

First Fridays Webinar Series: Medical Education Group (MEG)

Webinar #1 - May 7th, 2010



Series Goals (5)

1. To provide insights into how Pfizer's Medical Education Group (MEG) functions – an operational overview
2. To share an up-to-date status of Pfizer's MEG timelines and grant review cycles
3. To share best practices that the CME provider community has submitted in recent grant cycles
4. To answer outstanding questions from the CME provider community
5. To gain insights into how Pfizer's MEG might improve our processes to best support the CME community





Agenda

1. Introduction
2. Topic One: The MEG 2-Step
3. Topic Two: Mitigating Bias in CME
4. Q and A

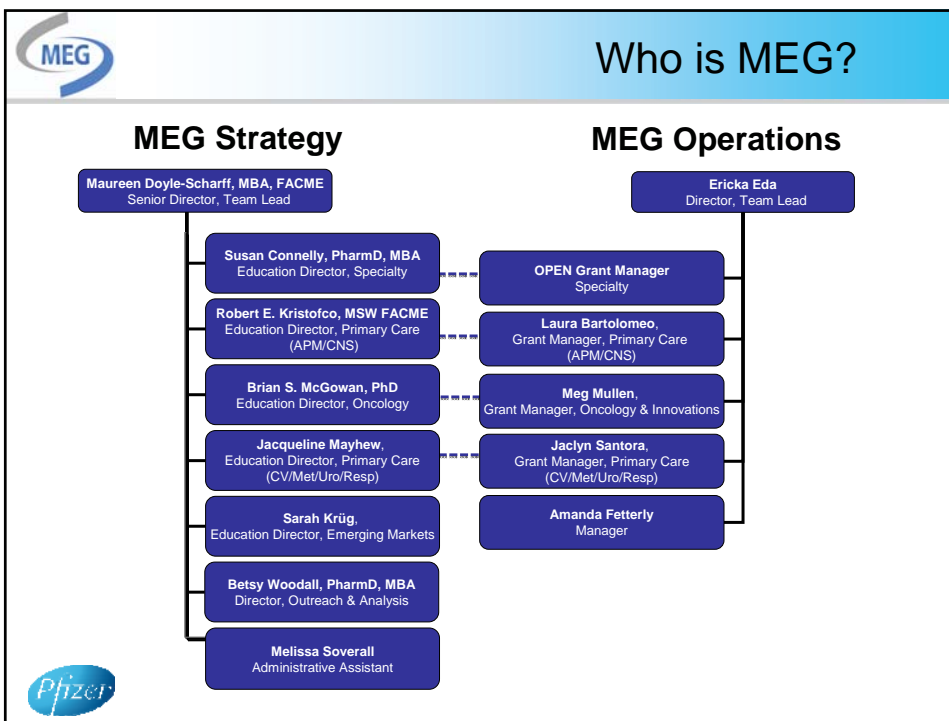


Today's Objectives (3)

Upon completion of today's call participants should be able to:

1. Understand how the processes of MEG are designed to support the Mission, Vision, and Goals of the group
2. Submit high-quality grant requests as prescribed by MEG's quarterly application windows
3. Identify resources for effective conflict of interest resolution and content validation policies in an effort to mitigate inappropriate bias and risk





MEG Mission, Vision, and Goals

VISION: Accelerating the translation of clinical science to quality patient care

MISSION: To cooperate with healthcare delivery organizations and professional associations to narrow professional practice gaps in areas of mutual interests through support of learning and change strategies that result in measurable improvement in competence, performance or patient outcomes.

GOAL: To increase the number of patients who receive the highest quality, safe and effective, individualized, and evidence-based care from physicians, other healthcare professionals, and the healthcare system.

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Why Does MEG exist?

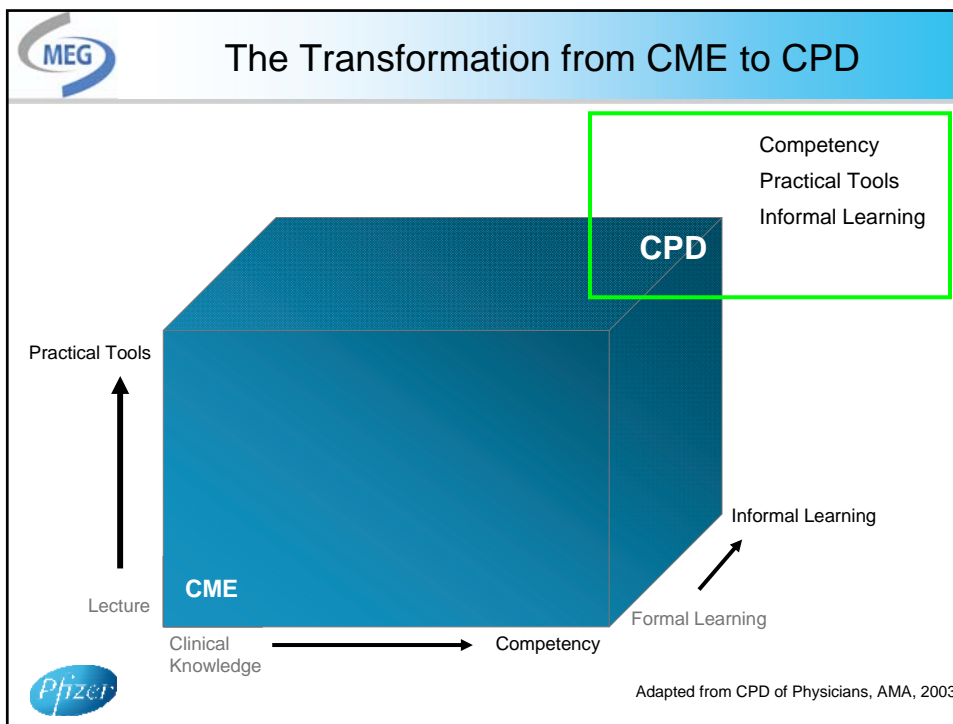
- MEG exist to provide educational grant support to the medical community in a compliant and effective manner
- Good education accelerates the adoption curve of evidence-based clinical skills and practices
- By funding good education, commercial support improves the quality of patient care



5-Year Transformation of MEG

Organizational Development Level	External Relationships	Pfizer History
Decentralized Brand Driven	Funder	Pre-2006
Decentralized Process Driven	Funder	2006
Centralized Process Driven	Funder	2007
Centralized Education Driven	CE Supporter	2007 - 2008
Center of Excellence for Healthcare Provider Education	CPD Supporter	2008 - 2009
Center of Excellence for Healthcare Quality Improvement	QI + CPD within systems of care supporter	2010 & beyond





MEG Medical Education Group

The MEG 2-Step:

