your plan to measure and analyze changes in learners' competence, performance, or patient outcomes as a result of the activity/educational intervention.
8. Describe how prospective learners will be informed of the expected changes in competence, performance or patient outcomes that will be the result of the participating in the activity.
9. How will you identify, plan and implement the needed or desired changes that are required to improve on the ability to meet your CME mission?
10. Describe the internal review and control procedure for your CME activities, including legal obligations (compliance with ADA and copyright laws), budgetary practices, and compliance with the Accreditation Council for Continuing Medical Education Standards for Commercial Support.
11. Describe how you will verify and document physician attendance at a CME activity.

## Policy on Commercial Support & Conflict of Interest and Guide to Implementation

### Introduction

The Hawaii Consortium for Continuing Medical Education (HCCME) adheres to the Standards for Commercial Support (*Standards to Ensure Independence in CME Activities*) of the Accreditation Council for Continuing Medical Education (ACCME). The individual responsible for the HCCME certified CME activity must see that the Standards are observed.

The ACCME defines a 'commercial interest' as "any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients." (Effective 8/07)

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

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

- 501-C non profit organizations (*Note: ACCME screens 501c organizations for eligibility. Those that advocate for 'commercial interests' as a 501-c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint sponsor, but they can be a commercial support.*)
- Government organizations
- Non-health care related companies
- Liability insurance providers
- Health insurance providers
- Group medical practices
- For-profit hospitals
- For-profit rehabilitation centers
- For-profit nursing homes.

CME activities must also conform to the American Medical Association Council on Ethical and Judicial Affairs (CEJA) opinions that address the ethical obligations that underpin physician participation in CME, 8.061 "Gifts to physicians from industry" and 9.011, "Ethical issues in CME". (For more information on CEJA ethical opinions visit [www.ama-assn.org/go/cega](http://www.ama-assn.org/go/cega))

**Summary:** It is the policy of the HCCME to ensure balance, independent, objective, and scientific rigor in all its individually certified educational activities. All individuals who may influence content, such as planners, speakers, authors, department chairpersons or others must disclose relevant financial relationships with commercial interests that pertain to the activity. Should a conflict of interest (COI) be identified, the COI must be resolved prior to the activity. Individuals, in the position to influence content, who refuse to provide disclosure information, will be disqualified from being a part of the planning or implementation of the activity. The presence and absence of relative financial relationships with commercial interests will be provided, in writing, to participants prior to the start of the activity. It is also recommended that speakers verbally state such relationships as part of the introduction to the presentation.

The HCCME's practice and mechanisms to ensure independence in CME activities follow.

## **1.0 Independence**

1.1 The HCCME, through committees of the Hawaii Medical Association (HMA), departments and programs of the John A. Burns School of Medicine, University of Hawaii (JABSOM), and joint sponsors conduct the following aspects of CME planning independently and free from the control of any commercial interests:

- 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 materials;
- f) Evaluation of the activity.

In the event technical input is required from commercial interests relating to the content of CME activities, the HCCME will request that input in writing and the input will be subject to content validation processes.

1.2 The HCCME will not enter into a joint sponsorship relationship with a commercial interest.

## **2.0 Resolution of Personal Conflicts of Interest**

2.1 Everyone who is in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interests. The mechanism used to *collect* the information is the *HCCME Disclosure Declaration and Attestation Form*.

Relevant financial relationships are those where the individual (including the individual's spouse /domestic partner) has a personal financial (any amount) with a commercial interest within the past 12 months. The absence of relevant relationships must also be disclosed.

2.2 Individuals who refuse to disclose relevant financial relationships cannot have a role in the CME activity.

### **2.3 Resolution of Conflicts of Interest (COI)**

Conflicts of interest are present when an individual has a current relevant personal financial relationship with a commercial interest. The fully executed *Disclosure Declaration/Attestation Forms* are collected by the activity staff and forwarded to the individual responsible for the CME activity. Upon review, COI's are identified and the appropriate measure for resolution is selected and taken. Resolution may be accomplished with guidance from a member of the HCCME committee. The measures taken for resolving COI in CME include, but are not limited to, the following:

- Review of the educational content by peers who have the authority to alter content of any educational material that has commercial bias.
- Alteration or limitation of the role(s) of the individual so that the financial relationship is no longer relevant.
- Excluding the individual from participating in content development or delivery.
- Denial of CME certification for selection portions of the educational activity.

Actions taken to resolve COIs is documented with the use of the 'Resolution of Conflict of Interest Form'.



### **3. Appropriate Use of Commercial Support**

3.1 All CME activity planners must obtain the HCCME's approval in advance of any solicitation of commercial support and the HCCME must make all decisions regarding appropriate disposition and disbursement of commercial support. Funds from commercial interests are to be awarded in the form of an unrestricted educational grant as to its use within the content of the topic area. Unused funds may be returned to the commercial interest as a condition of the grant. The HCCME may request that inappropriate expense items be removed from the proposed activity budget.

3.2 Conditions - no prerequisite conditions, except for the designation of topic areas under which the educational grant is given, will be allowed with regard to the receipt of the commercial support funds.

3.3 All commercial support associated with a CME activity will be given with the full knowledge and approval of the HCCME. No other payments 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. Other support associated with the CME activity (e.g. distributing brochures, preparing slides, etc.) must be given with the full knowledge and approval of the HCCME.

#### **Written agreement documenting terms of support**

3.4 The HCCME requires that a written letter of agreement (LOA) be signed between itself and the commercial supporter. The terms, conditions, and purposes of the commercial support must be documented in the written agreement. The HCCME has developed a standard LOA; however, it is acceptable to use LOAs from external organizations so long as all the key components of the HCCME LOA are present. The HCCME will not retroactively accept a grant from a commercial interest. Commercial support sent without a fully executed LOA will be returned to the commercial interest.

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

3.6 Both the commercial support and the HCCME Compliance & Accreditation Manager must sign the written agreement between the commercial supporter and the provider.

#### **Expenditures for an individual providing CME**

3.7 & 3.8 All honoraria and out-of-pocket expenses for speakers/faculty are paid directly by the HCCME, the joint sponsor, or a designated educational partner. Honoraria amounts are determined by the individual/planning group responsible for the CME activity and for University of Hawaii faculty, in accordance with the University of Hawaii Professional Assembly 2003-2009 Faculty Contract, Article III Conditions of Service. The application for credit designation requires that a proposed budget be submitted for review by the HCCME CME committee. (See HCCME Policy on Honoraria & Expense Reimbursement).

3.9 It is also the policy of the HCCME that supporters of an activity are prohibited from entering into any other compensation arrangement with planners, managers, and faculty relative to that CME activity.

3.10 Speakers will only be reimbursed for expenses incurred for the portion of the CME activity in which they participate in a teaching role. Expense amounts are reimbursed in accordance with the Honoraria Policy.

### **Expenditures for Learners**

3.11 The HCCME acknowledges the importance of peer interaction and recognize that much of the learning goes on during conversations with colleagues. Social events, such as receptions, may not compete with or take precedence over the educational events.

3.11.1 A general guideline is not to have any social event greater than 50% of the total time together.

3.11.2 A social activity should be one of the minor items on the brochure.

3.11.3 A social activity should be free of the appearance of impropriety.

3.11.2 Meals associated with the educational activity are to be modest (less than \$100.00 per person).

3.12 No commercial support may in any way be used to defray any part of the cost of attending a CME activity sponsored by the HCCME.

### **Accountability**

3.13 The HCCME will maintain records of receipt and disposition of commercial support grants.

## **4.0 Appropriate Management of Associated Commercial Promotion**

4.1.1 The HCCME may accept arrangements for displays and/or advertisements from commercial interests associated with a CME activity.

4.1.2 The receipt of display or advertisement funds does not constitute any agreement for influencing the content of the CME activity, nor is the receipt of those funds contingent on a commercial interests' support of a CME activity.

4.2 Displays, ads or any form of promotion are kept separate from the CME activity as follows:

4.2.1 For live activities, promotional materials are not displayed or distributed in the educational space immediately before, during, or after a CME activity; displays may not be placed in the obligate path to the educational space; representatives of commercial interests may not promote their products while in the space or place of the CME activity.

4.2.2 For print activities, no advertisement may be interleaved within the pages of the CME content; advertisements may face the first or last pages of printed CME content so long as those ads are not related to the CME content and are not paid for by the commercial supporter of the activity.

4.2.3 For computer-based activities, advertisements 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.

4.2.4 For audio and video activities, advertisements will not be included within the video activity nor will there be any commercial breaks during which an advertisement may be shown or heard.

4.2.5.1 Educational materials, such as syllabi, handouts, and slides may not contain any advertisements, trade names, or product group messages.

4.2.5.2 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 contain advertisements.

## **5.0 Content and Format Without Commercial Bias**

5.1.1 The content and materials of HCCME CME activities promote improvements or quality in healthcare.

5.1.2 The specific proprietary interests of a commercial interest are not promoted in CME activities sponsored by the HCCME although products may be referenced in the context of a balanced presentation that is scientifically objective.

5.2.1 CME activities offered by the HCCME must give balanced views of therapeutic options.

5.2.2 It is the policy of the HCCME to use generic, scientific names of products wherever possible to promote impartiality.

