

MUSC Office of Continuing Medical Education Policies on External Funding of CME Activities

MUSC Office of Continuing Medical Education (MUSC OCME) recognizes that educational grants from commercial interests as well as exhibit fees paid by vendors represent important sources of funding and are a traditional and accepted part of CME. In order to accommodate these funding sources while still providing CME activities that are independent and free of bias, MUSC OCME has developed the following policies for CME events sponsored by MUSC OCME.

The MUSC OCME provides continuing medical education activities free of commercial bias and independent of commercial influence. The following policies are in place to assure that our CME activities remain free of commercial bias and independent of commercial influence. MUSC OCME is the designated office with the authority and responsibility to utilize and maintain the CME accreditation of MUSC College of Medicine, which is granted by the Accreditation Council for Continuing Medical Education (ACCME).

Governing Policies

MUSC OCME requires all CME activities to comply with the Standards for Commercial Support (SCS) of the Accreditation Council for Continuing Medical Education (ACCME). The full text of these standards, along with related policies and clarifications, can be found on the ACCME website at www.accme.org. MUSC OCME also requires compliance with the AMA Code of Medical Ethics Section 8.061 regarding Gifts to Physicians from Industry, as well as all applicable University, State, and Federal policies.

Section I: Commercial Support

The following ACCME Standards are particularly relevant to commercial support:

1. 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.” MUSC OCME must be informed of any solicitations of financial support for CME activities, and will determine whether the entity is a commercial interest as defined by the ACCME.¹

¹ Grants from entities that are not considered “commercial interests”, such as federal or state grants, will be handled according to relevant University guidelines.

2. SCS 3.1-13 provide detailed instructions on handling commercial support. MUSC CME expects all educational partners to comply with all elements and will monitor all interactions with commercial interests to ensure compliance.
3. SCS 6.3-4 address disclosure of commercial support to learners.

Letters of Agreement for Commercial Support

4. In order to accept commercial support, MUSC OCME must have a letter of agreement approved and initialed by the University General Counsel's Office, signed by the Director of the MUSC Office of CME and signed by the approved designee of the commercial supporter **prior to the start of the activity.**
5. Letters of agreement must comply with all ACCME Standards and AMA policies, as well as State and University regulations.

Acknowledgment of Commercial Support

6. Commercial support will be acknowledged in the promotional materials if the signed letter of agreement is received prior to printing.
7. All commercial support, grant monies and in-kind support will be acknowledged prior to the start of the conference. The nature of the in-kind support will also be acknowledged.

Disbursement of Commercial Support

9. The commercial support funds will be utilized according to the letter of agreement between the commercial interest, the MUSC OCME and the educational partner, if applicable, and all ACCME Standards. Please refer to the relevant agreements for specifics.

MUSC OCME Policy on Commercial Support and Registration Fees

10. As a nationally accredited provider of *AMA PRA Category 1 credit(s)TM*, MUSC OCME complies with AMA Policy E-8.061, "*Gifts to Physicians from Industry*"
11. AMA Policy E-8.061 states:

"Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference."

12. MUSC OCME prohibits commercial interests and their representatives from paying the registration fees for participants who are not directly employed by the commercial interest.
13. Physicians and other health care professionals who receive research funding from a commercial interest, serve on a speakers bureau, or act as a consultant for the commercial interest are not considered to be directly employed by the commercial interest for the purposes of this policy.

Commercial Supporter Representatives at Activities

14. Commercial supporters may send **one** observer to a MUSC OCME activity for which it has provided an educational grant, in order to verify compliance with the conditions of the letter of agreement, if this is specifically requested in the letter of agreement.
15. The representative of the commercial supporter must register for the activity by the registration deadline, and must pay the appropriate registration fee.
16. The representative is only permitted to observe, and may not engage in discussions or participate in any question and answer sessions.
17. The representative may not engage in any sales activity.
18. Representatives who violate ACCME or MUSC policies will be asked to leave the conference.

Commercial Support and Exhibits

There can be no connection, explicit or implicit, between commercial support and exhibits. See *Section IV: Exhibits* for more details.

Section II: Federal and State Funds

1. Grants from Federal and State Agencies are exempt from the Standards of Commercial Support.
2. MUSC OCME may request a copy of the funding agreement for documentation purposes.
3. Disbursement of the funds will be handled according to the funding agreement and the department letter of agreement or joint sponsorship agreement.
4. The funding will be acknowledged according to the funding agreement.

Section III: Donations from Other Organizations

The following policy addendum covers organizations that 1) are not defined as commercial interests by the ACCME and 2) are not Federal or State agencies. These organizations are hereafter referred to as “donors”.

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.” Organizations such as insurance providers, hospitals, and banks fall under this policy. Grants from non-profits may or may not apply, depending on whether the ACCME has defined the particular non-profit as a commercial interest.