An Overview of the Education Grants Processes

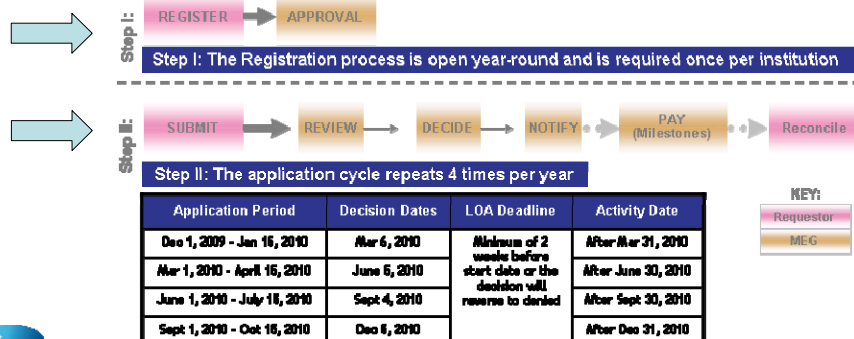
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The MEG 2-Step

1. Provider Registration (rolling)
2. Grant Application (quarterly)

Pfizer MEG utilizes a 2-step Registration and Application Process



Step I: Registration - How do I register?

1. Visit www.pfizermededgrants.com
2. Click [Go to the Grant System](#)

Medical Education Grants

Grants for Health Care Quality Improvement & Education
We're supporting you as you support patient care. Pfizer offers support for your independently-run health care quality improvement initiatives through online resources and medical education grants. Our full mission statement >

Resource Center
Publications, articles, needs assessments and more education literature
[Learn more about healthcare improvement >](#)

Medical Education Grants Process
Clinical areas of interest, who is eligible, criteria and how to apply
[Learn about the grants process >](#)

Your Grant Application
Apply for a new grant, register for eligibility or view the status of your existing applications.
[Go to the Grant System](#)

Important Grant Deadlines and Dates
Pfizer offers four grant application windows per year. All grant requests received within a single window are reviewed comparatively. Funding decisions are announced approximately 7 weeks following the close of these windows:





Step I: Registration - How do I register?

1. Click **Register** and complete the questionnaire

Welcome to the Pfizer Grant Management System

Pfizer's Medical Education Mission is to cooperate with healthcare delivery organizations and professional associations to narrow professional practice gaps in areas of mutual interests through support of learning and change strategies that result in measurable improvement in competence, performance or patient outcomes.

Please visit Pfizer.com/responsibility/grants_payments/medical_education_grants.jsp for further information regarding the Pfizer Medical Education Group and the grant submission process.

For any technical related inquiries or general questions concerning the process and procedure please email mededgrants@pfizer.com or call 1-866-MEG-4647 (international callers use 1-212-209-9997).

The following types of funding requests are **NOT** supported by this online system:

- Healthcare-related Charitable Contributions
- Fellowships and Scholarships
- Sponsorships

[Click here for definitions and information on how to apply for these grant types.](#)

Login

Are you a registered Pfizer Grants Application user?


email address:

password:

[password assistance?](#)

New User

Are you a new user?



For assistance:

mededgrants@pfizer.com or 1-866-MEG-4647



Step I: One Registration per Institution*

For every organization, the initial registration step must be completed by the Director of Continuing Medical Education or the person responsible for the Continuing Medical Education (CME) or Continuing Education (CE) program at the organization (or his/her designee). This individual will be considered the "CME/CE Registrant" and will be able to add and authorize additional users for their organization.

If you want to apply for a medical education grant but are not able to certify to the above, you should not proceed. If you are affiliated with an accredited CME/CE organization you should contact the office responsible for the CME/CE program and ask to be added as an organizational user to their registration.

Statement of Pfizer Commitment

Pfizer Inc is committed to complying with the guidelines and standards set by the Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Pharmacy Education (ACPE), American Medical Association (AMA), Association of American Medical Colleges (AAMC), American Association of Critical Care Nurses (AACN), American Nurses Credentialing Center (ANCC), Food and Drug Administration (FDA), Office of Inspector General (OIG) and the Pharmaceutical Research and Manufacturers of America (PhRMA) Code related to the support of professional education.

Applicant Statement of Commitment

Please read the following terms and conditions carefully.

Your certification represents your commitment to act in accordance with accepted standards in the event that Pfizer decides to fund an educational program based on your request. Your certification also represents that neither you nor your organization, (1) have been involved with any Pfizer promotional activities for the twelve months preceding the submission of a grant request, and (2) possess confidential information relevant to Pfizer promotional activities which remain subject to a non-disclosure agreement with Pfizer.

By certifying, you represent that you are fully authorized to submit an application and provide information in an application on behalf of the requesting organization and any partner organization(s), and you affirm that all responses and information provided in this application are truthful, accurate and complete. Your certification also represents that neither you nor your organization's directors, trustees, and/or principals are on the OIG debarment list. Further you certify that you are representing an accredited organization and that you will present a true and accurate report of the accreditation status of your organization.



* if there are separate offices for CME, CPE, and CNE – we will accept one registration per office



Step I: Registration - How do I register?

Overview

* Briefly describe your organization's Continuing Medical Education Mission Statement here or upload documents:

You may upload your organization's Continuing Medical Education Mission Statement here:

If applicable, briefly describe your parent organization's Continuing Medical Education Mission Statement here or upload documents:

You may upload your parent organization's Continuing Medical Education Mission Statement here:

Accreditation

* Please select all applicable bodies that accredit your organization or customarily accredit your individual activities if they do not accredit organizations. Ctrl+click to select multiple items.

If other, please describe:

ACCME Accreditation Status:

Date current ACCME accreditation ends:

ACCME Provider Number:

Note: If your organization has no number, please enter a brief explanation or "N/A"



Step I: Registration - How do I register?

Section 1: Independence

* What approximate percentage of your previous year's funding was received from commercial interests?

* What approximate percentage of your previous year's commercial support was received from Pfizer?

* Is any representative of your organization with direct interface responsibilities with commercial suppliers compensated in any manner in direct proportion to the amount of single or cumulative grant funding that may be received as a result of this interface? Yes No

* Do any practicing healthcare providers have a proprietary or ownership interest in your organization? Yes No
* If yes, please list their names and what role they have in your organization:

* Has your organization been involved in promotional programs/activities or acted as an agent for any commercial interest? Yes No
* If yes, please indicate the most recent date:

* Are you aware of any organizations under your parent's corporate umbrella that have been involved in promotional programs/activities or acted as an agent for any commercial interest? Yes No
* If yes, please name the organizations:

If you wish to provide additional documentation of the existence of internal firewalls that prevent the sharing of information acquired from promotional activities, please upload here:

* Are you currently acknowledged by your accrediting body (e.g., ACCME) as in compliance with all elements associated with the policies for disclosure and commercial support? Yes No
* If not, please explain the reason for non-compliance and what steps have been taken to remedy:





Step I: Registration - How do I register?