5.2.3 If CME educational material or content includes trade names, then the trade names of all referenced products are to be used.

## **6.0 Disclosures Relevant to Potential Commercial Bias**

Relevant financial relationships of those with control over CME content

6.1 Relevant financial relationship information is collected from all individuals, as well as the individual's spouse/partner, who have control over CME content. Relevant financial relationships are disclosed to learners. Whenever possible, this will occur in writing. The information disclosed will include the following:

6.1.1 The name of the individual

6.1.2 The name of the commercial interest(s)

6.1.3 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.**

6.3.1 The HCCME discloses to learners the name(s) of commercial interest(s) supporting each CME activity. When possible, information about the support is provided in the CME activity announcement.

6.3.2 When commercial support is 'in-kind', the nature of that 'in-kind' contribution is disclosed to the learner.

6.4 The verbiage of the disclosure to learners must never include the use of a trade name or a product-group message.

### **Timing of disclosure**

6.5.1 All disclosure information, including acknowledgement of commercial support, is communicated to learners in advance of the start of the CME activity. For conferences, written disclosure typically occurs in the first several pages of the CME syllabus or handout materials and is followed with verbal disclosures by the moderator or speaker.

6.5.2 For regularly scheduled series sessions, written disclosure may occur in the print or electronic announcement when the commercial support is received well in advance. Typically, disclosure information is printed on the evaluation form.

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## **Guide to Implementation**

1.0 Planning committee members must disclose relevant financial relationships with any commercial supporter in a timely manner or face dismissal from participation in the activity.

1.1 The fully executed forms completed by the planning group are reviewed by the activity chair during the early planning stages. Identified COI are subject to resolution as per 2.3. The disclosure forms are attached to the application for credit designation for review by the HCCME CME committee.

1.2 The activity chair issues to all individuals in the position to control the content of the CME activity the Disclosure/Attestation Form that is used to collect information on relevant financial relationships including the name of the commercial interest(s) and the nature of the relationship. Financial relationships that need to be disclosed are those that were in place over the preceding twelve month period of any amount for the individual and his/her spouse or life partner.

1.3 Chairperson reviews the forms and identifies potential conflicts of interests.

1.4 Chairperson takes action to resolve and manage the conflicts of interests prior to the activity. Resolution may include limiting the scope of the presentation, peer review of the slides, and divestiture of stock. In the event the conflicts of interest cannot be resolved or managed, the presenter may be disqualified. The chairperson is encouraged to consult a member of the HCCME to participate in the resolution process. Documentation of the intervention used to resolve the COI is recorded on the "Resolution of Conflict of Interest Form."

1.5 The presence and nature of relevant financial relationships are provided in writing to the learners prior to the activity. The absence of relevant financial relationships is also disclosed. CME activity promotional materials and educational handouts, as a matter of routine, include

acknowledgement of commercial support. In handouts, the acknowledgements are placed in the introductory sections so participants may review the information prior to the start of the activity.

1.6 The HCCME provides an example of a faculty letter that advises speakers, moderators, authors, and instructors of the requirements relative to the ACCME Standards for Commercial Support.

## Written Disclosure

The Accreditation Council for Continuing Medical Education (ACCME) has always required verification that disclosure of information about faculty/planner/provider relevant financial relationships with commercial interests to learners actually occurred. Written documentation has been the standard tool used. The following strategy demonstrates acceptable verification that disclosure information was transmitted to the learners in writing.

a) Planning group members and faculty are asked to complete, sign and return the HCCME Disclosure Declaration & Attestation Form to the designated department, division or program representative.

b) For conferences, the disclosure information is compiled on one sheet and inserted in the front of the syllabus. For regularly scheduled conference series, disclosure information is printed on the evaluation form and the activity moderator informs learners that written disclosure information is provided on the form. In order to fulfill ACCME's faculty disclosure requirements, the following information must be provided to learners:

*Name & role in the activity*

*Name of the commercial support or entity with which the faculty member has the relationship or affiliation; and*

*Type(s) of relationship*

*If faculty had nothing to disclose*

*Statement regarding discussion unlabeled uses of products*

Example: speaker has relationships to disclose and does not intend to discuss unlabeled uses of products.

*John Kelly, M.D. - speaker & moderator*

*Grant/Research Support: Aventis, Lilly Oncology, Schering, OSI, Imclone.*

*Consultant: AstraZeneca, BMS, Lilly Oncology.*

*Speakers' Bureau: AstraZeneca, BMS.*

*Does not intend to discuss unlabeled uses of products.*

Example: speaker has no relationships to disclose and does intend to discuss unlabeled uses of products.

*Joan Kelley, M.D. - speaker, planning group*

*Has no relevant financial relationships with commercial interests that pertain to this specific activity to report.*

*Does not intend to discuss unlabeled uses of products.*

c) Inclusion of the disclosure information on print and electronic announcements is encouraged as print deadlines allow.

### **Verbal Disclosure**

ACCME policy allows for information about relevant financial relationships with commercial interests to be disclosed to participants verbally. For providers who choose to make disclosure to their learners verbally, a system that demonstrates compliance with policy 2003-B-13 (see below) must be in place for activities that occur after November 1, 2003.

### **Strategies to Demonstrate Compliance When Disclosing Verbally**

#### **Written Attestation**

The following is a strategy provided by the ACCME that demonstrates compliance with policy 2003-B-12. As with written disclosure, the process begins with faculty completing, signing and returning the HCCME Disclosure Declaration and Attestation Form to the designated department, division or program representative.

“A written attestation by the activity moderator, observer or staff member, that is signed and dated within a week of the activity, states that all the relevant disclosure information was made known to the participants. Stapled to the attestation is the full detail of the information that was disclosed. In this case, the detail can be found in the faculty disclosure forms required by the provider.”

#### **Use of Moderator’s Script**

Many departments provide the activity moderator with a written script. The script generally includes a welcome, housekeeping announcements, HCCME accreditation statement, credit designation statement, introduction of HCCME observer, commercial support acknowledgement, evaluation form completion reminders, statement of learning objectives, speaker introduction with the required disclosure information, closing and thank you. A signature line could be added to the written script that serves as the moderator’s written attestation that the ACCME disclosure requirements were fulfilled. The signed script becomes part of the permanent file for the activity.

#### **Combination Written (Slide) and Verbal Disclosure**

The disclosure information may also be displayed on a slide that is projected on the screen prior to the beginning of the activity. In this case, the moderator must verbally direct the learner’s attention to the slide and allow time for the learner to read the information. A hard copy of the slide that is signed and dated on the date of the activity that attests that the slide was displayed prior to the activity is to be made part of the permanent file of the activity.

**Permanent File.** All required documents should be kept for the duration of the current HCCME accreditation period. The documents include: the faculty disclosure statement, copy of the print announcement, and written attestation.

#### **ACCME policy 2003-B-12:**

HCCME must be able to supply ACCME with written verification that appropriate verbal disclosure occurred at a CME activity. With respect to the documentation of verbal disclosure at CME activities: 1) A representative of the HCCME who was in attendance at the time of the verbal disclosure must attest, **in writing**: a) that verbal disclosure did occur; and b) itemize the content of the disclosed information (2000-B-14); or that there was nothing to disclose (1999-A-17). 2) The documentation that verifies that adequate verbal disclosure did occur must be completed within one month of the activity.

## Faculty Confirmation Letter

*This sample letter is provided to assist in implementing the ACCME Essential areas, policies and Standards for Commercial Support.. It represents one method of documenting compliance. When used, it may be modified to meet the needs of individual activity.*

The following summarizes the Essentials, Standards and other logistics that are addressed:

- Paragraphs 1, 2, and 3: Learning objectives are made known to prospective participants, including faculty.
- Paragraph 4: ACCME Standards for Commercial Support. Disclosures Relevant to Potential Commercial Bias
- Paragraph 5: ACCME Standards for Commercial Support. Content and Format without Commercial Bias
- Paragraph 6: Audiovisual requirements, handouts, copyright permission, and references. Request PowerPoint presentations.
- Paragraph 7: Financial arrangements.
- Paragraph 8: Information about the prospective audience

Dear *(name)*:

**pp#1** Thank you for agreeing to serve on our faculty for ("*title*") which will be held on (*day/date*), at the (*location*). Your presentation ("*presentation title*") is scheduled to begin at (*time*). We have allotted (*length of time*) for your presentation that is to be followed by a (*length of time*) period for audience questions. At (*time*) the three morning speakers will then serve as a panel, which will be moderated by (*moderator name*), to add special insights to the morning activities.

**pp#2** As we discussed, the following are the learning objectives that have been developed by the planning group:

At the conclusion of the conference, the participant will be able to:

1. Objective
2. Objective
3. Objective

**pp#3** If you have any questions concerning these learning objectives, need clarification regarding the expectations of the Committee, or would like to refine the learning objectives, please contact (*name at telephone or e-mail address*) by (*date*).

**pp#4** As a provider accredited by the Accreditation Council for Continuing Medical Education (ACCME) the Hawaii Consortium for Continuing Medical Education must insure balance, independence and scientific rigor in its individually and jointly sponsored educational activities.

