



May 17, 2016

TO: VMC Employees

FROM: Paul E. Lorenz
Chief Executive Officer, SCVMC

SUBJECT: **Continuing Medical Education – The Standards for Commercial Support**

REFERENCES: HHS #578.0 Conflict of Interest; County Conflict of Interest Policy
Board of Supervisors # 5.16 Conflict of Interest and Disclosure Requirements
ACCME Standards for Commercial Support
VMC #154.02 Continuing Medical Education – Honorarium

DEFINITIONS:

“Commercial Support” – Commercial support is financial or in-kind contributions given by a Commercial Interest, which is used to pay all or part of the costs of a CME activity.

“Commercial Interest” – A commercial interest is defined as any proprietary entity producing, marketing, re-selling, distributing or otherwise participating in or profiting from the distribution, promotion or sale of health care goods or services consumed by or used on patients. Providers of clinical services directly to patients are not commercial interests. A commercial interest is not eligible for accreditation by the Accreditation Council for Continuing Medical Education. The ACCME considers the following types of organizations to be eligible for accreditation and free to control the content of CME:

1. 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 commercial supporter.)
2. Government organizations
3. Non-health care related companies
4. Liability insurance providers
5. Health insurance providers
6. Group medical practices
7. For-profit hospitals
8. For-profit rehabilitation centers
9. For-profit nursing homes
10. Blood banks
11. Diagnostic laboratories

“Financial Relationships” - Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honorarium, ownership interest (e.g. stock, stock option 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. Relationships of the person involved in the CME activity include relationships of a spouse or partner.

“Relevant Financial Relationships” – Relevant financial relationships are financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

“Conflict of Interest” – A conflict of interest is created when the individual has both a financial relationship with a commercial interest and the opportunity to affect the content of the CME about the products or services of that commercial interest.

“Commercial exhibits and advertisements” – **Commercial exhibits and advertisements** are promotional activities and not continuing medical education. Monies paid by commercial interests to providers for this promotional opportunity are not considered to be commercial support of CME. Accredited providers are expected to fulfill the requirements of SCS Standard 4 (as defined below) and to use sound fiscal and business practices with respect to these exhibits.

“Honorarium” – A payment given to a professional person for services for which fees are not legally or traditionally required

“Provider” – SCVMC or other ACCME Accredited Organization.

POLICY:

The purpose of Continuing Medical Education (CME) is to facilitate life-long learning among physicians so that their practices may reflect the best medical care for their patients and to help physicians enhance their performance in practice.

This policy sets out standards of conduct when using commercial support for the continuing educational program. Funds or services contributed by commercial interests for the development of CME activities are commercial support.

Commercial support has significantly enhanced the ability of the CME enterprise to fulfill its purpose, but with the financial support and relationships comes the potential for commercial bias. Santa Clara Valley Medical Center (SCVMC) believes that CME must be free of the control of commercial interests to ensure that CME is free of bias.

The ACCME promulgated Standards for Commercial Support - Standards to Ensure Independence in CME Activities (SCS) to promote independence from commercial interests and to separate promotion from education.

Santa Clara Valley Medical Center (SCVMC) supports CME in compliance with this policy and the ACCME Standards for Commercial Support and other ACCME policies applicable to commercial support and disclosure. SCVMC will ensure that its CME activities are independent, free of commercial bias and beyond control of persons or organizations with an economic interest in influencing the content of CME.

The ACCME SCS describes six standards to which SCVMC ascribes:

1. Independence.

2. Resolution of personal conflicts of interest.
3. Appropriate use of commercial support.
4. Appropriate management of associated commercial promotion.
5. Content and format without commercial bias and
6. Disclosures relevant to potential commercial bias.

SCVMC as an accredited sponsor is responsible for the content, quality, scientific and clinical integrity and presentation of all CME activities approved for credit. Commercial supporters may not unduly influence the development of CME activities, nor may they enter into contractual arrangements that allow this to occur. The independence of the provider is the key element for a CME activity to meet the ACCME guidelines.

This policy and procedure is intended to supplement, but not replace or supersede existing County policies governing conflict of interest and ethical business practices.

PROCEDURE:

Responsible Party

Action

Standard 1: Independence

Medical Director and CME Committee

- Ensures independence in planning CME activities.
- Implements mechanisms to identify and resolve conflicts of interest.
- Uses commercial support appropriately.
- Manages commercial promotion appropriately.

Presents content that is without commercial bias.

Discloses required information.