Section 2: Professional Qualification Of Staff

* Briefly describe your organization's professional development program for staff that has any educational planning or interface responsibility with commercial supporters:

Is your organization or any of your staff a member of the following? (pick all that apply):

ACME SACME NAAMECC GAME If other, please describe

Section 3: Educational Planning Process

Quality education demands a comprehensive educational planning process. Please provide information on your organization's educational planning process. In the context of a specific activity/series that is typical of your organization, please briefly describe the following:

* Activity/Series Description:

* Process for establishing needs:

* Process for establishing educational objectives:

* Process for establishing educational methods:

* Process for evaluating outcomes:

If you find that the space provided is insufficient, please upload your supporting document here:



Step I: Registration – 3 Rationale

1. Centralizes responsibility and accountability
2. Simplifies reporting and communication
3. Serves as quality checkpoint





Step I: Registration Summary - What is MEG looking for?

1. Duty of Care
2. Accreditation – not just ACCME...
3. Experience and dedication to transforming medical education
4. Organization history
5. Conflict of Interest Resolution Processes
6. Content Validation Processes

To date ~1,400 providers have received approvals

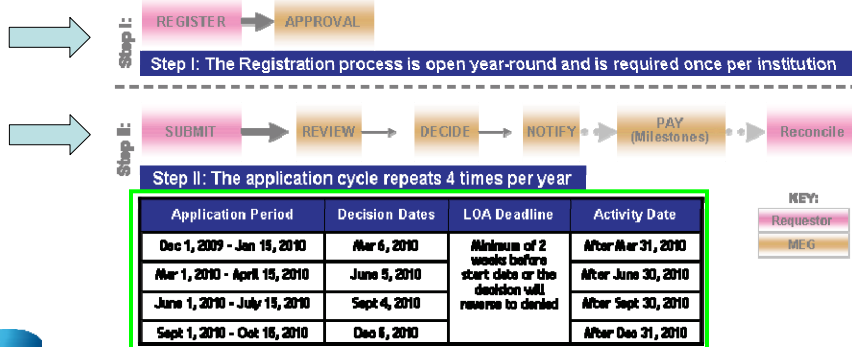
** Answers are typically provided within 2 weeks **



The MEG 2-Step: Step II

1. Provider Registration (rolling)
2. Grant Application (quarterly)

Pfizer MEG utilizes a 2-step Registration and Application Process





Step II: Application – How do I apply?

1. Visit www.pfizermededgrants.com
2. Click **Go to the Grant System**

Medical Education Grants

Grants for Health Care Quality Improvement & Education
We're supporting you as you support patient care. Pfizer offers support for your independently-run health care quality improvement initiatives through online resources and medical education grants. Our full [mission statement](#) >

Resource Center
Publications, articles, needs assessments and more education literature
[Learn more about healthcare improvement](#) >

Medical Education Grants Process
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Step II: Application - How do I apply?

1. Log in to access step-by-step application instructions

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Login

Are you a registered Pfizer Grants Application user?

email address:

password:

password assistance?

New User

Are you a new user?

**** Bookmark this page ****

**** Try not to lose your Log In information ****





Step II: Application – Rationale

Quarterly, batched review:

1. Ensures that highest quality request are supported
2. Standardizes processes and expectation
3. Simplifies reporting and communication
4. Simplifies financial accounting

Typical quarter:

- 550 of request / 110 of approvals ~ 20%



Step II: Application: What is MEG looking for (6)?

1. Scientific knowledge
2. Audience-driven need assessments
3. Compliant checks and balances
4. Result-driven planning
5. Educational architecture proven to work
6. Delivery methods that engage learners





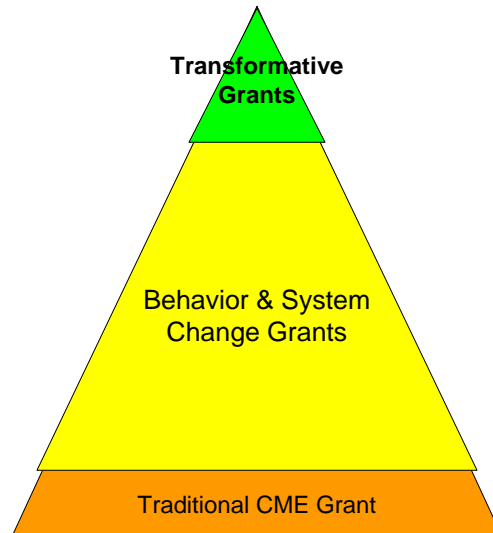
Step II: Application: What else is MEG looking for?

Pilot programs

Multi-year / multi-phase programs

Grants that span multiple therapeutic areas and have broader impact

Initiatives do not have to be certified for credit



A visual framework



Step II: Application – Alignment

Medical Education Grant Process

Pfizer is continuously striving to improve its medical education grant process with the goal of ensuring regulatory compliance while providing grants that accelerate the translation of clinical science into quality patient care.

Scope | Clinical Areas | Process | Policies | Approval

Scope of Medical Education Grants

Pfizer seeks to provide grant support for the continuing professional development of healthcare providers in areas aligned with the core competencies established by the Accreditation Council for Graduate Medical Education (ACGME) and American Board of Medical Specialties (ABMS). The six competencies are in the areas of:

- > Patient Care
- > Medical Knowledge
- > Interpersonal and Communication Skills
- > Professionalism
- > Systems-based Practice
- > Practice-based Learning and Improvement

[View the full descriptions of these six competencies.](#)

Pfizer medical education grant support goes beyond activities focused on traditional updates in knowledge to broader educational and systematic interventions related to these competencies.

Your Grant Application

Apply for a new grant, register for eligibility or view the status of your existing applications.

[Go to the Grant System](#)

Important Grant Deadlines and Dates

Pfizer offers four grant application windows per year. All grant requests received within a single window are reviewed comparatively. Funding decisions are announced approximately 7 weeks following the close of these windows:

- > December 1 to January 15, 2010
- > March 1 to April 15, 2010
- > June 1 to July 15, 2010
- > September 1 to October 15, 2010



www.pfizermededgrants.com



Step II: Application – Alignment

Clinical Areas | Process | Policies | Approval

Clinical Areas of Interest

Pfizer is currently accepting grant applications for independent education in the following areas:

Cardiology

- > Cardiovascular Risk
- > Thrombosis

Endocrinology

- > Growth Disorders

- > Healthcare Disparities
- > Adherence
- > Value-based Health Initiatives
- > CME/CPD Professional Competency Research

View additional information regarding Pfizer's areas of interest for grants in support of Healthcare Quality Improvement and Continuing Professional Development



www.pfizermededgrants.com



Step II: Application – Alignment

Pfizer

Pfizer Medical Education Group

Areas of Interest for Grants in Support of Healthcare Quality Improvement and Continuing Professional Development

Updated March 31, 2010

The current *Clinical Areas of Interest* and goal statements for the Pfizer Medical Education Group are listed below. New this quarter, a column providing examples of metrics for education (quality measures) has been added. The metrics are provided as examples only - there are many sources of nationally accepted measures (NCOA, AHRQ, PQRI, JCAHO, NQF, AMA etc) and individual hospitals and clinics also often establish their own metrics of quality care.