To comply with ACCME policies, disclosure of all relevant financial relationships with commercial interests is required for all individuals who control CME content. Disclosure is required even if you have no relevant relationships. Additionally, we ask that you disclose any intent to discuss unlabeled uses of products or products still under investigation. These disclosures will be provided to learners prior to your presentation.

**pp#5** The ACCME Standards for Commercial Support require that your presentation give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If your presentation includes trade names, where available trade names from several companies should be used, not just trade names from a single company. Please complete the all appropriate sections of the attached Disclosure Declaration and Attestation Form and return by *(due date)* by fax to 808-692-1246 or email to [jwoo@hawaii.edu](mailto:jwoo@hawaii.edu).

**pp#6** The *(program location)* is equipped with *(list equipment)*. Please inform this office of your requirements for audio-visuals. We are also providing uniform syllabus materials for CME activity participants. In order to meet our printing deadlines, it will be necessary for us to receive your syllabus materials no later than *(date)*. **Copyright Guidelines:** Please review the attached guidelines for obtaining copyright permission.

**pp#7** As agreed upon, your honorarium will be (\$ ) plus *(list expenses)*. At the conclusion of the activity please submit original receipts and an itemized list of expenses.

**pp#8** Once again, thank you for your willingness to participate in this CME activity. The planning committee has worked hard to develop a program designed to meet the expressed needs of our intended audience. *(Describe target audience including geographic regions if applicable)*. We will send you information about the registrants as we approach the conference date.

**pp#9** If we can be of any additional help, or can clarify any of the above statements, please contact me at *(telephone number)* or the HCCME Program Manager, Juliana Woo, at (808)692-0878; fax (808) 692-1246), e-mail [jwoo@hawaii.edu](mailto:jwoo@hawaii.edu).

Sincerely,

Enc: Disclosure Declaration and Attestation Form *(due date)*



**HAWAII CONSORTIUM FOR CONTINUING MEDICAL EDUCATION  
Disclosure Declaration and Attestation Form**

*Please print or type:*

<b>Name:</b>
<b>Role(s):</b> (e.g. speaker, moderator, panel, author, planning committee, other - please describe)
<b>CME Activity:</b>
<b>Date(s):</b>
<b>Presentation Title(s):</b>

◆ **CONFLICT OF INTEREST POLICY:** It is the policy of the Hawaii Consortium for Continuing Medical Education (HCCME) to ensure balance, independence, objectivity, and scientific rigor in all its individually sponsored educational activities. Individuals who may influence content, such as planners, speakers, authors or others must disclose relevant financial relationships with commercial interests that **pertain to this specific activity**. (See reverse for glossary of terms) Should it be determined that a conflict of interest exists as a result of a financial relationship you have disclosed, the conflict of interest must be resolved prior to the activity. If you refuse to provide disclosure information, you will be disqualified from being a part of the planning or implementation of this CME activity. All disclosed relevant commercial interests will be provided to meeting attendees prior to your presentation. It is also recommended that speakers verbally state such relationships when appropriate during their presentation.

◆ **UNLABELED USES OF PRODUCTS:** Speakers are also required to disclose to the audience when a product discussed is not labeled for the use under discussion or that the product is still investigational.

1) Will your presentation include discussion of any product not labeled for the use under?  
**Yes No** discussion or any product that is still investigational?

⇒ ⇒ ⇒ *Proceed to question 2.*

2) **Within the past 12 months**, have you or your spouse/partner had relevant financial relationships or affiliations with commercial interests?

⇒ ⇒ ⇒ *If answer to question 2 is No, please complete form by signing in box below.*

Signature:	Date:
------------	-------

⇒ ⇒ ⇒ *If answer to question 2 is Yes, please continue.  
Complete disclosure section below and sign on page 2.*

Type of Financial Relationship	List Name of Commercial Interest(s)
Grant/Research Support	
Consultant	
Speakers' Bureau	
Stock Shareholder	
Advisory Committee/Board	
Patent holder	
Other Financial or Material Support (please describe)	

In light of the relationships/affiliations I have listed, I ATTEST to all of the following:

- that these relationships/affiliations will not bias or otherwise influence my involvement in the program;
- that practice recommendations given relevant to the companies with whom I have relationships/affiliations will be supported by the best available evidence or, absent evidence, will be consistent with generally accepted medical practice;
- and, that all reasonable clinical alternatives will be discussed when making practice recommendations.

Signature:	Date:
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. . . . .  
**GLOSSARY OF TERMS**

**New (August 2007) Commercial Interest**

The ACCME defines a 'commercial interest' as "any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients." (Effective immediately.)

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

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

501-C Non-profit organizations (*Note: ACCME screens 501c organizations for eligibility. Those that advocate for 'commercial interests' as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint sponsor, but they can be a commercial support.*)

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

**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.

'Contracted research' includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

**Relevant financial relationships**

ACCME focuses on financial relationships with commercial interests in the **12-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 12 months that create a conflict of interest.

**Conflict of Interest**

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

*Hawaii Consortium for Continuing Medical Education*  
**Resolution of Conflict of Interest Form**

<b>Activity Title:</b>	<b>Activity Date:</b>
<b>Name of person with the conflict:</b>	
<b>Check one:</b> <input type="checkbox"/> speaker <input type="checkbox"/> activity director <input type="checkbox"/> planning group <input type="checkbox"/> moderator <input type="checkbox"/> panel <b>Other:</b>	

**Defining Conflict of Interest**

**When do relationships create 'conflicts of interest?' (SCS 2.1)**

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

**Where is the 'conflict?' (SCS 2.1)**

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

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

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

**Resolving Conflicts of Interest**

<b>Before Activity</b>  <i>(Check all that apply)</i>	<p><b>At least one intervention must happen BEFORE the activity.</b></p> <p><b>Option #1</b></p> <p><input type="checkbox"/> Activity Director reviewed slides of presentation before the activity. Outcome:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> No commercial bias was perceived.</li> <li><input type="checkbox"/> Commercial bias was perceived and the presentation was revised.</li> <li><input type="checkbox"/> Other (please describe):</li> </ul> <p><b>Option #2:</b></p> <p><input type="checkbox"/> Activity Director asked the person with the conflict to:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Refrain from making recommendations on topics in which the conflict exists.</li> <li><input type="checkbox"/> Base all recommendations on peer reviewed data.</li> <li><input type="checkbox"/> Other (please describe):</li> </ul> <p><b>Option #3:</b></p> <p><input type="checkbox"/> Other (please describe);</p>
<b>During Activity</b>  <i>(Check all that apply)</i>	<p><input type="checkbox"/> Activity Director (or HCCME observer) moderated the meeting:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> No commercial bias was perceived.</li> <li><input type="checkbox"/> Commercial bias was perceived and the Activity Director or Observer asked questions or made comments to counter the commercial bias.</li> </ul>
<b>Post-Activity</b>  <i>(Check all that apply)</i>	<p><input type="checkbox"/> Fewer than 5% of the audience perceived commercial bias. No action needed.</p> <p><input type="checkbox"/> Over 5% of the audience perceived commercial bias. Resolved by one of the following:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Activity Director spoke with person with conflict about the bias that was perceived and discussed how to avoid commercial bias in the future.</li> <li><input type="checkbox"/> Activity Director will not invite person to participate in subsequent meetings.</li> <li><input type="checkbox"/> Other (please describe):</li> </ul>
<p>↑ <i>Print Name of person completing this form</i>                      ↑ <i>Signature</i>    ↑ <i>Date</i></p>	

**HAWAII CONSORTIUM FOR CONTINUING MEDICAL EDUCATION  
WRITTEN AGREEMENT FOR COMMERCIAL SUPPORT**

The Hawaii Consortium for Continuing Medical Education is committed to presenting CME activities that promote improvements or quality in healthcare and are independent of the control of commercial interests. As part of this commitment, the Hawaii Consortium for Continuing Medical Education has outlined in this agreement, the terms conditions, and purposes of commercial support for its CME activities. Commercial Support is defined as financial or in-kind contributions given by a commercial interest<sup>1</sup>, which is used to pay all or part of the costs of a CME activity.

Title of CME Activity			
Activity Location		Activity Date(s)	
Name of Commercial Interest			
Amount of Educational Grant (direct or in-kind)			
Grant will be used for the following (check all that apply):			
Speaker Honoraria	Speaker Expenses (itemize)	Meeting Expenses (itemize)	Other (list

**TERMS, CONDITIONS AND PURPOSES**

**INDEPENDENCE**

- 1. This activity is for scientific and educational purposes only and will not promote any specific proprietary business interest of the Commercial Interest.
- 2. The HCCME is responsible for all decisions regarding the identification of educational needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content of the CME, selection of education methods, and the evaluation of the activity.

**APPROPRIATE USE OF COMMERCIAL SUPPORT**

- 3. Funds should be in the form of an educational grant made payable to the **Hawaii Medical Foundation** or an HCCME approved educational partner.
- 4. The HCCME will make all decisions regarding the disposition and disbursement of the funds from the Commercial Interest.
- 5. The Commercial Interest will not require the HCCME to accept advice or services concerning teachers, authors, or participants or other education matters, including content, as conditions of receiving this grant.
- 6. All commercial support associated with this activity will be given with the full knowledge and approval of the HCCME. No other payments 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.
- 7. The HCCME will, upon request, furnish the Commercial Interest documentation detailing the receipt and expenditure of the commercial support.
- 8. All other support associated with the CME activity (e.g., distributing brochures, preparing slides, etc.) must be given with the full knowledge and approval of the **Hawaii Consortium for Continuing Medical Education**.