MUSC OCME must be informed of any solicitations of financial support for CME activities, and will determine whether the entity is a commercial interest as defined by the ACCME.

All donations and exhibits, regardless of the source, must comply with the ACCME Standards, the AMA Guidelines, and all University, state, and Federal laws.

MUSC OCME Policies and Procedures for Donations (not Educational Grants)

1. The educational partner can solicit donations from donors.
2. Donors do not (and should not) complete educational grant letters of agreement. In the event that the donor requires a letter of agreement, MUSC OCME must be consulted regarding the proper signatory authority.
3. The donations will be acknowledged.
4. The donated funds will be handled according to the departmental agreement or joint sponsorship agreement.
5. Donors must comply with the provisions of the *AMA Ethics Guidelines on Gifts to Physicians*.
6. In the event that the donor wishes to send a representative please contact the Office of CME at 843-876-1925
7. As with commercial support and exhibits, there can be no connection, implicit or explicit, between donations and exhibits. Exhibit fees cannot be discounted for donors, nor can donations be made in the expectation of exhibit space.

Section IV: Exhibits

For live activities, MUSC OCME may permit an activity to sell exhibit space in the facility where the activity is being held. With regard to exhibit space, MUSC OCME does not distinguish between commercial interests as defined by the ACCME and non-commercial interests. **This policy applies to any organization purchasing exhibit space.**

MUSC OCME policy on exhibits complies with the Compliance Program Guidance for Pharmaceutical Manufacturers developed by the US Office of Inspector General [OIG] and published in the Federal Register [FR Doc. 03-10934.] This policy states **“To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions.”**

The following ACCME Standards are also particularly relevant to exhibits:

1. SCS 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.”
2. SCS 4.2: “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 to engage in sales or promotional activities while in the space or place of the CME activity.”
3. “Frequently Asked Questions” from ACCME website published 7/27/06: “With respect to commercial support, the terms and conditions of the support must be described in a written agreement between the accredited provider and the commercial supporter, as delineated in Standard 3 of the SCS. An exhibit that contains advertising or promotional opportunities **must not** be part of the educational CME activity and **must not be paid for by commercial support [educational grants].**”

Exhibits and Commercial Support

4. MUSC OCME has established a firewall between educational grants and promotional exhibit fees at CME events. In compliance with the OIG Guidance, exhibit fees cannot be paid with an educational grant, and there cannot be any link between exhibits and grants. Exhibit fees cannot be discounted or waived in exchange for commercial support, and there cannot be a tiered system of exhibit fees linked to the amount given in educational grants.

5. Exhibitors who do not comply with the ACCME SCS or with MUSC OCME policies will be asked to leave the educational activity areas, and may be asked to leave the conference.

Exhibit Space

6. Exhibits must be located in a space outside of and distinct from the educational space. Exhibits cannot be located in an obligate pathway to the educational space.
7. If MUSC OCME is handling facilities management, MUSC OCME will make the arrangements for exhibit space. If MUSC OCME is not handling facilities, MUSC OCME must be consulted on the location of exhibit space, and reserves the right of final approval of the exhibit space.

Exhibit Fees

8. Exhibit fees are to be set by the educational partner, that is, the department, office, or joint sponsor that is undertaking the educational planning. The schedule of exhibit fees must be submitted in writing to MUSC OCME, and must be approved by MUSC OCME *prior* to offering the exhibit space to vendors.
9. Exhibit fee rates cannot differ between specific companies. Exhibit fee rates can distinguish between types of companies (i.e. for profit/non-profit, pharmaceutical/biomedical device). If different levels of exhibit fee are offered, these levels must be offered to all companies that qualify (i.e. all non-profits must be offered the non-profit level).
10. Exhibit fee rates can incorporate logistical factors, including number of tables, number of days, and similar variables. Exhibit fees can also include fees for additional services, such as network capabilities, extra power outlets, etc.
11. Exhibit fees must be paid in full no later than five business days before the activity.
12. Exhibit fees are non-refundable.

Exhibitor Representative Privileges

13. Each exhibitor is permitted up to two representatives. Exhibitors may request permission to send an additional representative; such requests must be submitted at least three days in advance, and permission is not guaranteed. Please refer to the event specific exhibitor form for more details.
14. Exhibitor representatives can attend educational activities, if space permits.

15. Exhibitor representatives can also be given course materials, if supplies permit.
16. Exhibitor representatives will not receive credit for attending the CME activity unless they register in advance and pay the regular registration fee. Registration fees cannot be discounted for exhibitors.

Section V: Other Sales and Promotional Activities

1. Course directors, planning committee members, and presenters (including moderators and panelists) for MUSC OCME activities may not engage in any sales activity or promotional activity for personal gain in relation to the CME activity.