Ensures that the following decisions are made free of a conflict of interest:

- Identification of CME needs;
- Determination of educational objectives;
- Selection and presentation of content;
- Selection of speakers;
- Selection of all persons and organizations that will be in a position to influence the CME;
- Selection of educational methods; and
- Evaluation of the activity.

Ensures that a commercial interest does not take the role of non-accredited partner in a joint sponsorship relationship

Standard 2: Resolution of Personal Conflicts of Interest

PROCEDURE: (continued)

Responsible Party

Course Chairs, Faculty,
Planners, Staff and/or other
CME Providers

Action

Those who could influence the course content of an educational activity will provide written disclosure of all relevant financial relationships with any commercial interest to the provider and Medical Director or CME Committee. All disclosures will be made to the learners prior to the start of the educational activity. Individuals must include in their disclosure information concerning relevant financial relationships of their spouses or significant others.

Those who do not disclose relevant financial relationships will be disqualified from serving as a planning committee member, a teacher, or an author of CME, and may not have control over, or responsibility for, the development, management, presentation or evaluation of CME activity.

Must implement a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. The following are mechanisms for resolving conflicts of interest and assuring that content is free of commercial bias:

- Use non-conflicted course chair, speaker or planner.
- Conflicted planner or speaker ends the relationship.
- Replace the conflicted planner or speaker.
- Modify or alter the role of the planner or speaker to avoid any conflict.
- Have another speaker discuss the clinical implications or results

- Alter or modify the content.
- Change the focus of the activity.
- Disqualify the speaker.
- Use multiple presenters on each activity (promotes diverse opinions and perspectives, dilutes individual biases among presenters).
- Present evidence-based data from multiple sources (ensures quantifiable objectivity and fair balance).
- Vet the activity content by professional multidisciplinary advisory board review committee (ensures that control and validation of content resides with provider, fosters applicability to clinical practice).

Obtains from planner or speaker a statement that content is free of commercial bias.

PROCEDURE: (continued)

Responsible Party

Action

Any of the above steps taken must be documented in order for the CME education to be delivered to the learners. Any conflicts identified must be resolved in order for the individual to participate in the CME activity. If conflict is not resolved, the CME activity will not offer a CME credit.

Course Chairs, Faculty,
Planners, Staff or other CME
Providers

Abides by the County and SCVMC broader policy regarding conflicts of interest. (HHS 578 Conflict of Interest policy)

Standard 3: Appropriate Use of Commercial Support

Medical Director and CME
Committee

Will have full knowledge of and give approval for all commercial support associated with the CME activity.

Medical Director, CME
Committee, and CME staff

Ensures that all terms, conditions and purposes of the commercial support are documented in a written agreement signed by all required parties, including the SCVMC representatives, the commercial interest and the provider's signature authorities. The written agreement will specify the commercial support and the provider, if the provider is not SCVMC.

Ensures adherence to VMC Policy #154.03 regarding expenditures (including honoraria and reimbursement for out of pocket expenses).

Course Chairs, Faculty,
Planners, Staff or other CME
Providers

Ensures that social events or meals at CME activities do not compete with or take precedence over the educational events, and are in compliance with County rules regarding the provision of meals at SCVMC sponsored events

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

Must provide accurate documentation detailing the receipt and expenditure of the commercial support. (See Attachment A)

Standard 4: Appropriate Management of Commercial Promotion

Course Chairs, Faculty,
Planners, Staff or other CME
Providers

Must ensure that arrangements for commercial exhibits or advertisements neither influence planning nor interfere with the presentation, nor be a condition of the provision of commercial support for CME activities. (See Attachment B)

Must ensure that educational materials, such as slides, abstracts and handouts do not contain any advertising, trade name or product-group logo or message. Live exhibits or presentations or printed or electronic promotional activities must be kept separate from the CME.

PROCEDURE: (continued)

Responsible Party	Action
Course Chairs, Faculty, Planners, Staff or other CME Providers	<p>May include/distribute print or electronic product promotion material or product-specific advertisement information only when it is about the non-CME elements of a CME activity and provided that the material is not directly related to the transfer of education to the learner.</p> <p>May not use a commercial interest as the agent providing CME activity to learners, such as the distribution of self-study CME activities or arranging electronic access to CME activities.</p>

Standard 5: Content and Format without Commercial Bias

Medical Director and CME Committee	Ensures that the content or format of a CME activity and its related materials promotes improvements or quality in healthcare and not a business interest of a commercial interest.
Course Chairs, Faculty, Planners, Staff or other CME Providers	<p>Gives presentations that are balanced views of therapeutic options.</p> <p>Will not allow commercial interest to advise teachers, authors, or participants regarding content or other educational matters as a condition of contributing funds.</p>