**COMMERCIAL PROMOTION**

- 9. Product-promotion material or product-specific advertisement of any type is prohibited in or during the CME activity. The juxtaposition of editorial and advertising material on the same products or subjects is not allowed. Live or enduring promotional activities must be kept separate from the CME activity. Promotional materials cannot be displayed or distributed in the education space immediately before, during or after a CME activity. Commercial Interests may not engage in sales or promotional activities while in the space or place of the CME activity.
- 10. The Commercial Interest may not be the agent providing the CME activity to the learners.

**DISCLOSURE**

- 11. The Accredited Provider will ensure that the source of support from the Commercial Interest, either direct or "in-kind," is disclosed to the participants, in program brochures, syllabi, and other program materials, and at the time of the activity. This disclosure will not include the use of a trade name or a product-group message. The acknowledgment of commercial support may state the name, mission, and clinical involvement of the company or institution and may include corporate logos and slogans, if they are not product promotional in nature.

The Commercial Support and the Hawaii Consortium for Continuing Medical Education agree to abide by all requirements of the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support of Continuing Medical Education* (appended).

<b>Name of Accredited Provider : Hawaii Consortium for Continuing Medical Education</b>	
Contact Person Juliana J. Woo, MPH	Email Address jwoo@hawaii.edu
Phone Number 808-692-0878	Fax Number 808-692-1246
Address c/o John A. Burns School of Medicine, University of Hawaii 651 Ilalo St., CME/MEB	
City, State, Zip Honolulu, HI 96813-5534	

<b>Educational Partner (if applicable)</b>	
Contact Person	Email Address
Phone Number	Fax Number
Address	
City, State, Zip	

<b>Name of Commercial Interest</b>	
Contact Person	Email Address
Phone Number	Fax Number
Address	
City, State, Zip	

**AGREED BY AUTHORIZED REPRESENTATIVES**

**Accredited Provider**

**Commercial Interest**

\_\_\_\_\_  
Signature and Date  
*Juliana J. Woo*

\_\_\_\_\_  
Signature and Date

\_\_\_\_\_  
Print Name  
*CME Compliance & Accreditation Manager*

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Title

**Educational Partner (if applicable)**

\_\_\_\_\_  
Signature and Date

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Title

<sup>1</sup>The ACCME defines a 'commercial Interest' as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests.

# Hawaii Consortium for Continuing Medical Education

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c/o John A. Burns School of Medicine · University of Hawai'i  
651 Ilalo Street, CME/MEB · Honolulu, HI 96813-5534  
Tel: 808-692-0878 · Fax: 808-692-1246 · E-mail: jwoo @hawaii.edu

[Date]

[Name]

[Company name]

[Address]

[City, State Zip]

Dear [Name]:

This is a request for an educational grant in the amount of [\$ ] to be used to support [title of activity, date(s), location]. The purpose of this educational activity is to [describe]. Content areas include [list]. We expect an attendance of [describe who, how many, practice areas, etc.]

The grant will be used solely for educational purposes and not for general overhead or for expenses of attendees. In accordance with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial, we will disclose the source of all support from commercial interests to our attendees. Additionally the terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter and the accredited provider. Enclosed is a copy of the HCCME Letter of Agreement. If you prefer, your company's letter may be substituted so long as all the key components of the HCCME agreement are present.

Thank you in advance for your support and consideration.

Sincerely,

JJW

CME Compliance & Accreditation Manager

Enc: HCCME Letter of Agreement

## Policy on Honoraria & Expense Reimbursement

### Introduction

Generally speaking, an honorarium is a payment to an individual in recognition of a special service or distinguished achievement for which custom or propriety forbids any fixed price to be set. Honoraria services may include, but are not limited to: panel participation, reviewing manuscripts, leading group discussions, lectures and similar services. The HCCME, not the individual or group, determines the size of the honorarium.

Payment of reasonable honoraria and reimbursement of expenses for faculty and others who contribute to CME development and delivery is customary and proper. For University of Hawai'i faculty, the amount of the honorarium and details about allowable expenses must be consistent with relevant institutional policy.

### Responsibility

1. The HCCME allows a range of honoraria to be offered to speakers, authors, reviewers, and editors. The honorarium amounts will be determined by the activity director in consultation with the planning group and shall be based on the following criteria:

- reputation and CV of proposed speaker
- level of honorarium for the discipline
- academic appointment
  - junior faculty (clinical instructors, assistant professors, equivalent)
  - senior faculty (associate professors, professors, equivalent)
  - other faculty (nationally or internationally recognized faculty or those requiring more than 2 day travel)
- length and number of presentations
- nature of the activity
- intensity of preparation
- time and distance away from home institution
- available funding
- market rates

2. The honorarium is not linked to commercial support, or to specific requests of the commercial interest.

3. No individual (activity director, speaker, moderator, member of the planning group, etc) may receive payment directly from a commercial interest for honoraria, travel or out-of-pocket expenses.

### Control

1. For conferences, the HCCME CME committee will review the proposed amount and source of the honoraria and estimated travel expenses as part of the activity certification process. A justification will be required for honoraria and projected travel expenses in excess of market rates.

2. For regularly scheduled activities, the department chair has the responsibility of determining CME honoraria based the criteria listed above. Requests for payment will be accompanied by

documentation including program announcements, schedule of presentations, brief bio, and receipts. The "request for check" will be reviewed and approved by the one of the co-chairs of the HCCME CME committee.

### **Appropriate Use of Honorarium Payments**

#### **1. University Faculty**

Honoraria are not paid to University faculty presenting at regularly scheduled activities. These internal educational activities are within the academic mission of teaching during a normal work schedule.

University faculty may receive honoraria for presentations in multi-hour conferences which involve an extensive investment of time in preparation and planning. An honorarium may be subject to negotiation in each case and should be within the range stipulated by this policy and University of Hawaii policy.

#### **2. Visiting Faculty**

Visiting faculty may be paid honoraria for presentations at regularly scheduled activities and at multi hour conferences.

3. Staff employees may not receive honorarium payments.

### **Honorarium Procedures**

A commercial supporter may not pay honorarium directly to the speaker. Any commercial support must be made in the form of an unrestricted educational grant for a specific activity and not designated for specific presenters. Grants for all activities, including regularly scheduled activities are processed by the HCCME or a designated educational partner.

- a) The activity chair invites the individual to speak at an educational activity. In addition to the educational content, the honorarium and reimbursement criteria are offered as part of the invitation. The details are specified in an agreement or in correspondence with the individual who will receive the honorarium and reimbursement as part of the invitation/confirmation process.
- b) The individual faculty accepts the invitation, honorarium and reimbursement terms in writing.
- c) At the conclusion of the activity, the speaker submits original receipts to the activity chair for processing.
- d) HCCME pays the speaker honorarium/expenses; payment to the speaker may be made only after the activity.
- e) In the case of a jointly sponsored activity where the joint sponsor is authorized to receive the commercial support, evidence of compliance with the honorarium procedures is submitted as part of the post-activity packet.

### **Expense Reimbursement**

1. In addition to providing an honorarium, it is expected that speakers will be reimbursed for travel expenses related to their presentation. All pertinent rules and regulations set by the State of Hawaii, Hawaii Medical Association and joint sponsors will apply, such as per diem limits and mileage reimbursement rates. Reimbursement of airfare in excess of coach class will be subject to justification. Expense reimbursement is restricted to those of the invited speaker.



2. If the invited speaker is a foreign national, the program chair must contact the HCCME account manager several months in advance to determine the required documentation for paying honoraria and travel to foreign nationals. HCCME will not authorize payment to a foreign speaker without the proper documentation.

### **Honorarium Guidelines**

**Junior Faculty** (clinical instructors, assistant professors, equivalent):  
\$500 - \$1,500 per presentation

**Senior Faculty** (associate professors, professors, equivalent):  
\$750 - \$2,500 per presentation

Visiting faculty often participate in several teaching activities when they travel to Hawaii. The individual may give several presentations, discuss clinical cases with residents, and share their research findings during the same visit. The honoraria guidelines are as follows:

**Junior Faculty** (clinical instructors, assistant professors, equivalent):  
up to \$4,000 per visit

**Senior Faculty** (associate professors, professors, equivalent):  
up to \$5,000 per visit

The honoraria guidelines will be reviewed periodically for appropriateness of honoraria amounts.

## Accreditation Statement

The accreditation statement identifies which ACCME accredited organization is responsible for demonstrating the CME activity's compliance with the Essential Areas and Elements, including the Standards for Commercial Support, and Accreditation Policies.

The accreditation statement must appear on all CME activity materials and brochures distributed by the HCCME, except that the accreditation statement does not need to be included on initial, save-the-date type activity announcements. Such announcements contain only general, preliminary information about the activity like the date, location, and title. If more specific information is included, like faculty and objectives, the accreditation statement must be included.