The intent of listing example metrics is to highlight our interest in supporting education in which the provider has carefully identified needs/gaps and has clearly defined expected results.

Across clinical areas, the grants most likely to be funded are those that are designed to improve health care provider performance and patient health status indicators through the integration of educational, systems-based, and quality improvement strategies.

By supporting initiatives that target *measurable improvements* in professional practice we are in alignment with current guidance from the Accreditation Council for Continuing Medical Education (ACCME). (<http://education.accme.org/tags/performance-measures>)



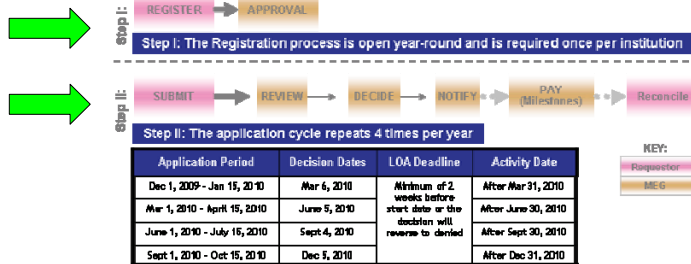
www.pfizermededgrants.com



The MEG 2-Step: Summary

1. Registration – Duty of Care Providers
2. Grant Application – Competitive Review

Pfizer MEG utilizes a 2-step Registration and Application Process



For assistance:

mededgrants@pfizer.com or 1-866-MEG-4647



Medical Education Group

Mitigating Bias in Medical Education

Conflict Resolution &
Content Validation





Mitigating Bias in Medical Education

1. Environment and Skepticism
2. Risk Mitigation Strategies
3. Impact on MEG
4. Examples



The Environment for Change

Continuing Education in the Health Professions-The Macy Report

“Accredited organizations that provide continuing education should not accept any commercial support from pharmaceutical or medical device companies...A five year “phase out” period should be allowed to meet this recommendation”

Macy Report, Continuing Education in the Health Professions: Improving Healthcare Through Lifelong Learning Nov 2007

IOM Report on Conflict of Interest in Research, Medical Education and Practice

“Recommendation 5.3: A new system for funding accredited continuing medical education should be developed that is free of industry influence, enhances public trust in the integrity of the system, and provides high quality education.

Institute of Medicine Report on Conflict of Interest in Research, Medical Education and Practice April 2009

American Psychiatric Association

“Among the recommendations submitted for board review was that the APA phase out industry-supported education programs and industry-supported meals served at the APA scientific meetings”

James H. Scully Jr. MD Medical Director and CEO, APA; Testimony at the Senate Committee on Aging July 2009





The Environment for Change

“... acknowledges the new policy directions being implemented in many medical schools and teaching hospitals to address industry support of medical education, and it urges all academic medical centers to accelerate their adoption of policies that better manage, and when necessary, prohibit, academic-industry interactions that can inherently create conflicts of interest and undermine standards of professionalism. Concomitantly, industry should voluntarily discontinue those practices that compromise professionalism as well as public trust.”

AAMC Report on Industry Funding of Medical Education – June 2008

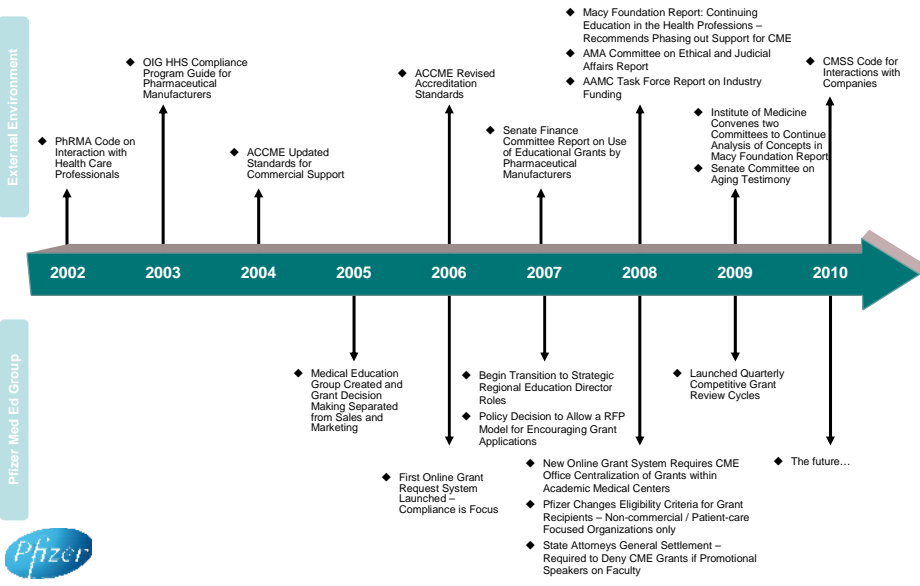


“Societies will make reasonable efforts to seek multiple sources of support for Society CME programs, including support from Companies, support from organizations outside the for profit healthcare sector, and tuition from attendees. .”

CMSS Code for Interactions with Companies – April 2010



U.S. External Environment & Pfizer Policy Change





Medscape Study

- 1,064,642 post-activity survey evaluations
 - 39.5% were commercially supported
 - 60.5% were funded by other sources (e.g. government, non-profit).
- 3,137 activities completed by physicians
 - 28.3% of which were commercially supported
 - 71.7% not commercially supported
- 58.6% of activities with bias reports were not commercially supported



Ellison JA et al. *Am J Med.* 2009;122:875-878.



Medscape Study (II)

- Less than 1% of physician participants report bias
- Only 0.63%, Disagreed or Strongly disagreed “The activity was presented objectively and free of commercial bias”
- The differences in reporting rates of bias were small
- The top 10 activities with the highest rates of bias reports
 - Only 3 received commercial supported



Ellison JA et al. *Am J Med.* 2009;122:875-878.



Cleveland Clinic Experience

- 346 CME activities of numerous types; 95,429 participants in 2007
- Results (Question on Absence of Bias)
 - 98% for no commercial support (149 activities);
 - 98.5% for single source commercial support (79 activities); and
 - 98.3% for multiple source commercial support (118 activities).



Kawczak S et al. *Acad Med.* 2010;85:80-84.