Standard 6: Disclosures Relevant to Potential Commercial Bias

Course Chairs, Faculty, Planners, Staff or other CME Providers	<p>Must disclose to learners any relevant financial relationship(s), to include the following:</p> <ol style="list-style-type: none">1. the name of the individual;2. the name of the commercial interest(s);3. the nature of the relationship the individual has with each commercial interest.; and4. for an individual with no relevant financial relationship(s), the learners must be informed that no relevant financial relationship(s) exist. <p>Must disclose to the learner the source of support from the commercial interests, including “in-kind” support.</p> <p>Must ensure that disclosure does not use the trade name or a product group message. The provider’s acknowledgment of commercial support may state the name, mission, and areas of clinical involvement of the company or institution and may include the corporate logo and slogans if they are not product promotional in nature.</p>
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PROCEDURE: (continued)

Responsible Party	Action
Course Chairs, Faculty, Planners, Staff or other CME Providers	<ol style="list-style-type: none">1. Must ensure that these disclosures occur prior to the beginning of the educational activity. If disclosure is verbal, the provider must supply SCVMC with written verification that appropriate verbal disclosure occurred at the activity.2. Must be able to supply ACCME with written verification that appropriate verbal disclosure occurred at a CME activity. Documentation may be made by a representative of the provider who is in attendance at the time of the verbal disclosure at the CME activity and the representative must attest in writing:<ol style="list-style-type: none">a. The verbal disclosure did occur;b. Itemize the content of the disclosed information or that there was nothing to disclose; andc. The documentation that verifies that adequate verbal disclosure did occur must be completed within one month of the activity.

Issued: 03/16/07
Revised: 11/20/10, 08/11/15

Signature approval on file.
Signature approval on file.

Attachments:

Attachment-A – Commercial Support Agreement
Attachment-B – Exhibitor Form



COMMERCIAL SUPPORT AGREEMENT

Regarding Terms, Conditions, and Purposes of an Unrestricted Educational Grant

Title of CME Activity:

Course Chair(s):

Location:

Date(s):

Name of company as you would like it to appear in course materials:

Commercial Supporter (Company:

Name/Branch) and Contact Person:

Address:

City:

State:

Zip:

Telephone:

Fax:

Email:

The company listed above wishes to provide an unrestricted educational grant for support for the above-named CME activity in the amount

of: \$ _____

Support may be designated to: _____

Terms, Conditions and Purposes of Commercial Support for SCVMC CME Activity

1. **Statement of Purpose:** CME is for scientific and educational purposes only and will not promote any products or services, directly or indirectly.
2. **Control of Content & Selection of Presenters & Moderators:** Commercial supporter agrees to SCVMC designated CME course chair/planner being responsible for the content and selection of presenters and moderators. Any commercial supporter, or its agents, will respond only to SCVMC initiated requests for suggestions of presenters or sources of presenters. SCVMC will seek suggestions from other sources and will make the final decision on presenter(s) selected.
3. **Disclosure of Financial Relationships:** Commercial supporter agrees that SCVMC designated CME course chair/ planner will disclose to the audience any significant relationships as specified by ACCME Essentials and Standards.
4. **Promotional Activities:** No promotional activities will be permitted in the same room as the educational activity, nor in any material disseminated as part of the program.



5. Independence of commercial support in the Use of Grant Funds:

- a. Funds should be in the form of an educational grant and made payable and mailed to “**VMC Foundation**”, Attention: Julie Ott, Director of Events, Tax ID# **77-0187890**.
VMC Foundation, 2400 Moorpark Ave. Suite 207, San Jose, CA 95128
All other support associated with this CME activity (e.g., distributing brochures, preparing slides) may only be provided with the full knowledge and approval of the SCVMC CME Committee.
- b. No other funds from the commercial supporter besides the educational grant listed in this agreement will be paid to the course chair, CME Committee members, faculty, attendees or others involved with the CME activity for any reason including, but not limited to, additional honoraria and extra social events.

- 6. SCVMC designated CME course chair/planner will furnish the **Provider**, SCVMC who is the IMQ/CMA Accredited Organization with documentation detailing the receipt and expenditure of the Commercial Support.
- 7. SCVMC designated CME course chair/CME planner will ensure that the source of support from any **Commercial Interest** (as defined in VMC Policy #154.02) is disclosed to the learners in all CME activities supported by the commercial funds prior to the start of the activity.