The ACCME accreditation statement is as follows:

### **For directly sponsored activities:**

The Hawaii Consortium for Continuing Medical Education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

### **For jointly sponsored activities:**

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the Hawaii Consortium for Continuing Medical Education and [name of non-accredited provider]. The Hawaii Consortium for Continuing Medical Education is accredited by the ACCME to provide continuing medical education for physicians.

*NOTE: The ACCME accreditation and the AMA PRA credit system designation statements must be displayed as two separate paragraphs. The paragraphs may appear in different sections of the print or electronic announcement.*

Designation Statement  
2006 Revision  
AMA PRA (Physician's Recognition Award) credit system

**Credit** is the 'currency' assigned to 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), and ACOG (Cognates).

The American Medical Association (AMA) is responsible for the AMA Physician's Recognition Award. The AMA PRA Certificate and related AMA PRA credit system recognize physicians who, by participating in CME activities, demonstrate their commitment to staying current with advances in medicine. AMA PRA credit offers a system to measure and track physician participation in certified CME activities. *AMA PRA Category 1 Credit™* is a trademark of the AMA.

To designate (or certify) activities for *AMA PRA Category 1 Credit™*, the HCCME, through compliance with AMA PRA rules, establishes that an activity meets AMA PRA standards and assigns a maximum number of credits.

**Assigning Credit for Learning Participation**

Sixty minutes of physician participation (i.e. formal interaction between faculty and the physician audience) in a certified live activity equals one (1) *AMA PRA Category 1 Credit™*.

Activities may be designated for, and credit awarded to physicians in 15 minutes or .25 credit increments; in both cases providers or physicians may round to the nearest quarter hour.

In the event an activity experiences a significant shortfall in time; the HCCME will reassess the maximum corresponding credits designated for the activity. If the maximum is reduced, a note must be placed in the activity file stating that the maximum was changed from [x] *AMA PRA Category 1 Credits™* to [x] *AMA PRA Category 1 Credits™* because the program was completed in a shorter time period than anticipated. Additionally, the reason for the change should be communicated to all attendees, particularly to those who are claiming the maximum credits (e.g., speaker ended talk early). [Approved HCCME 10/18/06]

**Credit Designation Statement:**

The Hawaii Consortium for Continuing Medical Education designates this educational activity for a maximum of [number of credits] <i>AMA PRA Category 1 Credit(s)™</i> . Physicians should only claim credit commensurate with the extent of their participation in the activity.
--

The trademark language "*AMA PRA Category 1 Credit(s)™*" is displayed in italics; <sup>™</sup> is in regular font. This standard language, along with the Designation Statement, benefits both providers and physicians by clearly communicating the HCCME's privilege to award *AMA PRA Category 1 Credit™* on behalf of the AMA.

**Note:** the ACCME accreditation statement and the AMA PRA credit system designation statements must be displayed as two separate paragraphs. The paragraphs may appear in different sections of the promotional announcement.

Source: The AMA Physician's Recognition Award information booklet, 2006 revision. Available free online in Adobe Acrobat (PDF) format at [222.ama-assn.org/go/ora](http://222.ama-assn.org/go/ora)

## **Brochures, Announcements and Electronic Postings**

All CME brochures, announcements and electronic postings must be reviewed and approved by the HCCME prior to final printing, posting and or distribution.

While an application for credit designation is in process, an unauthorized mailing will be just cause for the HCCME to decline consideration of the application. Corrections of unauthorized brochures will be made at the expense of the applicant.

**Save-the-date** announcements are permitted. Such announcements contain only general preliminary information like the date, location, and title. Specific information like faculty and objectives may not be included. The Accreditation Council for Continuing Medical Education prohibits the use of statements such as “CME pending” or “CME applied for”. Save-the-date announcements must also be approved by the HCCME.

**The following are Section Headings for information that is REQUIRED to be in all CME brochures:**

### **1. Face Cover:**

- Title of Program
  - Days and Dates
  - Venue, City/State
  - Presented by: [School of Medicine Department] or [Hawaii Medical Association]
  - Sponsored by: Hawaii Consortium for Continuing Medical Education, a joint venture between the Hawaii Medical Association and the John A. Burns School of Medicine, University of Hawai`i
- OR
- Jointly Sponsored by: Hawaii Consortium for Continuing Medical Education, a joint venture between the Hawaii Medical Foundation and the John A. Burns School of Medicine, University of Hawai`i and [name of Joint Sponsor]

### **2. Program/Conference Schedule**

- Day/Date
- Start-End times, Titles of Presentations, Speaker Names & Degree(s)
- Breaks/meals

### **3. Accreditation**

Include one of the following Accreditations Statements (verbatim) on **all** CME brochures:

*• Directly Sponsored Activities - activities planned and implemented by John A. Burns School of Medicine, University of Hawaii or the Hawaii Medical Association - should use the following:*

The Hawaii Consortium for Continuing Medical Education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

- *Jointly Sponsored Activities - activities planned and implemented by the HCCME and a non-ACCME accredited provider - should use the following:*

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 the Hawaii Consortium for Continuing Medical Education and [name of non-accredited provider]. The Hawaii Consortium for Continuing Medical Education is accredited by the ACCME to provide continuing medical education for physicians.

**4. Credit Designation** - include the following credit designation statement (verbatim, including italics) on **all** CME brochures:

The Hawaii Consortium for Continuing Medical Education designates this educational activity for a maximum of [number] *AMA PRA Category 1 Credits*<sup>™</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.

**5. Faculty and Sponsor Disclosure**

The HCCME must insure balance, independence, objectivity, and scientific rigor in all certified activities. Disclosure information about financial relationships between the faculty and commercial interests will be revealed in writing in the course materials. Faculty will disclose discussions of unlabeled/unapproved uses of drugs or devices during their presentations.

**6. Purpose and/or Objectives**

- Include description of educational format(s)

**7. Intended Audience**

**8. Faculty**

- Name & Degree(s)
- Credentials

**9. Program Planning Committee**

- Name & Degree(s)
- Credentials

**10. Conference Information**

- Identify contact person, telephone, fax, email, mailing address.
- Americans with Disabilities Act - include the following disability statement on **all** CME brochures:

The HCCME fully complies with the legal requirements of the Americans with Disabilities Act rules and regulations. Persons with disabilities who may need auxiliary aids or services must request the accommodations at least one month prior to the program date, so that appropriate arrangements can be made.

## **11. Cancellations**

- Registration cancellation instructions
- Conference cancellation or speaker substitutions

The [presenting department or joint sponsor] reserves the right to cancel this conference or make speaker substitutions in the event of unforeseen or extenuating circumstances.

## **12. Acknowledgement**

The program planning committee acknowledges the support of this conference through educational grants and display fees. The HCCME, however, does not imply endorsement of any commercial products. A list of exhibitors and grantors will be provided to each attendee in the conference syllabus.

## **13. Registration**

- Instructions
- Information
- Fees (early/late)
- Deadlines
- Payment instructions & options

## **Optional**

### **1. Program Location (optional)**

- Map
- Directions
- Parking

### **2. Travel Information**

- Accommodations
- Ground transportation
- Conference attire

## Attendance

### Regularly Scheduled Conference Series

It is standard practice for participants at all department RSCs to complete a written evaluation/registration form for each session they attend. In order for the physician participant to claim credit for the session, he/she must complete, sign, and submit the form at the conclusion of the activity. The forms are collected by department CME coordinators. A typewritten list, compiled from the evaluation/registration forms, is submitted to HCCME for data entry within one week of the session. The record of the actual number of *AMA PRA Category 1 Credits*<sup>™</sup> claimed by each physician participant is retained in an electronic database for 6 years. Upon the request of the physician, a record of the credit awarded is provided with a transcript.

### Conferences

Typically, a sign-in sheet is used to track attendance, to assist conference planners with accurate headcounts for food and beverage orders, and to confirm distribution of conference materials.

The heading of the sign-in sheet should include:

<u>Required</u>	<u>Example</u>
Title:	Asthma Update
Date(s) of activity:	January 23-26, 2006
Location of activity:	Ala Moana Hotel, Honolulu, Hawaii
# of <i>AMA PRA Category 1 Credits</i> <sup>™</sup>	16.0

number of physician participants (to be completed post activity)

number of non-physician participants (to be completed post activity)

Column Headings:

name (typed or printed in alpha order, last name first)

degree

signature

### Credit Claim Form

The HCCME is in compliance with the American Medical Association's requirements in regards to recording and awarding *AMA PRA Category 1 Credit*<sup>™</sup> to physicians. Credit is awarded based on the number of credits the physician participant submits on the credit claim form. Participants may claim credit as a physician learner or physician teacher.

The credit claim form may be distributed as a single sheet or stapled to the evaluation form.

When an educational activity is carried out over the course of more than 1 day, daily sign-in is optional.

A summary (sorted by credit hours claimed) listing the names, identification number, and total number of credits claimed must be submitted with the original sign-in sheets to HCCME within 45 days of the activity.

*Incomplete attendance records will be returned.*

Attendance Summary

Example:

<b>Name</b>	<b>ID #</b>	<b>Total Credits</b>
Doe, John		8.0
An, Steven	82222	8.0
Adams, Carole	05849	7.0
Ching, Pam	08829	7.0
Dee, Daniel	29999	6.0

[Title of Activity]  
[Date]

**Credit Claim Form**

• **As a physician learner:**

I claim \_\_\_\_\_ *AMA PRA Category 1 Credits™* for participating as a learner in this activity (1 credit for each hour of participation, not to exceed [maximum number] credits.)