Cleveland Clinic Experience (II)

Factor	Responses that activity was free of commercial bias: Mean % (95% CL) [†]
Type of certified CME activity	
• Regularly scheduled series	97.3 (96.2, 98.4)
• Dinner meeting	99.0 (97.6, 100.0)
• Short live course	97.6 (95.7, 99.5)
• Live course	98.0 (97.0, 98.9)
• Journal-related CME	99.2 (97.0, 100.0)
• Web-based CME	98.5 (97.7, 99.4)
• Other enduring materials	99.2 (96.9, 100.0)
Type of industry support	
• None	98.0 (97.3, 98.8)
• Single source	98.5 (97.5, 99.5)
• Multiple sources	98.3 (97.4, 99.1)

* CME indicates continuing medical education; CL, confidence limits.
[†] Results correspond to ANOVA.



Kawczak S et al. *Acad Med.* 2010;85:80-84.



UCSF Experience

- 213 Courses; 132 Participants/Course = > 28,000 participants
- Results
 - The perceived overall quality of CME mean rating of 4.4 on a five-point Likert scale;
 - 97% of respondents stating that the activity they attended was free of commercial bias;
 - There was no association between extent of commercial support and the degree of perceived bias



Steinman MA et al. *Acad Med.* 2010;85:74-79.



Risk Mitigation Strategies

Internal:

- Structure
 - Organizational
- Funding model
 - Budgeting Path
- Policies and Processes
 - Interactions
 - Checks & Balances
 - Evidence-Base
 - Alignment begins w/ externally validated needs

External:

- *Structure* ✓
 - *Firewalls*
- *Funding model* ✓
 - *Standard for Support*
- Policies and Processes
 - Conflict of Interest (COI)
 - Content Validation (CV)





Direction from the ACCME

Standards for Commercial Support:

1. Independence
2. Resolution of Conflict of Interest
3. Appropriate Use of Commercial Support
4. Appropriate Management of Associated Commercial Promotion
5. Content and Format without Commercial Bias
6. Disclosure Relevant to Potential Commercial Bias



Direction from the ACCME

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 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 parties 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, 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 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. ¶



ACCME Standards for Commercial Support



Direction from the CMSS

5.1. Educational Grants and Society CME

5.1.1. Societies will comply with ACCME Standards for Commercial Support, including by adopting policies and procedures designed to identify and manage conflicts of interest in Company-supported Society CME programs.

Annotation: Societies should adopt policies and procedures for managing the relationships of individuals who plan, carry out, or contribute to the content of Society CME activities. Adopting and rigorously enforcing these policies precludes Company influence over Society CME content.



CMSS Code for Interaction with Companies



to begin the process of managing COI...

In order to begin the process of managing COI, the provider must know about relevant financial relationships prior to the activity being developed and delivered to the learners. CME providers must obtain from the planners, speakers or authors disclosures of their financial relationships that are relevant to the content being considered or planned for the activity (SCS 2.1). This disclosure information is so important to the CME process that individuals who refuse to disclose relevant financial relationships are disqualified from having a CME role that will give them the opportunity to affect the development, management, presentation or evaluation of that CME activity (SCS 2.2).



Two approaches that providers have offered to ACCME as their mechanisms for getting disclosure information -

Provider asks for...

1. ...disclosure of all financial relationships from planners, speakers or authors.
2. ...disclosure only of financial relationships from planners, speakers or authors where the relationship is associated with the content of the activity.



ACCME Standards for Commercial Support Including Tools for Implementation;
http://www.accme.org/dir_docs/doc_upload/700a1624-d6f0-46d8-a4bc-88e12a56eca2_uploaddocument.htm



When is COI present?

2 Identifying Conflicts of Interest (SCS 2.3)

From the ACCME's perspective, a COI is present when a planner, speaker or author has **both** a current financial relationship with a commercial interest **and** the opportunity to affect content relevant to products or services of that commercial interest.

The CME provider must have a mechanism to determine if conflicts of interest are present for individuals who have control of CME content.

Conflicts of interest are identified through an analysis of the information disclosed and an understanding of the planned content of the CME. Circumstances create COI. Context counts. A passage from one ACCME accredited provider's institutional COI Policy may help put this issue in perspective.



"A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to [the institution] such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual."

When a person has divested themselves of a relationship any associated conflict of interest is resolved. However, the relationship must be disclosed to the learners for the next 12 months, as part of demonstrating compliance with SCS 6.



ACCME Standards for Commercial Support Including Tools for Implementation;
http://www.accme.org/dir_docs/doc_upload/700a1624-d6f0-46d8-a4bc-88e12a56eca2_uploaddocument.htm



How is COI Resolved?

3 Resolving conflict of interest in CME (SCS 2.3)

What can a provider do to manage COI? A provider's 'best' strategy depends, largely, on the facts and circumstances of the activity. So, any examples the ACCME offers are presented for clarification and explanation. Providers must develop solutions that best fit the facts and circumstances of their program of CME.

In CME there are two components to conflict of interest – a current financial relationship with a commercial interest **and** the opportunity to affect content relevant to products or services of that commercial interest. So, as long as the relationship is current, managing or resolving the COI must involve the content of the CME. This is where the provider and teacher/author need to identify safeguards that can be, or already are, incorporated into the process to prevent the insertion of commercial bias.



ACCME Standards for Commercial Support Including Tools for Implementation;
http://www.accme.org/dir_docs/doc_upload/700a1624-d6f0-46d8-a4bc-88e12a56eca2_uploaddocument.htm



By Addressing Who Does What...

Sometimes the mechanism involves specifying, "Who does what?" within an activity:



"Because our medical staff only wanted to know about patho-physiology and to understand the mechanisms of disease we asked the person with the conflict of interest to limit their presentation to these areas, so that her financial relationships were not relevant to the educational event."



"We managed the person's COI and took steps to prevent commercial bias by asking someone else, without a COI, to evaluate and discuss the clinical implications of the primary speaker's discovery for us - after the primary speaker reported on her scientific discovery."



"When a proposed speaker has a conflict of interest related to the content, we choose someone else, who does not have a relationship to the commercial interests related to the content to resolve the conflict of interest."



"When a proposed speaker has a conflict of interest related to content we sometimes will change the focus of the activity so that the content is not about products or services of the commercial interest that are the basis of the conflict of interest."



"When an individual has been the principal investigator on a project funded by a commercial interest, we will choose to limit the individual's presentation to the data and results of the research. Someone else could be assigned to address the broader implications and recommendations for clinical care."



ACCME Standards for Commercial Support Including Tools for Implementation;
http://www.accme.org/dir_docs/doc_upload/700a1624-d6f0-46d8-a4bc-88e12a56eca2_uploaddocument.htm



By Ensuring Content Validation...