The above commercial supporter agrees to abide by the ACCME Standards for Commercial Support of Continuing Medical Education and Administrative Policies and Procedure of VMC #154.02 regarding Standards for Commercial Support at SCVMC.

VMC Foundation and the SCVMC designated CME course chair/planner of this activity will acknowledge educational support from the commercial support in program brochures, syllabi, and other course materials, and upon request, furnish the CME committee and commercial supporter a final accounting of the expenditure of the funds provided.

Date Approved by SCVMC CME Committee: _____

AGREED:

Company Representative (Print Name): _____

Signature: _____ Date: _____

VMC Foundation, Chief Executive Officer
Or Designee (Print Name): _____

Signature: _____ Date: _____

Acknowledgement of
Conference Planner (Print Name): _____

Signature: _____ Date: _____

Exhibitor Form

The Conference Presented by the VMC Foundation:

(Name)

Exhibitor Information

We wish to exhibit at: _____

On _____ DATE(s).

Amount: \$ _____

Organization Name:

Contact Person: _____

Address:

City, State, Zip Code:

Contact Person Email Address:

Exp. Date:

The _____
(INSERT NAME) Conference Presented
by the VMC Foundation

Payment Information

[] Enclosed is a check for \$ _____

Please make checks payable to the VMC

Foundation, c/o _____
(INSERT NAME) Conference

Contact Person & Telephone Number:

Brief Description of Product or Service:

The standard exhibit fee includes 1 full registration and the premium exhibit fee includes 2 full registrations for the conference. A badge will be issued to the following representative/registrants:

Name 1 (Exactly as it is to appear on the badge)

Name 2 (Exactly as it is to appear on the badge)

[] Charge my credit card for:

\$ _____

Card Type: _____

Cardholder's Name

Billing Address:

City, State, Zip

Card Number:

Terms and Conditions:

1. Standard exhibit space includes: shared six-foot draped materials table in the sponsor atrium, opportunity to place materials on resource table if shared table is not desired, quarter page size advertisement in the conference program, and complimentary registration for one company representative.
2. Premium exhibitor fee includes: recognition in conference program, marketing materials and website, one six-foot draped materials table in the sponsor atrium, one half page advertisement in the conference program and a complimentary registration for two company representatives.
3. Space is limited, and will be reserved on a first-come, first-serve basis as payment is received.

Questions?

For exhibitor questions, please contact one of the below **VMC Foundation** Contacts:

Julie Ott, Director of Events – 408/282-2687
Christina Salvatier, CFO – 408/282-0545

Mail completed forms to:
VMC Foundation,
Attn: Christina Salvatier, CFO
2400 Moorpark Ave., Suite 207
San Jose, CA 95128

Terms, Conditions and Purposes of Exhibiting at a CME Program

Title of CME Activity: _____

The above company wishes to exhibit or sponsor at this CME activity. An exhibit fee or sponsorship fee in the amount of \$_____ will be used to provide unrestricted support for the CME Activity.

1. Statement of Purpose: This CME program is for scientific and educational purposes only and will not promote the company's products, directly or indirectly.
2. Ancillary Promotional Activities:
 - a. Arrangements for exhibits may neither influence planning nor interfere with the presentation of the educational activity;
 - b. Commercial/promotional materials may not be displayed nor distributed in the same room immediately before, during, or immediately after the CME activity nor in any material disseminated as part of the program;
 - c. Representatives of commercial supporters and exhibitors may attend the CME activity if they wish, but may not engage in any sales activity in the room where the educational activity is held.
3. Independence of VMC Foundation and CME planners in the use of Contributed Funds: No funds from the Exhibitor/Sponsor will be paid to the program director, faculty, or others involved with the CME activity. No funds from the Exhibitor or Sponsor will be used to reimburse or defray the costs of traveling, conference fees, or other expenses of any SCVMC employee or any non-faculty healthcare professionals attending continuing medical education activities.
4. The Exhibitor/Sponsor agrees to abide by all requirements of the ACCME *Standards for Commercial Support of Continuing Medical Education*, SCVMC VMC Policy # 154.02 regarding Standards for Commercial Support at SCVMC
5. VMC Foundation and the SCVMC designated CME course chair/planner of this activity will acknowledge educational support from the Exhibitor/Sponsor in program brochures, syllabi, and other course materials, and upon request, furnish the CME committee and commercial supporter a final accounting of the expenditure of the funds provided.

Company Representative (name): _____

Title: _____

Signature: _____ Date: _____

VMC Foundation
Chief Executive Officer or Designee (name): _____

Signature: _____ Date: _____