• **As a physician teacher/faculty/presenter:**

I taught for \_\_\_\_\_ hours \_\_\_\_\_ minutes.

I claim \_\_\_\_\_ *AMA PRA Category 1 Credits™* for participating as faculty in this activity (2 credits for each hour of interaction).

- The formula for claiming credit as faculty is 2 *AMA PRA Category 1 Credits™* per hour of presentation time (or a 2:1 ratio). Credit can be designated in 15 minute increments.
- Faculty panel presenters are to claim credit dependent of the time of their actual presentation and not on the amount of time they sat in the panel.
- Faculty may not claim simultaneous credit as physician learners for sessions at which they present; however they may claim participant credit for other sessions they attend as learners at a designated live activity.
- Physicians may only claim credit as faculty for presentations that are original and presented for the first time.

• **As a non-physician healthcare professional:**

I participated in \_\_\_\_\_ hours of the activity that was designated for [number of credits] *AMA PRA Category 1 Credits™*.

\* \* \* \* \*

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Signature



## Certificates Credit Certificates for Physician Participants

Only physicians may be awarded *AMA PRA Category 1 Credit*<sup>™</sup>. Credit certificates are the responsibility of the department, HMA, or joint sponsor and are optional. Credit certificates must be based on the actual credit claimed by the physician. **Accordingly, certificates are to be produced at the conclusion of the educational activity, so that physicians can accurately claim their credit for participating.**

This 3-part process starts with:

1. the physician first claiming their amount of participation;
2. continues with the provider recording these credits;
3. and concludes with the provider producing a credit certificate that accurately reflects those credits.

While the final format, design and paper stock are choices of the department, HMA or joint sponsor, the HCCME must review and approve the final draft.

***AMA PRA Category 1 Credit*<sup>™</sup> certificates for physicians should read as follows:**

The [name of accredited provider] certifies that [name of physician] has participated in the educational activity titled [title of activity] at [location] on [date] and is awarded [number of credits] *AMA PRA Category 1 Credits*<sup>™</sup>

### **Example: Credit Certificate for physician learners**

The Hawaii Consortium for Continuing Medical Education  
*a joint venture between the Hawaii Medical Association and the John A. Burns School of Medicine, University of Hawai'i*

certifies that

John Carl, MD

has participated in the educational activity titled  
Updates in Cardiology  
at the Hilton Hawaiian Hotel, Honolulu, Hawaii  
on January 23, 2006  
and is awarded 6.0 *AMA PRA Category 1 Credits*<sup>™</sup>

*Signature*

Richard L. Lake, MD  
Course Director (etc)

### **Example: Credit Certificate for physician teachers**

has participated as faculty in the educational activity titled

## Certificates Certificates of Attendance for Non-physician Participants

Providers may choose to issue non-physician health professionals a certificate of attendance that references *AMA PRA Category 1 Credit™*, to help them document their attendance at certified educational activities.

### **Attendance certificates for non-physician participants can read:**

The [name of accredited provider] certifies that [name of participant] has participated in the educational activity titled [title of activity] at [location] on [date] jointly sponsored by [name of non-accredited organization, when applicable]. This activity was designated for 6.0 *AMA PRA Category 1 Credits™*

### **Example: Certificate of attendance for non-physicians participants**

The Hawaii Consortium for Continuing Medical Education

*a joint venture between the Hawaii Medical Association and the John A. Burns School of Medicine, University of Hawai'i*

certifies that

Carl Jones, RN

has participated in the educational activity titled  
Cardiology Updates  
at the Hilton Hawaiian Hotel, Honolulu, Hawaii  
on January 26, 2006.

This activity was designated for 6.0 *AMA PRA category 1 credit(s)™*

*Signature*

Richard L. Lake, MD  
Course Director (etc.)

## Americans with Disabilities Act

The University of Hawai`i is committed to providing persons with disabilities equal access to conferences, workshops and other meetings open to the public and sponsored by the University and therefore the Hawaii Consortium for Continuing Medical Education. The following responsibilities are mandatory and provided for by the Americans with Disabilities Act of 1990 and Sections 503 and 504 of the Rehabilitation Act of 1973.

### Registration Forms and Announcements

All public announcements for workshops and conferences should indicate who to call for information regarding access for persons with disabilities.

All conference registration forms should contain a statement inviting participants to indicate if they have special needs due to their disability, which require assistance.

The meeting planner should respond individually to persons with disabilities who request assistance.

### Program Access (Auxiliary Aids and Services)

Printed materials used at conferences should be made available in enlarged print or on cassette tape for persons who are visually impaired or who have print handicaps, if requested.

Qualified sign language interpreters must be provided for persons who are deaf or hard of hearing, if requested with reasonable advance notice.

Persons with disabilities may not be charged separate fees for cassette tapes, sign language interpreters, or other assistance needed to make the conference accessible. **Projected costs of providing assistance should be factored into conference fees or grant proposals.**

### Physical Access

All meeting planners must ensure that their conferences, workshops, and meetings are held in accessible locations or sites where barriers can be readily compensated for by the provision of personal assistance in a way that does not invade individual privacy. Entryways, parking, restrooms, meeting rooms, dining rooms, guest rooms, and conference-related social activities must be accessible. It is strongly recommended that pre-conference planning include an access review of the meeting or conference site.

Source: University of Hawai`i Equal Opportunity and Affirmative Action Office

For more information contact: Commission on Persons with Disabilities, 919 Ala Moana Blvd.,  
Honolulu, HI 95814, (808) 586-8121.

## Copyright Guidelines

\Copyright\, n. The right of an author or his assignee, under statute, to print and publish his literary or artistic work, exclusively of all other persons. This right may be had in maps, charts, engravings, plays, and musical compositions, as well as in books.

*Source:* Webster's Revised Unabridged Dictionary, © 1996, 1998, MICRA, Inc.

An important exception to the owners' rights is fair use. The entire fair-use statute, as enacted by Congress, is as follows:

The Fair-Use Statute Section 107 of the Copyright Act of 1976.

Limitations on exclusive rights: Fair Use

*Notwithstanding the provisions of sections 106 and 106A, the fair use of a copyright work, including such use by reproduction in copies or phonorecords or by any other means specified in that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include –*

- 1. The purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;*
- 2. The nature of the copyrighted work;*
- 3. The amount and substantiality of the portion used in relation to the copyrighted work as a whole; and*
- 4. The effect of the use on the potential market for or value of copyrighted work.*

*The fact that a work is unpublished shall not in itself bar in finding of fair use if such finding is made upon consideration of all the above factors.*

### Checklist for Fair Use

For each possible "fair use" of a copyrighted work, a copy of the "Fair Use Checklist" must be completed and attached to handout materials submitted to the HCCME as part of the post-activity requirements.

If the copyright work is not fair use, a copy of the letter from the publisher stating permission to reproduce the material must be attached to the handout materials submitted to the HCCME as part of the post-activity requirements.

The "Fair Use Checklist" is reproduced with permission from the Copyright Management Center, Indiana University – Purdue University, Indianapolis (IUPUI), 530 W. New York Street, Indianapolis, IN 46202.

# CHECKLIST FOR FAIR USE

Please complete and retain a copy of this form in connection with each possible "fair use" of a copyrighted work for your project

Name: \_\_\_\_\_ Date: \_\_\_\_\_ Project: \_\_\_\_\_

Institution: \_\_\_\_\_ Prepared by: \_\_\_\_\_

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## PURPOSE

### *Favoring Fair Use*

- Teaching (including multiple copies for classroom use)
- Research
- Scholarship
- Nonprofit Educational Institution
- Criticism
- Comment
- News reporting
- Transformative or Productive use (changes the work for new utility)
- Restricted access (to students or other appropriate group)
- Parody

### *Opposing Fair Use*

- Commercial activity
- Profiting from the use
- Entertainment
- Bad-faith behavior
- Denying credit to original author

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## NATURE

### *Favoring Fair Use*

- Published work
- Factual or nonfiction base
- Important to favored educational objectives

### *Opposing Fair Use*

- Unpublished work
- Highly creative work (art, music, novels, films, plays)
- Fiction

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## AMOUNT

### *Favoring Fair Use*

- Small quantity
- Portion used is not central or significant to entire work
- Amount is appropriate for favored educational purpose

### *Opposing Fair Use*

- Large portion or whole work used
- Portion used is central to work or "heart of the work"

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## EFFECT

### *Favoring Fair Use*

- User owns lawfully acquired or purchased copy of original work
- One or few copies made
- No significant effect on the market or potential market for copyrighted work
- No similar product marketed by the copyright holder
- Lack of licensing mechanism

### *Opposing Fair Use*

- Could replace sale of copyrighted work
- Significantly impairs market or potential market for copyrighted work or derivative
- Reasonably available licensing mechanism for use of the copyrighted work
- Affordable permission available for using work
- Numerous copies made
- You made it accessible on Web or in other public forum
- Repeated or long-term use

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This document is provided as a courtesy of the Copyright Management Center, IUPUI, 530 W. New York St., Indianapolis, IN 46202.