Sometimes the mechanism involves **content validation** --- Providers have offered the following as elements of their mechanisms to resolve COI when they chose not to alter the content of the activity or the role of the person with a conflict of interest.



"We notify potential teachers, in writing, that we follow the ACCME Standards for Commercial Support. We tell them that they have an important role in maintaining these standards. We require them to base their presentation and recommendations on the 'best available evidence.' Our audience judges if commercial bias is present. Our planning committee monitors the presentations."



"We limit or specify the sources for recommendations that the teacher or author can use - as per the American Academy of Family Physicians Evidence Based CME requirements. Rather than having a person with a conflict of interest present personal recommendations or personally select the evidence to be presented, we limit the role of the person to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria stated (known as 'Evidence-based education'). For example, the individual could present summaries from the systematic reviews of the Cochrane Collaboration."



"We have always asked our teachers/authors to submit their presentations for peer-review. In this way our planning committee identifies bias before publication on our website."



"Over the years, we have combined several tactics into a mechanism to resolve conflicts of interest that preserves participation of experts with financial relationships. First, presenters, authors, planners and reviewers are instructed to base recommendations for clinical care on the best available evidence. This is in addition to our peer review of content prior to presentation or publication that ensures the content is valid and aligned with the interest of the public. Then in addition, as a form of peer review, participants are asked to evaluate the objectivity of the presentation or publication, and to identify any perceived commercial bias. We intervene at the activity, or after the activity, to address any bias issues that have crept in."



ACCME Standards for Commercial Support Including Tools for Implementation;
http://www.accme.org/dir_docs/doc_upload/700a1624-d6f0-46d8-a4bc-88e12a56eca2_uploaddocument.htm



Direction from the ACCME

Describing and Documenting a Mechanism to Identify and Resolve Conflict of Interest

The provider needs to document the implementation of the safeguards they have chosen so that ACCME can verify the provider has a mechanism to identify and resolve COI. As has always been the case, providers will be asked to **1) describe their practices in the Self-Study Report prepared for the initial accreditation and reaccreditation process and 2) provide examples and documentation of how the process was actually used for their CME activities.**



ACCME Standards for Commercial Support Including Tools for Implementation;
http://www.accme.org/dir_docs/doc_upload/700a1624-d6f0-46d8-a4bc-88e12a56eca2_uploaddocument.htm



An Example of Documentation...

Describing a Mechanism to Identify and Resolve Conflict of Interest
An Example

"There are a number of "luminatee" or world-renowned experts we (and other organizations) would like to have speak to our members. Many of these are "conflicted" in that they have done high-level, original research in conjunction with industry in the development and clinical testing of new drugs or products. Their papers have been published in peer-reviewed journals, and they are recognized as the most knowledgeable and most desired speakers on the subject. The case in question is an anesthesiologist expert who has done research and received support in the development of a new anesthetic agent. This individual has performed such research with new anesthetic agents for more than 20 years. The results of the current research, performed at a highly respected university center, clearly demonstrate the new agent has desirable properties vs. older agents, and the investigator has found clinical and patient-related advantages in his peer-reviewed, published research.

Communicating expectations →

When inviting this speaker to our meeting, we know his conflict, and my interpretation of the guidelines is that we should make sure the speaker himself understands the new guidelines. In addition as part of our "management plan" we should have his presentation "peer reviewed" by non-conflicted individuals on our program committee, and the speaker should understand we may ask him to change his presentation if commercial bias is apparent. However, the peer review might conclude that while the presentation does make the new drug appear better than older ones, the studies quoted are strong and peer reviewed, and the speaker's conclusions are justified. No "evidence based reviews" will be available on this subject for some time, if ever.

Mechanism to resolve COI →

A second part of "management" would be to have the session moderator (or other designee of the program committee) evaluate the lecture when given, for bias. The society would take the position that if commercial bias was present, the speaker would not be invited back for some period of time (if ever)."

← **Identification of COI**

← **Evaluation of effectiveness of mechanism to resolve COI**

← **Evaluation of effectiveness of mechanism to resolve COI**



ACCME Standards for Commercial Support Including Tools for Implementation;
http://www.accme.org/dir_docs/doc_upload/700a1624-d6f0-46d8-a4bc-88e12a56eca2_uploaddocument.htm

MEG

What does this mean for MEG?

Remember back to Step I of the MEG 2-Step...

MEG Step I: Registration
What is MEG looking for?

1. Duty of Care
2. Accreditation – not just ACCME...
3. Experience and dedication to medical education
4. Organization history
5. Conflict of Interest Resolution Processes
6. Content Validation Processes

* Do you have a mechanism in place to identify and resolve conflicts of interest? Yes No

If yes, please describe here or upload the document below.

* Do you have a mechanism in place to ensure content validity? Yes No

If yes, please describe here or upload the document below.

Pfizer

MEG

Look to learn from each other

Policy Revised 6.2.09

Vanderbilt University
Conflict of Interest and Commitment Policy

ASHP Policy on Accepting Corporate Support and Avoiding Conflicts of Interest

Approved by the ASHP Board of Directors, November 18, 2008

Introduction

This document states ASHP's philosophy and guiding principles with respect to corporate support of pharmaceutical companies and other for-profit organizations and for resolving conflicts of interest in pharmacy practice, in a non-profit professional and scientific environment. These principles have provided and many others which ASHP develops and continues to update with the goal of business ethics, ensuring a high standard for independence and integrity. Corporate support has potential ASHP to advance and enhance programs that help it achieve its purposes and fulfill its mission.

Chapter 10

One of ASHP's core values is its commitment to independence and integrity in expressing the best practice, along with relationships with leaders and staff of the ASHP.

ASHP does not accept corporate support.

ASHP is a non-profit organization.

ASHP does not accept corporate support.

ASHP does not accept corporate support.

ASHP does not accept corporate support.

ASHP does not accept corporate support.

UNIVERSITY OF IOWA
CARLE COLLEGE OF MEDICINE
University of Iowa Health Care

Content Validation Guidelines for Course Directors, Speakers and Planners of CME Activities

As a provider of CME accredited by the Accreditation Council on Continuing Medical Education, the University of Iowa College of Medicine must ensure fairness, independence, objectivity, and scientific rigor in all continuing education activities for all categories of CME activities, the Carle College of Medicine of the University of Iowa gives a higher priority to the health and well-being of the public than to individual financial interests.

Policy for Disclosure of Conflict of Interest and Procedures for Meeting ACCME Requirements Regarding Disclosure and Resolution of Personal Conflicts of Interest When Producing CME Courses at Southern Illinois University School of Medicine

Policy

It is the policy of the Office of CME at Southern Illinois University School of Medicine to ensure fairness, independence, objectivity, and scientific rigor in all educational activities. All faculty (S2703) and guest) participating or requested to disclose to the audience any real or apparent conflicts of interest with any commercial or proprietary entity that produces, distributes, markets, or sells products or services related to the content that is being planned, developed, or presented in a CME activity or that may conflict with its mission. The faculty are deemed "conflicted" within the first 12 months, as well as former financial relationships of speakers, planning partners, or immediate family members.