## Fee Schedule and Other Expenses

The cost of HCCME's administration of a sponsorship program in continuing medical education is partially offset by sponsorship fees. Every activity certified by the HCCME will be assessed a fee for processing of applications, for the number of credits designated, and for recording the participation in the participant's individual record. HCCME sponsorship fees and reimbursements of the observer's expenses are due 30 days upon receipt of HCCME's invoice. The fees are subject to review and change. CME activity deficits will be the responsibility of the presenting School of Medicine Department, Hawaii Medical Association committee, or joint sponsor.

### Fees for Directly Sponsored Activities:

#### *Topical conferences, workshops, symposia*

Application for credit designation: \$50.00 (non-refundable)

Per credit fee: \$25.00

Per CME eligible participant fee (MDs or Dos): \$5.00

*Example:* 3 credit program with 28 MDs, 2 DOs, 5 nurses, 2 residents

Processing fee	\$50.00
\$25.00 x 3 credit	\$75.00
\$5.00 x 30 CME eligible	\$150.00
Total	\$275.00

#### *Department Regularly Sponsored Conferences*

Processing Fee, Initial Application for Credit Designation: \$50.00 (non-refundable)

Per credit fee: \$15.00 per session conducted during the year

Annual Report Fee: \$50.00

### Fees for Jointly Sponsored Activities:

#### Step 1

Request for Joint Sponsorship Processing Fee (for new applicants): A one-time, non-refundable fee of \$100.00

#### Step 2

Application for credit designation: \$100.00 for each specific CME activity the non-accredited joint sponsor wishes to jointly sponsor with the HCCME.

Per credit fee: \$100.00

Per CME eligible participant fee (MDs or DOs): \$5.00

*Example:* 6 credit program with 95 MDs, 5 DOs, 10 medical students, 6 pharmacists

Processing fee	\$100.00
\$100.00 x 6 credits	\$600.00
\$5.00 x 100 CME eligible	\$500.00
Total	\$1,200.00

### HCCME Observer Expenses

The department, HMA, or joint sponsor will bear the responsibility of all expenses (airfare, hotel, ground transportation and meals) incurred by the HCCME Observer.

**ENDURING MATERIALS** (approved 9/15/04)  
**INTERNET CME** (approved 1/17/07)

**Policy and Procedures**

**1.0 PURPOSE**

The Policy on Enduring Materials and Internet CME provides guidance for the HCCME on the requirements mandated by ACCME and the AMA regarding the production and delivery of continuing medical education enduring materials and Internet CME. All directly-sponsored and jointly-sponsored programs must adhere to these policies.

**2.0 DEFINITION**

Enduring materials are printed, recorded, audio, video, and electronic activities that may be used over time at various locations, and that in themselves constitute a planned CME activity. Live or enduring material activities that are provided via the Internet are considered to be "Internet CME," and have additional requirements noted below. Not included are "reference materials" such as books, journals, or manuals.

To be designated for *AMA PRA Category 1 Credit™*, enduring materials must:

- Provide clear instructions to the learner, including a determination of how long most physicians will take to complete the activity (the credits physicians can claim for the activity, also reflected in the designation statement).
- Provide access, where appropriate, to bibliographic sources that allow for further study, and that reinforce and clarify specific program topics.
- Provide for some type of learner interaction, such as a patient-management situation or a series of thematically relevant questions. This can be done by testing the physician's recall of program content, and/or ability to apply new concepts in response to simulated problems.
- Verify physician participation. Providers typically accomplish this through the examination or activity evaluation. Whatever mechanism a provider chooses must include a place for physicians to record the actual time spent on the activity, up to the maximum for which it is designated.
- As with live activities, providers may award credit to physicians who submit materials that verify their participation in the activity. Providers may issue credit certificates that recognize the extent to which physicians claim they participated in an activity.
- If examinations are used, then providers should score these confidentially and return them to the physician along with his or her credit certificate.
- If a group of physicians chooses to use *AMA PRA Category 1 Credit™* enduring materials, then a facilitator needs to be assigned in order to lead discussion.

**3.0 POLICY**

3.1 Enduring materials are planned just like any other CME activity. As such, all rules and regulations, specifications for development, content review, and distribution must be followed as they are for all activities that are certified for *AMA PRA Category 1 Credit™* by the HCCME. In addition, ACCME mandates that certain additional special requirements must be met. Enduring materials that involve Internet CME must comply with all ACCME Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies. There are additional special requirements for Internet CME that are annotated below.

- 3.2 Enduring materials shall not include any product-specific advertising whatsoever. Internet CME: Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer-based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer “windows” or screens of the CME content.
- 3.3 Reference to products or devices used in the care of patients may be made as long as the discussion is fair, balanced, and only refers to studies that are scientifically objective. Scientific or generic names shall be used whenever possible; trade names or brand names of products or devices shall not be referenced in continuing medical education enduring materials sponsored by the HCCME. Exceptions are those cases where the nature of the discussion makes this unavoidable (e.g., a discussion of adverse consequences associated with a particular branded product and not with its generic formulation), or where the brand has entered common usage as a colloquialism (e.g., “bovie”, as distinct from “surgical electro-coagulation device”). Internet CME: With clear notification that the learner is leaving the educational website, links from the website of an ACCME accredited provider to websites of commercial interests are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity.
- 3.4 Enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.
- 3.5 Acknowledgement of the receipt of commercial support for the enduring material must be made, and that acknowledgement must be made only at the beginning of the course content of the enduring material. Specific instructions apply, depending on the type of enduring material produced.
- 3.5.1 • 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.
- 3.5.2 • 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
- 3.5.3 • For **audio and video recording**, advertisements and promotional materials will not be included within the CME. There will be no ‘commercial breaks.’
- 3.6 General CME information – including the accreditation statement, credit designation statement, sponsorship statement, target audience, all special enduring material statements (see “Implementation”), and disclosure of both financial relationships and discussion of unlabeled or unapproved uses – must be made prior to the beginning of the course content of the enduring material.
- 3.7 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.

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. Internet CME: ACCME accredited providers may not place their CME activities on websites of commercial interests.

- 3.8 Whenever the copyright of any enduring material sponsored by the HCCME is not owned by the HCCME, the University of Hawaii, John A. Burns School of Medicine and/or the joint sponsor, the HCCME will document that it either has received permission to use those materials or that it is otherwise permitted to use the materials.
- 3.9 Because advances in medicine occur on a regular but unpredictable basis, the HCCME reserves the right to terminate a CME enduring activity at any time if the educational content becomes out of date.
- 3.10 Internet CME - Privacy and Confidentiality. The accredited provider must have, adhere to, and inform the learner about its policy on privacy and confidentiality that relates to the CME activities it provides on the Internet.
- 3.11 Internet CME - Hardware/Software requirements. The accredited provider must indicate, at the start of each Internet CME activity, the hardware and software requirements required for the learner to participate.
- 3.12 Internet CME – Provider Contact Information. The accredited provider must have a mechanism in place for the learner to be able to contact the provider if there are questions about the Internet CME activity.

#### 4.0 IMPLEMENTATION

- 4.1 The following information must be made available to learners prior to the beginning of the course content:
- 4.1.1 **Direct Sponsorship or Joint Sponsorship Statement:**  
For a directly sponsored enduring material, the following language should be used in both the promotional material and course materials:
- “Sponsored by the Hawaii Consortium for Continuing Medical Education, a joint venture between the University of Hawaii, John A. Burns School of Medicine and the Hawaii Medical Association”
- For a jointly sponsored enduring material, the following statement should appear:
- “This activity is jointly sponsored by the Hawaii Consortium for Continuing Medical Education and <Insert Name of Joint Sponsor>.”
- 4.1.2 **Accreditation Statement:**  
The following statement should be used in both promotional materials and in the enduring material itself for a **directly sponsored** enduring material:
- “The Hawaii Consortium for Continuing Medical Education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.”

For a **jointly sponsored** activity, the statement should read:

“This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the Hawaii Consortium for Continuing Medical Education and <name of non-accredited provider>. The Hawaii Consortium for Continuing Medical Education is accredited by the ACCME to provide continuing medical education for physicians.”

**4.1.3 Credit Designation Statement**

The following statement should appear in both promotional materials and in the enduring material itself:

“The Hawaii Consortium for Continuing Medical Education designates this educational activity for a maximum of <number of credits> *AMA PRA Category 1 Credit(s)*<sup>TM</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.

**4.1.4 Target Audience and Prerequisites (if any):**

Both the promotional materials and course materials should clearly indicate the audience for which the enduring material has been developed. If there are special requirements for participants in the enduring material (prerequisites), those prerequisites should be stated in this section.

**4.1.5 Topics, Faculty Credentials and Production Information:**

Information about the topic(s) of the enduring material, the principal faculty and their credentials, and production information must be included in both the materials announcing the educational activity and in the enduring material itself.

**4.1.6 List of Authors or Producer.**

**4.1.7 Acknowledgment of Commercial Support:**

The following statement should appear in both promotional materials and the actual enduring material:

“This educational activity is supported by <an> educational grant<s> from <list individual company names>.”

**NOTE:** No other company messages, product advertisements, product logos, or product inserts are to appear or be included in or be distributed with these materials.