Wisconsin Medical Society
Your Doctor. Your Health.

CONFLICT OF INTEREST AND PROFESSIONAL INTEGRITY POLICY

Effective Date: March 18, 2010

By a significantly conflicted investigator that can be overcome only by the demonstration of "compelling circumstances" in the following CME:

E. EDUCATION

Faculty with regard to the section on Training and Education Regarding Use of Medical Devices or the Department Integrity (Professional Handbook Board of Continuing Education, amended July 10, 2009) should disclose any potential conflicts of interest to the program chair and the ACCME. The program chair should disclose any potential conflicts of interest to the ACCME.

Jefferson Medical College
Office of Continuing Medical Education

CME Conflict of Interest Policy

Jefferson Medical College
310 Locust Street, Suite 500
Philadelphia, PA 19106
Telephone: 215 955-4912 Fax: 215 955-3522
http://www.jefferson.edu

LIAMS

Office of Continuing Medical Education
Policy on Conflicts of Interest

The purpose of this policy is to ensure that the content of the educational activity is based on scientific evidence and is not influenced by commercial interests. The purpose of this policy is to ensure that the content of the educational activity is based on scientific evidence and is not influenced by commercial interests.

1. Independence

1.1. Independence of the educational activity

1.2. Independence of the educational activity

1.3. Independence of the educational activity

1.4. Independence of the educational activity

1.5. Independence of the educational activity

1.6. Independence of the educational activity

1.7. Independence of the educational activity

1.8. Independence of the educational activity

1.9. Independence of the educational activity

1.10. Independence of the educational activity

Pfizer

Google: Conflict of Interest site:.edu file:.pdf



There seems to be a plethora of solutions

**RIVERDE METHODIST HOSPITAL'S
POLICY ON FULL DISCLOSURE**

As you undoubtedly know from the national media, there has been much discussion concerning the relationships between CME providers, faculty and commercial companies providing support for CME. Both the AMA and the Accreditation Council for CME (ACCME) have adopted regulations for ethical actions in this area, which we endorse and have adopted for all our educational activities.

We are required, by the Standards of Commercial Support, to determine if you have any relevant financial relationships with any commercial products that will be discussed in your presentation. Please be assured that having an affiliation with a company does not imply in any way that something is wrong or improper. Rather, as a CME-accredited institution, we are required to inform the attendees prior to the activity of any such financial interests or relationships. The audience may then form their own judgments about the presentation.

Please check the appropriate box in each section, complete any applicable information and sign.

CME Activity _____

I do not have any relevant financial interest or other relationship with the manufacturer of any commercial products (discussed in this presentation in any amount occurring within the past 12 months).

I do have a relevant financial interest or relationship with one or more of the commercial products (discussed in my presentation which has occurred with the past 12 months). I have indicated the nature of this relationship below.

AFFILIATION/FINANCIAL INTEREST	NAME OF ORGANIZATION(S)
Grant/Research Support	
Consultant	
Speaker's Bureau	
Major Stock Shareholder	
Other Financial or Material Interest	

NOTE: If a significant relationship exists, you must sign the following page as well.
AMA Standard 3.0

I attest that all recommendations involving clinical medicine in this CME activity must be based on evidence that is acceptable within the profession of medicine as adequate justification for their use. I further attest that all scientific research referred to, reported or used in this CME presentation must conform to the generally accepted standards of experimental design, data collection and analysis. I attest that this CME activity does not promote recommendations, treatments or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.

By signing this Disclosure, I agree that any potential conflict of interest noted above will not influence the content of this presentation and/or who is selected to participate in the presentation.

Signature: _____ Date: _____

**UHealth UNIVERSITY OF MIAMI
MILLER SCHOOL OF MEDICINE**

**Division of Continuing Medical Education
Conflicts of Interest Resolution for Planners**

CME Activity: _____
Planner: _____
Activity Date(s): _____

You have indicated that your control over the content of this CME activity pertains to products/services of the commercial interests with which you have a financial relationship, which may result in a conflict of interest. To ensure that this CME activity is planned free from commercial bias, please indicate how the conflict of interest will be resolved:

Choose someone else to control the part of the content that pertains to the products/services of the commercial interests with which you have a financial relationship(s). (Please explain who will be involved and how this will be done): _____

Change the focus of the CME Activity (Please explain how this will be done): _____

Change the content of your assignment as a planning committee member so that it no longer pertains to the products/services of the commercial interests with which you have a financial relationship(s). (Please explain what this change will involve): _____

I have carefully read and considered each item on this form and have completed it to the best of my ability.

Signature of Planner _____ Date _____
Signature of Co-Planner _____ Date _____

This process has been reviewed with the above planner and the designated others involved and the conflict of interest in planning has been resolved.

Manager, CME Signature _____ Date _____
Director, CME Signature _____ Date _____


Rev. 2/15a



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Examples of COI and CV Policies

 **Council of Medical
Specialty Societies**

To minimize the potential for bias in Satellite CME Symposia, Societies may also consider the following best practices:

1. *Requiring presentations to be evidence-based;*
2. *Requiring peer review of slide presentations in advance;*
3. *Prohibiting presenters who disclose unmanageable conflicts from making practice recommendations. These presenters may present on general topics only (e.g., pathophysiology, research data). An additional speaker without unmanageable conflicts may be added to the program to make practice recommendations instead.*
4. *Requiring presentations to be monitored by reviewers trained to recognize bias.*



CMSS Code for Interaction with Companies



Examples of COI and CV Policies

IDENTIFICATION AND RESOLUTION OF CONFLICTS OF INTEREST – In addition to SCS 2:

1. Duke is required to have a mechanism to identify and resolve (manage, minimize, or mitigate) all conflicts of interest prior to the educational activity being delivered to learners; the primary mechanism is to have all individuals who are in a position to control the content of an educational activity complete an attestation that they have read and agreed to abide by this policy and that any and all clinical recommendations that they make for patient care as part of their planning and/or CME presentation/activity materials will be based on the best available evidence, that they will give a balanced view of therapeutic options, and that the content will be in accordance with ACCME's Content Validation Statement (see <http://Duke.CME.mc.duke.edu/ada/index.asa>).
2. Additional and supplemental mechanisms to resolve conflicts of interest include but are not limited to:
 - a) An individual without a conflict of interest replaces the conflicted individual.
 - b) The conflicted individual renounces the relationship(s) with the commercial interest(s).
 - c) The scope of the conflicted individual's role is restricted (the conflicted individual will not be determining content and/or making recommendations for clinical practice).
 - d) The conflicted individual attests in writing that recommendations s/he will make for clinical practice will be based upon data derived from multiple randomized clinical trials or meta-analyses and s/he will disclose this to learners.
 - e) The CME materials (presentation, monograph, etc.) prepared by the conflicted individual will be peer reviewed for content validation and fair balance (and modified accordingly, if need be).
3. 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 (ACCME Standard 2.3).