**4.1.8 Provider and Faculty Financial Relationships Disclosure:**

The following language must appear prior to course content in printed and electronic materials, and/or on video/audio tapes:

“As a provider accredited by the ACCME, it is the policy of the Hawaii Consortium for Continuing Medical Education to require the disclosure of the existence of any significant financial interest or any other relationship the sponsor or presenting faculty members have with the manufacturer(s) of any commercial product(s) discussed in an educational presentation. The presenting faculty reported the following: . . .”

**List Presenters’ Declarations** — Include all faculty disclosure statements as well as those who have no disclosure to report. 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.

#### 4.1.9 **Faculty Discussions of Unlabeled or Unapproved Uses**

Information that is obtained from faculty concerning their discussion of unlabeled or unapproved uses of drugs or devices in their CME presentations must be communicated to participants.

#### 4.1.10 **Release Date, Review Date, Termination Date, Estimated Time to Complete the Activity**

The following information should be listed in the enduring material:

- Date of Original Release: <insert month/day/year or season/year>
- Date of Most Recent Review and Update, or Approval: <insert month/day/year or season/year> *(use only if applicable)*
- Termination Date: <insert month/day/year or season/year *(no longer than 3 years from most recent review date)*>
- Estimated Time to Complete This Educational Activity: <number of credits designated>
- Media or Combination of Media Used: *(example: This is a CD-ROM activity and also includes an interactive web-based component)*
- Method of Physician Participation in the Learning Process: *(example: Participants must listen to the audiotape and then answer a multiple choice quiz online)*
- Bibliographic sources Include a list or access to (as applicable) bibliographic sources that allow for further study, and that reinforce and clarify specific program topics.

#### 4.2 **Learner Interaction, Evaluation and Post-Test**

Enduring materials must provide for some type of learner interaction, such as a patient-management situation or a series of thematically relevant questions. This can be done by testing the physician’s recall of program content, and/or ability to apply new concepts in response to simulated problems. When possible, a set of test questions will be developed that address the material presented. These questions should be developed with the activity objectives as a guide. In addition, a program evaluation instrument will be included with each enduring material. If post-tests are used, answers to post-tests will not appear with the enduring material itself. Tests will be graded confidentially and the results will be returned to the participant.

**4.3 Instructions for Participating in the Activity and Securing CME Credit**

Clear instructions describing how participants can participate in the activity and receive CME credit, including completion of any test questions and methods to return them for scoring will be included in the enduring materials. Tests should be sent to the Hawaii Consortium for Continuing Medical Education (or main faculty/CME contact for directly sponsored or jointly sponsored programs) per the instructions in each enduring material, prior to the published termination date. A certificate will be mailed or electronically transferred within sixty (60) days of receipt. Each JABSOM Department (or the joint sponsor) will set criteria for passing, depending on the nature of the content and the specific target audience.

**4.4 Using enduring materials for group activities**

If a group of physicians chooses to use *AMA PRA Category 1 Credit™* enduring materials, then a facilitator needs to be assigned in order to lead discussion. The interested group of physicians should contact the program coordinator/contact for that particular enduring material to discuss this issue and see if a facilitator can be arranged (either live, local or via distance education technology (examples include, but are not limited to: phone teleconference, video teleconference, Internet meeting)).

###

**References:**

University of Wisconsin Medical School Policy on Enduring Materials  
AMA Physician's Recognition Award and credit system 2006 revision  
2004 Updated Accreditation Council for Continuing Medical Education Standards for Commercial Support, *Standards to Ensure Independence in CME Activities*, Adopted, April 2004, Approved, September 2004.

ACCME Activity Review. Form 20060515.

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## THE ACCME'S 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 ACCME's policies for disclosure and commercial support.

[NOTE: The ACCME's policies for disclosure and commercial support are articulated in: (1) *The Standards For Commercial Support: Standards to Ensure Independence in CME Activities*, as adopted by ACCME in September 2004; and (2) ACCME policies applicable to commercial support and disclosure. All materials can be found on [www.accme.org](http://www.accme.org).]

### 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.'

Essential Area and Element(s)		Criteria for Compliance
<b>Essential Area 1: Purpose And Mission</b>	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.	<b>C 1</b> 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.
<b>Essential Area 2: Educational Planning</b>	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.	<b>C 2</b> The provider incorporates into CME activities the educational needs (knowledge, competence, or performance) that underlie the professional practice gaps of their own learners.  <b>C 3</b> The provider generates activities/educational interventions that are designed to change competence, performance, or patient outcomes as described in its mission statement.  <b>C 4</b> The provider generates activities/educational interventions around content that matches the learners' current or potential scope of professional activities.  <b>C 5</b> The provider chooses educational formats for activities/interventions that are appropriate for the setting, objectives and desired results of the activity.  <b>C 6</b> The provider develops activities/educational interventions in the context of desirable physician attributes (e.g., IOM competencies, ACGME Competencies).  <b>C 7</b> The provider develops activities/educational interventions independent of commercial interests (SCS 1, 2 and 6).  <b>C 8</b> The provider appropriately manages commercial support (if applicable, SCS 3).  <b>C 9</b> The provider maintains a separation of promotion from education (SCS 4).  <b>C 10</b> The provider actively promotes improvements in health care and NOT proprietary interests of a commercial interest (SCS 5).
[Note: Regarding E 3.3 and C7 to C10 - The ACCME's policies for disclosure and commercial support are articulated in: (1) The Standards For Commercial Support: Standards to Ensure Independence in CME Activities, as adopted by ACCME in September 2004; and (2) ACCME policies applicable to commercial support and disclosure. All these materials can be found on <a href="http://www.accme.org">www.accme.org</a> .]		

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



**THE ACCME STANDARDS FOR COMMERCIAL SUPPORT<sup>SM</sup>**  
*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. (See [www.accme.org](http://www.accme.org) for a definition of a 'commercial interest' and some exemptions.)
- (a) Identification of CME needs;
  - (b) Determination of educational objectives;
  - (c) Selection and presentation of content;
  - (d) Selection of all persons and organizations that will be in a position to control the content of the CME;
  - (e) Selection of educational methods;
  - (f) Evaluation of the activity.
- 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. ¶



## Addendum II: Council on Ethical and Judicial Affairs Clarification on Gifts to Physicians from Industry (E-8.061).

### About this Document

The clarification below is offered as an addendum to Opinion 8.061, "Gifts to Physicians from Industry," of the Code of Medical Ethics in response to frequent questions that are received by the Council. The statements that appear in **bold type** below are the original guidelines excerpted from Opinion 8.061. The questions and answers that follow are provided as clarifications of the individual guidelines.

This addendum, and a full-length report of the document, will also be available in *The Food and Drug Law Journal*, Volume 56, Issue 1, in early April, 2001. Visit [www.fdpi.org](http://www.fdpi.org) for more information.

### Scope

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

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

### General Questions

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

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

### Guideline 1

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Council views gift certificates as a grey area which is not per se prohibited by the guidelines. Medical text books 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 text book 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 E-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.

#### 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).**

#### 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 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 4b) 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, e.g., 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 5 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.

Accordingly, "carefully selected educational conferences" should be interpreted as follows: funds may be used for the reasonable travel and lodging expenses of students, residents and fellows to attend the major educational, scientific or policymaking meetings of national, regional or specialty medical associations.

The Council recognizes that there may be some exceptional conferences for all physicians or even for just students, residents, or fellows that do not fall within this definition of carefully selected educational conferences but that meet the spirit of Guideline 5. Accordingly, the Council will consider proposals for travel and lodging subsidies for such conferences on a case-by-case basis and grant approval to those that meet the spirit of the guidelines.

#### Guideline 7

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

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

No. There can be no link between prescribing or referring patterns and gifts. In addition, travel expenses, including cruises, are not permissible.

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

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

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

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

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# American Medical Association

## E-9.00 Opinions on Professional Rights and Responsibilities

### E-9.011 Continuing Medical Education

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

Attendees. Guidelines for physicians attending a CME conference or activity are as follows:

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

Faculty. Guidelines for physicians serving as presenters, moderators, or other faculty at a CME conference are as follows:

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

Sponsors. Guidelines for physicians involved in the sponsorship of CME activities are as follows:

- (1) Physicians involved in the sponsorship of CME activities should ensure that (a) the program is balanced, with faculty members presenting a broad range of scientifically supportable viewpoints related to the topic at hand; (b) representatives of industry or other financial contributors do not exert control over the choice of moderators, presenters, or other faculty, or modify the content of faculty presentations. Funding from industry or others may be accepted in accordance with Opinion 8.061, "Gifts to Physicians from Industry."
- (2) Sponsors should not promote CME activities in a way that encourages attendees to violate the guidelines of the Council on Ethical and Judicial Affairs, including Opinion 8.061, "Gifts to Physicians from Industry," or the principles established for the AMA's Physician Recognition Award. CME activities should be developed and promoted consistent with guideline 2 for Attendees.
- (3) Any non-CME activity that is primarily promotional must be identified as such to faculty and participants, both in its advertising and at the conference itself.
- (4) The entity presenting the program should not profit unfairly or charge a fee which is excessive for the content and length of the program.
- (5) The program, content, duration, and ancillary activities should be consistent with the ideals of the AMA CME program. (I, V)

HCCME Handbook; updated 10/07