CONTENT VALIDATION AND FAIR BALANCE – In addition to SCS 5:

1. The CME activity will comply with ACCME's Content Validation Statement (Policy 2002-B-09):
 - a) All 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 contra-indications in the care of patients.
 - b) All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
2. Activities that promote recommendations, treatment, or manners of practicing medicine or pharmacy that are not within the definition of CME or, are known to have risks or dangers that outweigh the benefits or, are known to be ineffective in the treatment of patients will not be certified for credit.
3. Presentations and CME activity materials must give a balanced view of therapeutic options; use of generic names will contribute to this impartiality. If the CME educational materials or content includes trade names, where available, trade names from several companies must be used.



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Examples of COI and CV Policies

IV. Policy: Mechanisms for Resolving Conflicts of Interest:

The following are suggested mechanisms for resolving conflicts of interest (COI).

A. Attestation:

Persons who indicate the existence of potential or actual COI will be asked to agree in writing that said conflicts or relationships will not bias or otherwise influence their involvement in the CME activity and will be evidence-based.

B. Evaluation:

Attendees will be asked about bias (or absence of bias) within the activity. Activity Directors and teachers/authors will receive copies of the evaluation summaries and comments.

C. Peer Evaluation:

An informed learner or peer who is not involved in the planning and/or teaching of the activity will observe the CME activity. This evaluator will be asked to complete an evaluation to note any bias in the activity.

D. Independent content evaluation:

E. Altering financial relationships:

An individual may change his/her relationships with commercial interests, however, when individuals divest themselves of a relationship, it is immediately not relevant to conflicts of interest, but still must be disclosed to learners for 12 months.

F. Altering control over content:

- Change the focus of the CME content
- Choose someone else to control that part of the content
- Change the content of the person's assignment
- Limit the content to a report without recommendations
- Limit the sources for recommendations

G. Elimination:

Activity Directors, activity planning committee members, and/or teachers/authors who are perceived as either manifesting irresolvable COI or being biased may be eliminated from consideration as resources for the CME activity.



Mount Sinai School of Medicine
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Examples of COI and CV Policies

Following extensive discussions with ACCME, Clinical Care Options has adopted the following procedures for developing medical education programs, to ensure that faculty COIs are effectively resolved prior to submitting the content to the accredited provider for review and approval:

1. The CCO editorial team exercises final control over the selection of faculty, topics, and final content for each CME program. The CCO editor in control of the content for a continuing education activity will not have any personal conflicts of interest with the supporter(s) for that CME program. The faculty and members of the content review process are selected by CCO, with no input from the commercial supporter.
2. Faculty members are instructed to restrict their material to evidence-based discussion of the topic in question. Where there is debate in the field, competing points of view should be presented, and any expressions of the author's opinion (as opposed to fact) must be clearly identified as such, and the data that lead the author to hold that opinion must be discussed and referenced.
3. To resolve faculty COIs, the draft content for all continuing education activities is peer-reviewed by an independent reviewer with appropriate expertise in the content matter. Peer reviewers are instructed to ensure that the content is evidence based, objective, balanced, and free from commercial bias. Peer reviewers may not themselves have any COI with the commercial supporter of the activity in question or any other pharmaceutical company actively involved in the specialty area. The editorial team then works with the author to ensure that peer review comments are all addressed in the final content.
4. Specific record is kept of peer review comments, and the steps taken by the editorial team in conjunction with the author to address their comments. Both the final draft of the content, and this documentation of the peer review process and revisions, is reviewed by the CCO specialty Editorial Director and/or the CCO Vice-President, Editorial prior to submission to the accredited provider. The material is only submitted to the accredited provider for certification after the CCO specialty Editorial Director and/or the CCO Vice-President, Editorial is satisfied both that the material is evidence-based, objective, balanced, and free from commercial bias, and that the peer review and faculty recommendations were adequately addressed.
5. Finally, as required by the ACCME, the accredited provider is responsible for undertaking its own final review of content to ensure that it is balanced and lacks any commercial bias.



Google: Conflict of Interest CME



Examples of COI and CV Policies

Primary COI Resolution Method for All Activity Types:

Completion of the CWRU SOM CME Disclosure of Commercial Relationship Form as described above. In addition, learners will have the opportunity to identify any perceived commercial bias through the course evaluation.

Secondary COI Resolution Method Options by Activity Type:

All Activities:

- The Activity Director(s) prospectively review the content (slides) and completes a Resolution of Conflict of Interest Form stating the action taken to resolve the COI.
- The Disclosure of Commercial Relationship Form, completed Resolution of Conflict of Interest Form and content (slides) will be forwarded to the CME staff.
- The CME Medical Director reviews the above materials and either signs off or content will be revised as needed according to the results of the review.

Situations where Conflict of Interest cannot be effectively resolved

While CWRU SOM CME strives to be flexible, accessible and helpful in the development and implementation of CME certified activities, there are some situations where adequate resolution of COI may not be feasible. In these situations, CME certification will not be provided. Examples of these situations include:

- Requests for CME certification of the content after the majority of the planning for the CME activity has occurred with faculty and/or content selections already determined;
- Short planning timeframes that don't permit adequate planning and implementation of required ACCME and CWRU SOM CME policies and procedures;
- Inappropriate processes in educational planning and/or financial management that are not consistent with ACCME and/or CWRU SOM CME policies and processes.



Case Western Reserve University
Google: Conflict of Interest site:.edu file:.pdf



Summary of Mitigating Bias in CME

1. Significant steps have been taken to address the risk of inappropriate bias in commercially funded CME, but much work is left to be done
2. It is vital to the future of CME and commercial support that all stakeholders continue to improve and evolve risk mitigation strategies
3. MEG-eligible providers are expected to provide policies that describe the provider's COI and CV processes
4. Dozens of examples of COIP and CVP are available on the internet



Final – Latest MEG Activities

1. Wyeth IME departmental integration is complete
2. Annual registration database review continues
 - Opportunity to update registration data
 - Opportunity to clarify registration data
3. 2010 goal to improve dialog with the CME community
 - Upcoming webinars:
 - June 4th – Overview of 2nd Quarter Review Cycle
 - July 9th – Aug. 6th – Sept. 10th – Oct. 1st – Nov. 5th
 - Please send in topics, suggestions, and feedback to brian.mcgowan@pfizer.com



How can we help?